Ministry for Primary Industries
Manatū Ahu Matua

Guidance Document

Further Processing

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Title

Guidance Document: Further Processing

About this document

The Guidance Document for Further Processing has been developed to assist secondary processors of non-dairy animal products to meet the requirements of the Animal Products Act 1999 (APA). It provides guidance on key process operations carried out by further processors, such as heat treatment, canning (commercial sterilisation), drying, acidification and high pressure processing.

Related Requirements

- Animal Products Regulations 2000 [AP Regs]
- Animal Products (Risk Management Programme Registration—Required Part) Regulations 2020
- Animal Products (Risk Management Programme Specifications) Notice 2008 [RMP Spec]
- Animal Products Notice: Risk Management Programme Specifications Amendment and Requirements for Risk Management Programme Outlines Revocation 2020
- Animal Products Notice: Specifications for Products Intended for Human Consumption 2020 [HC Spec]
- Australia New Zealand Food Standards Code [FSC]

Document history

Version	Version Date	Section Changed	Change(s) Description
0	July 2009		
1	November 2018	All	General update Chapters combined into a single document
2	February 2021		Update parameters for thermal inactivation of *V. parahaemolyticus in oysters* Added Section 7: High Pressure Processing (Content updated, reformatted and rebranded.)

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Contents

CHAPTER 1: Overview

1 Purpose

Further processing is a term used to describe processing operations such as heat treatment, canning and high pressure processing. Further processing operations are also referred to as secondary processing under the Animal Products Act 1999 (APA).

This Guidance Document has been developed to assist further processors of non-dairy animal products (such as meat and seafood) to meet the requirements of the APA. It has been developed by MPI with input from people with expertise in the various processing operations. As this Guidance Document is process operation based, model HACCP plans have not been provided. The sector specific Operational Codes, such as those for Processed Meats and Seafood contain model HACCP plans, which can be referred to when developing HACCP plans.

The focus of this Guidance Document is on the development, validation and operation of certain processes used to control hazards. It contains references to legislation under the APA that is directly relevant to the operation. It also contains guidance to assist in meeting those legal requirements. Export requirements have not been addressed. If you are intending to export, you need to be aware of and meet any export requirements relevant to the product and intended market.

1.1 Who should read this Guidance Document?

This Guidance Document applies to the processing of non-dairy animal products, and more specifically, for the processing of meat and seafood. Other processors, for example, processors of dairy or egg products, and business operating under the Food Act 2014 may also find the contents useful. This Guidance Document should be read by:

- Further processors of animal products including red meat, poultry, seafood and eggs products;
- Regulators;
- Recognised evaluators;
- Recognised verifiers; and
- Consultants assisting with the development and validation of further processing operations.

1.2 Contents of the Guidance Document

This Further Processing Guidance Document comprises two chapters:

Chapter 1: Overview

This Chapter provides an overview of the Guidance Document and highlights the requirements for further processors under the APA. It explains the purpose, scope and application of the document, and the legislative framework under the APA that underpins the requirements. Information is also provided to help operators decide which regulatory regime (the APA or Food Act 2014) they should operate under. Guidance on developing a risk management programme (RMP) and links to other useful documents published by MPI is also given.

Chapter 2: Good Operating Practice (GOP)

Chapter 2 is made up of Sections, each of which addresses a specific processing operation. It sets out the matters that should be considered when developing, validating and operating these processes. Each Section contains:

- procedures to assist with compliance with the regulatory requirements; and
- additional information (shown in boxes).

Regulatory requirements are identified by citing the legal reference in square brackets. You must comply with regulatory requirements and should follow the procedures, unless alternative practices have been included in your registered RMP. The additional information is given to assist with understanding or to provide further guidance.

The Sections in this Chapter are being revised. Each Section will be consulted on separately as this happens. Chapter 2 will also continue to be expanded upon as new Sections are developed.

2 Which Regulatory Regime Applies?

As a further processor of animal products, you may operate under:

- an RMP under the APA; or
- a Food Control Plan (FCP) or National Programme under the Food Act 2014.

Key considerations when deciding which regime to operate under are whether:

- the product is to be exported, and if so, is an official assurance needed. If yes, an RMP will be required; or
- any other activities are being carried out at the premises (e.g. primary processing), that must occur under an RMP. In this case an RMP maybe the best option.

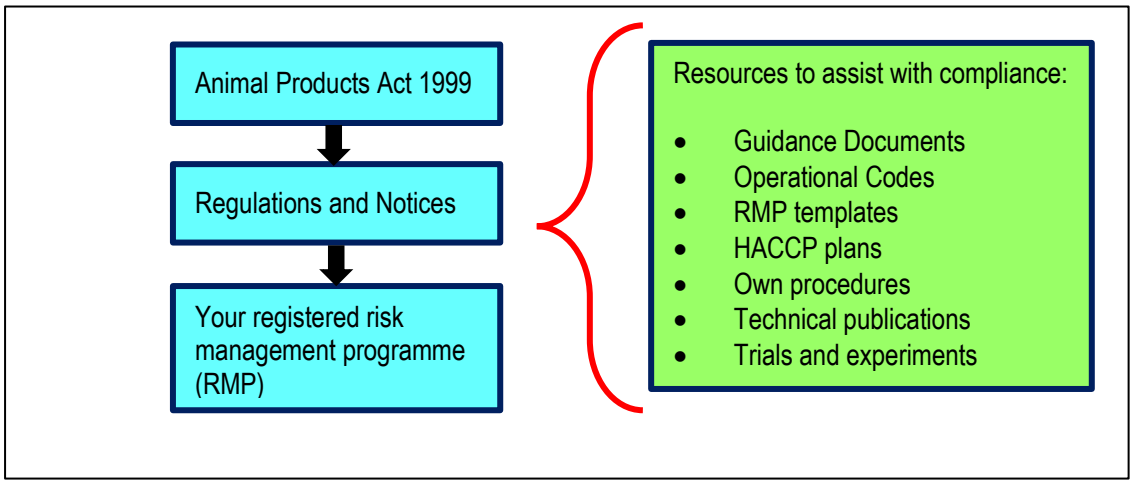
If neither of these factors apply, it is likely that you should operate under the Food Act.

2.1 The Animal Products Act 1999 (APA) Regime

The APA provides New Zealand's legal framework for the processing of animal products. It establishes a risk management system that requires animal products to be "fit for intended purpose". The APA sets out the duties of operators and the requirements for RMPs, Regulated Control Schemes (RCS), and exporter controls. Figure 1 illustrates the framework of the APA.

You must comply with the legal requirements of the APA and your registered RMP, adequately resource your operations (including having competent staff) and operate within the capacity and capability of your premises, facilities and equipment.

Figure 1: APA Framework



2.1.1 Risk management programmes

An RMP is a documented programme designed to identify and manage hazards and other risk factors when processing animal materials and products, to ensure that the product is fit for its intended purpose. The risk factors to be considered are:

- risks from hazards to human and animal health, e.g. things that could make consumers (people or animals) sick;
- risks from false or misleading labelling; and
- risks to the wholesomeness of animal material or product, e.g. things that are unexpected or unwanted in the product but would not make a consumer sick.

A registered RMP is "legally binding". It must be developed and implemented in accordance with New Zealand legislation and be specifically tailored to your processes, products and premises. The Risk Management Programme Manual provides comprehensive information about how to develop, register and operate your RMP.

2.1.2 Exporter controls

If you are going to export animal product, you must meet the requirements of the APA and any additional market access requirements of foreign governments. Exporters must also be registered with MPI.

You need to ensure that your documented systems have the necessary procedures and records to demonstrate compliance with the Official Assurance Specification and the relevant Overseas Market Access Requirements (OMARs). For more information about exporting refer to the "exporting" tab on the MPI website.

2.1.3 Recognition of people and agencies

MPI recognises agencies and persons to carry evaluation and external verification of RMPs on its behalf. A public register of recognised agencies and persons is available on the MPI website. You can select a recognised evaluator and verifying agency from this list when it is time to have your RMP evaluated and verified. The relevant lists are:

- Animal Products Recognised people – Evaluators; and
- Animal Products Recognised people – Verifiers.

For some process operations, the recognised evaluator or verifier will need to meet mandatory competencies, for example, if evaluating or verifying commercial sterilisation operations. If the recognised person does not have the required competency, another evaluator or technical expert with the required competency must be used for those activities.

2.2 Food Act 2014

The Food Act is a risk-based and outcome-focused approach to managing food safety. Food businesses that are higher risk from a food safety standpoint operate under more stringent food safety requirements than lower-risk food businesses. If you are interested in operating under the Food Act 2014, see the MPI website for detailed information.

2.3 Australia New Zealand Food Standards Code (FSC)

The FSC sets out the standards relating to labelling, composition and contaminants of food sold, processed or handled for sale in Australia or New Zealand, or imported into Australia or New Zealand. The FSC is developed by Food Standards Australia New Zealand (FSANZ).

The FSC applies regardless of whether you operate under an RMP, FCP or a National Programme. You can access the FSC here.

2.4 Regulatory Requirements

Legislation under the APA that is directly applicable to the processing operations in this Guidance Document are listed in Table 1: Selected Regulatory Requirements under the APA. Legislative requirements that are more generic in nature such as design and construction, personnel health, hygiene, and waste management have not been included. To see these other requirements, refer to the list of Related Requirements.

(1) The legislation cited in Table 1 is limited to the requirements in the:

a) Animal Products Regulations 2000 [AP Reg]; and
b) Animal Products Notice: Specifications for Products Intended for Human Consumption 2020 [HC Spec].

(2) Requirements in the FSC, the Food Act, and export requirements have not been included.

(3) Operators must ensure that they comply with all legislation applicable to their business.

2.5 Other Legislation

You must ensure that you comply with all other legislation relevant to your business. Examples may include:

a) Food Act 2014;
b) Australia New Zealand Food Standards Code;
c) Agricultural Compounds and Veterinary Medicines Act 1997;
d) Biosecurity Act 1993;
e) Fair Trading Act 1986;
f) Commerce Act 1986;
g) Consumer Guarantees Act 1993;
h) Resource Management Act 1991;
i) Weights and Measures Act 1987.

Table 1: Selected Regulatory Requirements under the APA

Processing operations in Chapter 2	Animal Products Regulations 2000	Animal Products Notice: Specifications for Products Intended for Human Consumption 2020										
	Regulation number	Clause number										
	5, 6, 7, 8, 9, 12, 14, 16, 18, 19	2.5-2.8	5.2	5.3	6.2	7.2	9.3	Eggs 19.4-19.6	22.1-22.3	22.4	Chilled ready-to-eat animal product 24.1-24.4	Sched 3.3 & 4
1. Heat treatment	✓	✓		✓	✓	✓	✓	✓	✓		✓	
2. Commercial sterilisation	✓	✓	✓	✓	✓	✓	✓		✓	✓		✓
3. Concentration and drying	✓	✓		✓	✓	✓	✓	✓	✓			
4. Hurdle technology	✓	✓		✓	✓	✓	✓	✓	✓		✓	
5. Smoking	✓	✓		✓	✓	✓	✓	✓	✓		✓	
6. Acidification	✓	✓		✓	✓	✓	✓	✓	✓		✓	
7. High Pressure Processing	✓	✓		✓	✓	✓	✓	✓	✓		✓	

The citations were current at the time of publication. You should check for any amendments when developing updating your RMP.

3 Other Sources of Information

The MPI website contains a lot of information to assist as you develop and operate your RMP. The following sections provide links to information that are particularly relevant to this Guidance Document.

3.1 MPI Food Science

This page contains links to a wide range of technical publications produced by or on behalf of MPI. You can use this information to help support your decisions. For example, when considering the chemical or biological hazards that are reasonably likely to occur in your product or process, and appropriate controls that could be applied.

3.2 Hazard Data Sheets

This page contains links to a series of hazard data sheets for microbiological pathogens and chemicals. The pathogen data sheets can be used to help understand the characteristics of microorganisms that need to be controlled by a process, their sources, growth parameters and examples of processing guidelines.

The chemical information sheets provide information about the safety of chemicals in food. They describe the compounds, their sources, potential health effects and estimate the likelihood of dietary exposure to the chemicals.

3.3 Food Risk Profiles

This page contains links to the food risk profiles for specific food/hazard combinations, for example shiga-toxin producing *E. coli* in red meat and meat products, or *Listeria monocytogenes* in processed ready-to-eat (RTE) meats. These risk profiles provide comprehensive information that identify the hazards to be controlled and their significance to public health.

3.4 Hazard Database

The Hazard Database is a searchable database that provides information on food safety hazards that are reasonably likely to occur in New Zealand foods and ingredients. The search results list the hazard(s) associated with the food, the source of the hazard, the regulatory limit (if applicable) as well as actions to control the hazard.

3.5 Shelf Life

The Guidance Document: How to Determine the Shelf Life of Food can assist in determining the shelf life of products and how to apply appropriate date marking. It provides useful information about preparing and handling foods for retail sale.

3.6 Control of *Listeria monocytogenes* in ready-to-eat (RTE) foods

Part 24 of the HC Spec requires operators processing certain chilled ready-to eat (RTE) animal products to implement systems to manage *Listeria monocytogenes.* The microbiological limits for *L. monocytogenes* in ready-to-eat products are in standard 1.6.1 of the FSC.

MPI has developed a range of *Listeria* resources to help you understand the issue and why it receives so much attention, the risks when *Listeria* is not managed effectively, and to assist with the developing and implementing controls for your operation. The resources include:

- a series of simple fact sheets;
- training resources and a sampling video; and
- a detailed four-Part Guidance Document:

  - Part 1: *Listeria* management and glossary;
  - Part 2: Good operating practices;
  - Part 3: Monitoring activities; and
  - Part 4: Corrective actions.

CHAPTER 2: Good operating practice

1 Heat Treatment

1.1 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 and to achieve the desired sensory attributes. The heat treatment processes addressed in this Section 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 aim of this Section is to apply heat treatments 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 is referred to as pasteurisation in this Section.

This Section focuses on 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.

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.

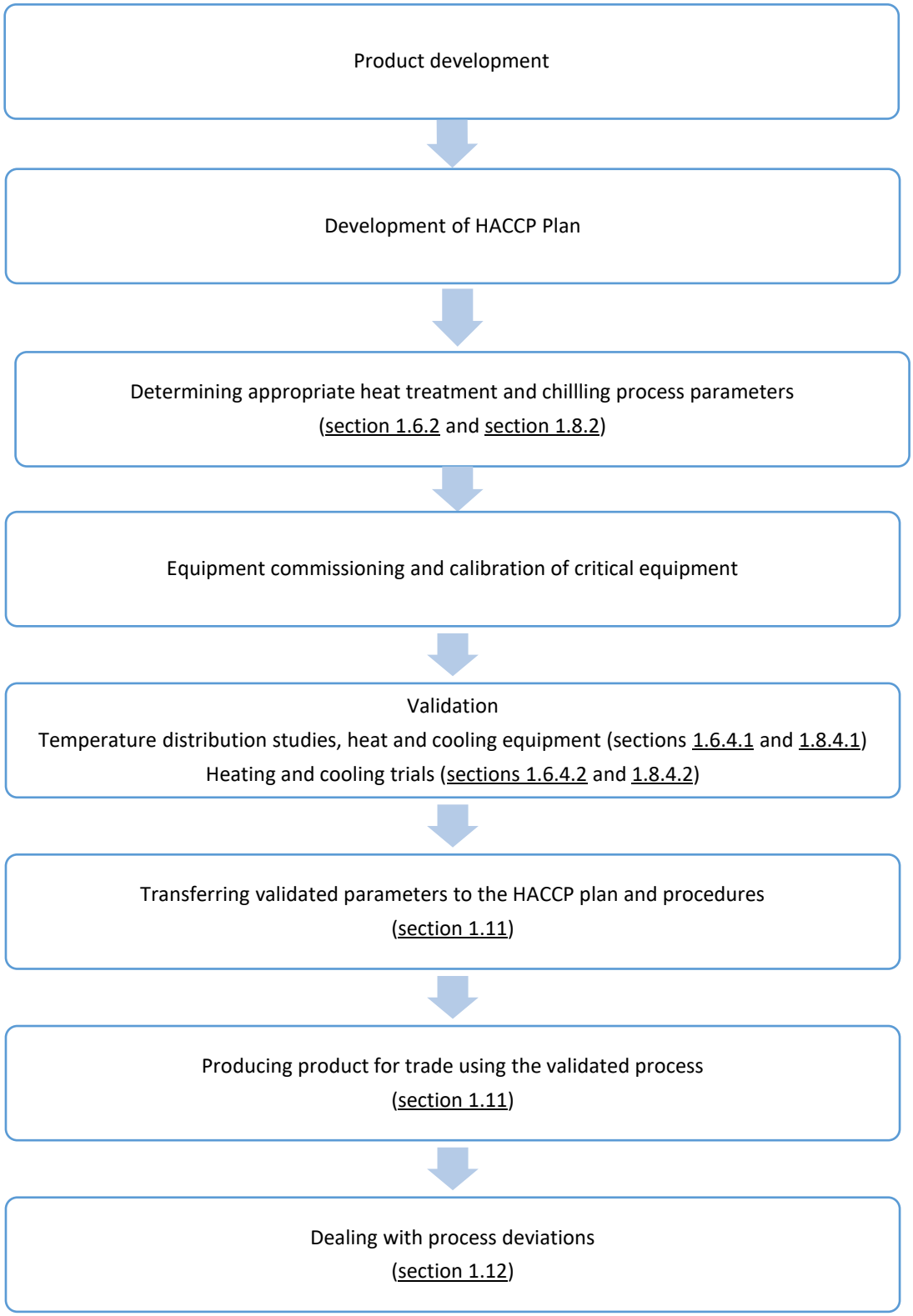
This Section does not apply to shelf stable commercially sterilised products. Guidance on commercial sterilisation of low acid canned products can be found in Section 2.

1.2 Layout of Section

This Section has been written to align with the activities carried out as an operator develops, validates and operates a heat treatment process. Some or all of this Section may be relevant, depending on the process and equipment being operated.

Figure 2 summarises the key steps in the development and validation of a heat treatment process, with references to those Sections where further information is provided.

Figure 2: Steps in developing and validating a heat treatment process



1.3 Definitions

In this Section, 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 Section, 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 cause 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

1.4 Heat Treatment Procedures

1.4.1 General requirements

(4) The operator must:

a) document and meet any regulatory limits applicable to the product [RMP Spec 7 and 11];
b) establish, document and meet operator-defined limits that are appropriate for the product and have evidence to justify their selection [RMP Spec 7 and 11]; and
c) demonstrate that the process is capable of consistently achieving the regulatory and/or operator-defined limits [RMP Spec 18].

(5) Processes should be developed and validated[1] by suitably skilled persons.

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

(7) 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 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 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. equipment commissioning, temperature distribution studies, heating and cooling trials, and shelf life studies);
e) thermal process calculations; 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.

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

(9) Any validation report and associated records must be kept by the operator [RMP Spec 18].

Additional Information – Reports and records

This should include the documentation recommended in Part 4.4.3 of the Risk Management Programme Manual.

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

(11) The frequency of assessment under the clause 1.4.1.7 should be documented in the RMP.

(12) 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.

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

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

1.5 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 in 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; and
c) the potential for exposure of pathogens to sub-lethal temperatures for a time that could increase 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 controlled to ensure that conditions favouring growth of pathogens does 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 or sensory characteristics (e.g. grill marking, browning by flash frying); and
- ease product handling (e.g. reducing viscosity to assist in pumping viscous materials, dissolving powders, melting fats).

1.6 Pasteurisation

Additional Information

The reduction in the levels of microorganisms 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.

1.6.1 Outcome of pasteurisation

(1) Pasteurisation must ensure the elimination or reduction to acceptable levels of the pathogens of concern, as 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 control measures) to ensure the product is fit for its intended purpose, method of storage and shelf life.

Additional Information – Other considerations

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

When dealing with spore forming pathogens, pasteurisation usually targets the vegetative cells only. Other control measures (such as reduced pH and refrigeration) are then applied to ensure that the remaining spores cannot germinate and grow during the product shelf life.

1.6.2 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 their initial concentration in the raw materials;
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.

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 may be derived from:

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

If appropriate parameters are not available from these sources, trials may need to be carried out. This may include challenge trials, which in simple terms, is where a cocktail of strains of a target pathogen(s) is inoculated into the product and it is then processed to determine whether the required pathogen reduction is achieved.

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 these parameters, the pathogens will also be controlled. Other control measures could also reduce the heat treatment parameters needed to ensure food safety, for example, if the product has a reduced pH or a_w.

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

1.6.3 Pasteurisation parameters

Additional Information

Table 1 is useful for identifying the 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 occurring in the food, its thermal resistance, the outcome to be achieved and the intended use of the product.

Table 1: Potential pathogens of concern for growth studies[2] based on interaction of product pH and a_w (NACMCF, 2010)

a_w	**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.

[2] This table was developed for growth rather than inactivation studies, but still provides useful information about hazards of concern.

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 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 the 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 may include:

- the **default** *D* and z values for the target pathogen are too high, and the operator has evidence to support lower *D* and z values for their product[4];
- higher or lower levels of the target pathogen in the raw materials such that a 6 $\log_{10}$ reduction in concentration 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 applied, reducing the $\log_{10}$ reduction needed from the pasteurisation process.

1.6.3.1 *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-spore forming pathogens, a process that is designed to eliminate *L. monocytogenes* is sufficient to eliminate all other vegetative 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**
62	7.3	**43.8**
64	3.5	**21**
66	1.7	**10.2**

[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.

[5] Horn B, 2015.

68	0.8	**4.8**
70	0.4	**2.4**
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
60	44.8	26.5	12	45
62	19.4	12.5	5.5	19.5
64	8.4	6	3.0	8.5
66	3.7	3.3	1.6	4.2
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

1.6.3.2 *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, 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 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 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**
62	6.1	**36.6**	**62**	3.6	**21.6**
64	3.0	**18.0**	**64**	1.9	**11.4**
66	1.5	**9.0**	**66**	1.0	**6.0**

[6] Bremer and Osborne, 1997.

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

[8] Horn B, (2015).

68	0.8	**4.8**	**68**	0.5	**3.0**
70	0.4	**2.4**	**70**	0.3	**1.8**

1.6.3.3 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 by the pasteurisation process, the process should achieve a 6 $\log_{10}$ reduction of this pathogen.

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.**

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**

Non-proteolytic (psychrotrophic) *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 in combination with refrigeration, such as:

- 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)[9].

Currently, for 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 raw materials are used, it is expected that the operator will assess whether non-proteolytic *C. botulinum* is reasonably likely to occur and where necessary, implement appropriate control measures.

To illustrate this, operators using imported fish to process ready-to-eat vacuum packed fish 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 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".

[9] These control measures may be inadequate for the control of other pathogens that may be present the product (for example *L. monocytogenes*). The operator needs to implement control measures that will ensure that all hazards will be appropriately addressed.

1.6.3.4 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 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.

1.6.3.5 *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 process, a heat treatment of 50°C for 10 minutes or equivalent 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).

1.6.4 Pasteurisation validation

Additional Information – Validation activities

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; and
- shelf life trials.

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).

1.6.4.1 Temperature distribution studies of the 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 temperature variation throughout a piece of equipment during processing. The equipment design and set up, product and packaging, and packing configurations can all impact on temperature distribution. Because of 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 spot(s) have been located, processes can then be developed taking those locations into account.

During routine processing, the temperature of products placed at the location(s) delivering the least pathogen reduction (e.g. the cold spots) 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(s) may need to have a measurable temperature of 77°C at the accessible monitoring point.

Temperature distribution studies may not always be appropriate or necessary. For example:
- if the equipment design and use ensure that heat will always be evenly distributed, e.g. pasteurisation in a small steam jacketed pan with good product mixing; or
- if 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 this case the hot spot may actually be the location delivery the least pathogen reduction.

(3) Temperature distribution studies should:

a) be carried out under the most demanding normal operating conditions (e.g. loading configurations, equipment or essential services operating at full capacity);
b) be repeated if there are changes to the equipment design, installation (e.g. after maintenance or repairs), operation, 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.

1.6.4.2 Heating trials (heat penetration tests)

(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

When validating a pasteurisation process, the critical product and process factors that could impact on the temperatures achieved in the product should be considered. These could include:

(a) the product, for example:
  i) formulation and composition;
  ii) any additional control measures e.g. pH, a_w; and
  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; and

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(s)), if any;
   ii) maximum capacity;
   iii) potential for surface fouling; and
   iv) equipment settings for example:
      – temperature (wet and dry bulb temperature);
      – pressure;
      – time to reach process temperature (come up time);
      – process time, line/belt speed;
      – relative humidity; and
      – air flow rate.

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

   a) be carried out under the most demanding normal operating conditions;
   b) be 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, be repeated at least every 3 years to check that the results remain valid.

(3) The process and product factors that are critical to achieving product that is fit for its intended purpose, should be identified in the RMP and managed, including those that would require revalidation if changed.

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;
- product homogeneity;
- variability of the process including variation across process shifts or seasons; 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).

1.7 Post-heat treatment handling[10]

1.7.1 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.

[10] 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.

(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 hazards may be introduced and ensure that where appropriate, they have been 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 RMP and must justify that it is appropriate, considering the intended use of the product [RMP Spec 10].

1.7.2 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).

1.7.3 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).

1.7.4 Separation of raw and cooked product

(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, and those who move into pasteurisation or post-heat treatment areas must complete an appropriate hygiene routine [AP Reg 12].

(3) Where applicable, operators must comply with the requirements in Part 24 of the HC spec "*Listeria* requirements for processors of certain ready-to-eat animal products".[11]

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

1.8 Cooling

Additional Information – Purpose of controlled cooling

Pathogens may also be present in heat treated product if the heat treatment was insufficient or there was post-heat treatment contamination. A valid pasteurisation process should 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, pathogen spores will survive. If product is cooled slowly these could germinate and grow, particularly if there are no other control measures in place such as a_w, pH or preservatives.

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). Also, some strains are psychrotrophic *B. cereus* are capable of growth at 4°C (Tucker et al 2011).

It is particularly important to consider the potential for the germination and growth of *C. perfringens* in meat products, and *B. cereus*[12] in battered, or coated products or products containing dried spices or herb.

1.8.1 Outcome of cooling

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

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

1.8.2 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 1.8.3 Cooling Parameters.

If developing cooling parameters, the operator should consider whether any additional control measures could slow or inhibit microbial growth.

1.8.3 Cooling parameters

Additional Information – Default cooling parameters

The following are default cooling parameters:

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

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

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:

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

Predictive modelling programmes can assist in justifying alternative cooling regimes for the control of *C. perfringens*. Mohr *et al* (2015) evaluated a selection of cooling models for cooling 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; and
- UK IFR ComBase Perfringens Predictor.

1.8.4 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 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 by 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 met.

Some products, such as frankfurters, cool very rapidly due to their size and so are unlikely to exceed default cooling parameters. 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. That is, 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 are met; and
- product testing (e.g. microbiological testing) to confirm that regulatory or operator-defined limits are met.

1.8.4.1 Temperature distribution studies of the 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 during processing. Equipment design and set up, product and packaging, and packing configurations can all impact on temperature distribution.

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

1.8.4.2 Cooling trials

(1) Trials should be carried out, where necessary, to validate cooling processes and ensure the process will consistently produce product that is fit for its intended purpose.

Additional Information

When validating a cooling process, the critical product and process factors that could impact on the temperature achieved at the slowest cooling points in the product should be considered. 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;
  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.

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

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

(3) 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.

(4) The process and product factors that are critical to the cooling process should be identified in the RMP and managed, including those that would require revalidation if changed.

1.8.5 Cooling medium

(1) The cooling medium must not be a source of contamination to 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 2.5.1]; and
b) checked regularly and replaced as necessary so as to not contaminate the product [AP Reg 6].

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

Additional Information

Microorganisms can potentially grow in cooling water, 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 aerobic plate count (APC) of less than 100cfu/ml.

Wherever possible to minimise microbial contamination and growth, 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.

1.9 Packaging and labelling

(1) The type and composition of packaging must be appropriate for the intended purpose [HC Spec 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, Standard 1.2.6 Directions for Storage and Use.

Additional Information

The operator should have evidence that the cooking instructions, when followed by the consumer, will result in properly cooked product. Discussions/focus groups about instruction wording and trials with consumers could be used to assist with this.

1.10 Shelf life and storage

(1) The operator should have evidence to support the shelf life of the product.[13]

Additional Information – Chilled storage temperatures

When selecting storage temperatures for shelf life trials, operators should be aware that the chilled storage temperature at retail required by the Food Act 2014 is 5°C.

1.11 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 staff.

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

(3) Heat treatment should commence promptly after product preparation. Any delays or holding of product between preparation and 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 22.3].

(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 and 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 are met [RMP Spec 16].

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

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

Additional Information

It is a 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.

1.12 Deviation from the validated process

(1) The operator must take immediate action if there is a process deviation that could impact on food safety, 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 potential for pathogen growth to high numbers that cannot then be reduced to acceptable levels by the process;
- the production of heat stable toxins e.g. by *S. aureus*, that will not be inactivated by the process (*S. aureus* toxin can withstand heating at 149°C for over 100 minutes);
- whether affected product could have contaminated product contact surfaces and therefore other product.

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

(2) Product affected by a 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].

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1.14 Appendix

The default pasteurisation parameters given in Table 2 to Table 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. 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[14].

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 (IT) 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

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

e.g. =0 004+0.0083

[14] 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 (IT) at slowest heating point (°C)	Lethal rate (L) at T_{ref} 70°C, z =6.25	Cumulative lethality (Pasteurisation value $P_{70}^{6.25}$)
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 must be carried out by suitably skilled persons.

2 Commercial Sterilisation

2.1 Purpose

Commercial sterilisation is the process of heating products to achieve long term shelf stability at room temperature. This Section explains the requirements for operators carrying out commercial sterilisation of low acid canned foods (i.e. retorted products with a pH of 4.6 or higher or a water activity of greater than 0.85). The term 'canned' includes rigid, semi-rigid and flexible packaging options such as cans, glass jars, trays and pouches.

There are detailed requirements for those operating commercial sterilisation processes, contained in the Codes listed in HC Spec clause 22.4 (see section 2.4.1). Operators must apply one of the Codes and ensure that their operation complies.

This Section provides guidance on aspects of the Codes, and other legal requirements under the APA (e.g. competency and calibration). If there is a contradiction in this Section with a Code, the Code takes precedence. As the focus of the Codes is on the control of biological hazards the operator must ensure that their RMP also addresses any chemical and physical hazards, and wholesomeness risk factors.

This Section does not apply to ultra-high temperature processing and aseptic packaging (i.e. UHT processing).

2.2 Layout of Section

This Section has been written to align with the activities carried out by an operator who develops, validates and operates a commercial sterilisation process. Some or all of this Section may be relevant, depending on the process and equipment being operated.

2.3 Definitions

canned product means food that:

a) is processed and packed in accordance with good manufacturing practice; and
b) is packed in clean or sterilised containers that are hermetically sealed; and
c) is processed by heat to ensure preservation, whether before or after being sealed in a container. [HC Spec]

come up time means the time between the introduction of heat to the retort and when the retort reaches the specified processing temperature

commercial sterilisation means the condition achieved by application of heat, alone or in combination with other treatments to eliminate microorganisms capable of growing under normal non-refrigerated conditions at which the product is likely to be held during distribution and storage

critical failure, in relation to container closures, means anything that would affect the integrity of the container

F0 means a measure of the amount of lethal heat which results from a specified thermal process (usually measured at the point of lowest lethality in the container). The F0 number is the lethal effect equivalent to the number of minutes at 121.1°C when assuming instantaneous heating and cooling and a **z value** of 10°C

flexible container means a container whose shape is affected by the enclosed product (e.g. retort pouches) (Codex)

headspace means the volume in a container not occupied by the product

heat penetration tests mean experiments conducted to determine heating and cooling behaviour of a product/package combination, processed in a specific retort system, to establish safe thermal (scheduled) processes that will result in commercially sterile product or to evaluate process deviations

heat processing time means the time that the containers are held at the specified processing temperature

heat transfer distribution study means a study used to determine the ability of the retort to uniformly mix and distribute the heat transfer medium

hermetically sealed means air tight, completely sealed and impermeable to gas

initial temperature (IT) means the average temperature of the contents of the coldest container to be retorted when heat processing begins, (i.e. at the start of the come-up time), and is usually the first container to be prepared for processing

leaker means a sealed and heat processed container which has a defect that allows the passage of water, gas or microbes into the container

lethality means the effect of exposure to time and temperature transformed mathematically to give a measure of the sterilisation achieved (summed values usually being expressed as F or F0)

low-acid product means:

a) any animal product, other than an alcoholic beverage, where any component has a pH value greater than 4.6 after heat processing, and a water activity (a_w) greater than 0.85; but
b) does not include animal product in a hermetically sealed container that is required to be stored under refrigeration [HC Spec]

minimum initial temperature means the lowest initial product temperature in a container (specified in the scheduled process) that the process has been developed for

operator means the owner or other person in control of the business

over pressure means pressure in excess of that corresponding to the saturated steam pressure at a given temperature and corrected for altitude

qualified person means a person who meets the competency specification set out in clause 5.2 of the HC Spec

retort means a pressure vessel, designed for heat processing product packed in hermetically sealed containers

rigid container is a container whose shape is not affected by the enclosed product or deformed by an external mechanical pressure of up to 0.7kg/cm2 (10psig) (e.g. cans, glass jars) (Codex)

saturated steam means pure steam in equilibrium with water at the same temperature. Under these conditions, the temperature of the steam is entirely dependent on its pressure

scheduled process means the thermal process alone or in combination with critical factors for a given product formulation, container type and size and thermal processing system that will achieve commercial sterility of the product

semi-rigid container means a container whose shape is not affected by the enclosed product under normal atmospheric temperature and pressure but can be deformed by an external mechanical pressure of less than 0.7kg/cm2 (10 psig) (e.g. tetra-bricks, pottles) (Codex)

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 using distributed measuring devices to establish venting schedules, and temperature stability and uniformity throughout the retort system

vacuum means the negative internal pressure in the container produced during the seaming process

venting means flushing air out of steam retorts at the beginning of a heat process. It is done by allowing large volumes of steam to flow through the retort to drive and carry air out through open vents in the retort

z value means a measure of the temperature resistance of the target microorganism, i.e. the temperature change required to effect a tenfold change in the rate of microbial destruction

2.4 Commercial Sterilisation Procedures

2.4.1 General requirements

(1) The operator must document procedures for the commercial sterilisation of low acid canned products that comply with the principles detailed in one of the following codes [HC Spec 22.3]:

a) the Code of Hygiene Practice for Low Acid and Acidified Low-Acid Canned Foods, as published by the Codex Alimentarius Commission: (CAC/RCP 23-1979); [Codex] or
b) the United States Food and Drug Administration requirements for Thermally Processed Low-acid Foods Packaged in Hermetically Sealed Containers, as contained in 21 CFR Part 113; and Acidified Foods as contained in 21 CFR Part 114 [CFR].

(2) The operator must:

a) document and meet any regulatory limits applicable to the product [RMP Spec 7 and 11];

Additional Information – Regulatory limits

There are currently no regulatory limits for commercially sterilised products.

b) establish, document and meet operator-defined limits that are appropriate for the product and have evidence to justify their selection. [RMP Spec 7 and 11]; and
c) demonstrate that the process is capable of consistently achieving the regulatory and/or operator-defined limits [RMP Spec 18].

Additional Information – Operator-defined limits

The operator should ensure that an F0 of 3 or greater is achieved in the product, unless scientific justification for a lower F0 has been validated in the RMP.

(3) The operator must ensure that any spoilage organisms capable of growing under normal non-refrigerated conditions (at which the product is likely to be exposed to) are eliminated or reduced to acceptable levels by the process [definition of commercial sterilisation, Codex, CFR 113.3].

(4) Calibrated equipment with sufficient accuracy must be used to take critical measurements during validation work and routine processing and must be records kept [HC Spec Part 6].

2.4.2 Competency requirements

(1) Personnel who supervise low acid canned food operations must meet the competency requirements for "Supervisors of thermal processing of low acid canned products" in clause 5.2(1)(b) of the HC Spec.

Additional Information

Personnel who are carrying out the following activities should be supervised by a qualified person who meets the competency requirements in part 2.4.2.1:

- operators of heat processing systems (retort operators);
- those involved with product preparation; and
- those performing container closure inspections.

At least one qualified supervisor with the specified competency should be on-site when processing. The operator should ensure that there are sufficient trained staff available to cover for illnesses, holidays and resignations etc.

(2) Personnel carrying out container closure evaluations must be suitably skilled [HC Spec 22.4].

(3) Scheduled processes (including equipment commissioning) must be:

a) developed by or under the supervision of a person who meets the competency requirements for "Qualified persons" [HC Spec 5.2(2)].

b) checked and signed off prior to release for commercial production by a person independent of the development process who meets the competency requirements for "Qualified persons" [HC Spec 5.2(2)].

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

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

2.4.3 Equipment [Codex 7.5.3.6, Codex 7.6, CFR 113.40 and 113.100]

Additional Information

Detailed equipment requirements are specified in the two Codes listed in 4.1 General Requirements. The following information highlights the key equipment requirements only.

(1) Retorts must be equipped with:

a) a pressure gauge;
b) an independent temperature measuring device (e.g. resistance-temperature device (RTD)) that:
   i) is calibrated in accordance with HC Spec 6.2; and
   ii) if defective or cannot be adjusted to the accurate calibrated reference device, is repaired before further use, or replaced.
c) an automatic temperature recording device adjusted to read no higher than the known accurate independent temperature measuring device, to provide a permanent record of the process;
d) an accurate temperature controller; and
e) for automated systems, a programmable logic controller (PLC) or computer to run the system, that is protected from unauthorised access [HC Spec 22.3].

(2) An accurate, readable timing device must be readily visible to personnel in the retorting room.

2.4.4 Raw materials

(1) Raw materials must comply with the requirements of the FSC.

(2) Raw materials must be protected from contamination, handled hygienically and stored in a manner that will minimise deterioration [AP Reg 9].

(3) When developing new products or modifying existing formulations, the microbiological loading of the raw material should be considered [Codex 7.1.1 and CFR 113.81(a)].

(4) The operator should have procedures to ensure that raw materials are not changed in a formulation (including supplier, type or addition rate) without input from a qualified person.

Additional Information – Microbiological loading

The microbiological loadings of raw materials should not exceed the ability of the process to reduce the loadings to acceptable levels.

Raw materials should be handled to minimise contamination and growth prior to thermal processing.

2.4.5 Packaging

(1) All packaging must:

a) comply with clause 7.2(1) of the HC Spec and the operator must have documented evidence of compliance, by stating the reference to the regulation, part, section or standard with which the packaging complies; and
b) be used in accordance with the manufacturer's specifications;
c) be appropriate to the intended use, and filling and sealing equipment used [HC Spec 7.2(2), Codex 7.4.1]; and
d) be clean and sound before filling [Codex 7.4.2].

Additional Information – Package sealing and cleaning

Sealing
Packaging should be obtained from reputable suppliers who can provide competent technical support. Written specifications for can or other packaging sealing parameters should be obtained from the supplier.

Cleaning
Rigid containers may be cleaned by:
- inverting the containers to dump out dust and foreign matter, where appropriate; and
- blasting their interior surfaces with water (including steam), air, or vacuum to loosen and remove dust and foreign matter.

Semi-rigid containers should not be washed prior to use (unless effective drying is possible) as water in the sealing area may reduce the seal reliability. Flexible containers (pouches) usually don't require cleaning before use.

(2) Packaging must be stored in a way that prevents contamination [AP Reg 16].

2.4.6 Thermal process development [Codex 7.5 and CFR 113.83]

(1) A qualified person must carry out or supervise the development and validation of each scheduled process [HC Spec 5.2(2)].

(2) A qualified person who is independent of the development process in the clause 2.4.6.1 must check and sign off the scheduled process prior to release to commercial production [HC Spec 5.2(2)].

(3) The qualified person must have confidence that the temperature measuring devices and/or data loggers (e.g. thermocouples, wireless data loggers) used to collect data, provide accurate readings under the conditions of use [Codex 7.5.1.2 and CFR 113.83].

(4) The operator must have evidence that the RMP is effective [RMP Spec 18].

Additional Information – Evidence of effectiveness

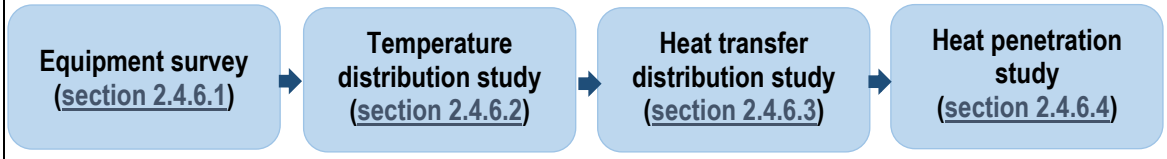
Part of the evidence is the validation report(s) produced by qualified persons.

(5) Validation reports must be retained for the life of the process. If the reports are superseded, the obsolete documents must to be stored for an additional 4 years [RMP Spec 18].

(6) If production of a particular product ceases, the validation reports for that process should be kept for a further 4 years (or for the shelf life of the product, if that is longer than 4 years) [RMP Spec 18].

Additional Information
Qualified persons are expected to use their knowledge and experience, gained through training and other means when developing and validating scheduled processes. The following documents may provide useful guidance:
- The Institute for Thermal Processing Specialists provides Guidelines for conducting thermal processing studies
- The Canadian Food Inspection Agency provides guidance on Process Determinations for Thermal Processes

Developing a scheduled process is likely to involve some, or all, of the following activities:



These activities are discussed in the following sections.

2.4.6.1 Processing equipment survey

(1) A survey of all retort installations should be carried out to ensure that they are properly installed.

Additional Information

Further detail about equipment surveys is given in the IFTPS Guidelines for conducting thermal processing studies.

2.4.6.2. Temperature distribution studies

Additional Information

When validating a scheduled process, it is important to know that each retort will deliver the required thermal process to all product. Before a retort is brought into service and any heat penetration work undertaken, temperature distribution studies should be carried out. If only one retort from a range is to be tested rather than each individual retort, the justification for selecting the retort should be documented.

Temperature distribution studies may not be necessary for continuous retorts, at the discretion of the qualified person.

(1) Temperature distribution studies must be carried out to:

a) determine temperature uniformity and stability throughout the loaded retort; and
b) identify the point that is slowest to reach the scheduled processing temperature; and
c) where required, establish an adequate venting schedule for each container size and loading configuration, or the venting schedule for the most difficult container size and loading configuration to vent that can then be used as the standard.

(2) The decision to carry out temperature distribution studies rests with the qualified person. If the trials are not carried out, justification for this should be documented in the RMP.

(3) The qualified person must identify all factors critical to temperature distribution within the retort.

(4) Temperature distribution studies must be carried out under worst case conditions for temperature uniformity and that are likely to be encountered during commercial operations, for example:

a) operating at full design capacity and under partial loading;
b) using each container size or loading density, or using the container size and loading density that would be most difficult to achieve uniform temperatures;
c) using retort separator or divider sheets that have the smallest percentage of open areas;
d) operating at full capacity of the essential services; and
e) operating at the highest retort temperature to be used during commercial production.

(5) Temperature distribution studies should be conducted:

a) when a retort is commissioned;
b) when there are changes to a critical factor such as a retort component, plumbing, container arrangement, introduction of dividers, retort relocation or any other change that could negatively impact on heat transfer; and
c) as a minimum, every 2-3 years.

(6) The retort installation and process lines should be assessed at least annually by the qualified person to check for any unplanned 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.

(7) The frequency of assessment in the clause 2.4.6.2.6 should be documented in the RMP.

Additional Information – Records

Records may include diagrams of the retort and temperature probe placements, photos, calibration records, descriptions of the test conditions, retort programme, readings and records taken during the trials, trial data, results and analysis.

2.4.6.3. Heat transfer distribution studies

Additional Information – Heat transfer distribution studies

In addition to temperature distribution studies, heat transfer distribution studies may be needed (e.g. if using steam and air overpressure systems) to ensure adequate heat transfer into packages throughout the retort.

See the IFTPS Guidelines for conducting thermal processing studies for further guidance on when heat transfer distribution studies maybe needed and how to carry them out.

2.4.6.4. Scheduled process and heat penetration tests

Additional Information - Heat penetration tests

Heat penetration tests are used to collect the time-temperature history of a product in a specific retort system, measured at the slowest heating point in the container, to establish the scheduled process. The results are used to calculate the lethal effect of the process, usually expressed as an F0 value.

The tests are carried out at locations in the retort that will achieve the lowest lethality. All critical factors associated with the product, package, retort loading and process which may affect heating rate are investigated. The tests are carried out using the product formulation, package, loading and retort process that will be used for commercial production.

(1) The maximum time from the containers being filled to being processed should be specified as part of the scheduled process, taking into consideration the:

a) conditions that may permit microbial growth;
b) production of heat stable toxins; and
c) impact on heat transfer characteristics of the product [Codex 7.1.5].

(2) The time referred to in (1) should not exceed 2 hours unless the operator has evidence to support a longer time.

Additional Information – Longer holding times

Evidence for longer holding times may be gained using computer modelling programmes, literature or trials and experiments, considering the factors listed in the clause 2.4.6.4.1.

(3) The qualified person should have evidence to support the location selected to be the slowest heating point (i.e. cold spot(s)) of the product inside the container.

(4) The qualified person must use their experience to ensure that all relevant factors are addressed when developing and validating the scheduled process. Some of the factors that should be addressed are:

a) date of development of the scheduled process;
b) name of the qualified person that developed the scheduled process;
c) name of the qualified person who independently checked the scheduled process;
d) product name, code, type and formulation reference;
e) preparation, filling and closure of product (e.g. hot fill, cold fill, product arrangement, headspace, pre-cook);
f) detailed formulation (including maximum particle size, fat content, % composition, % solids, pH, net weight, consistency or viscosity (particularly for rotary processes));
g) weight, size, type and manufacturer of the containers;
h) minimum initial product temperature;
i) all other critical factors in the product that must be controlled and the associated parameters (e.g. maximum product thickness for flexible containers);
j) pre-process hold time (minimum and maximum);
k) retort(s) the process applies to;
l) container/tray loading, nesting, orientation;
m) the line speeds for continuous operations, and rotation speed where appropriate;
n) venting schedule where appropriate;
o) come up time and temperature parameters;

p) sterilisation time and temperature parameters;
q) over-pressure schedule where appropriate;
r) cooling procedure, including cooling water temperature;
s) testing carried out to validate the scheduled process, including information about the equipment used to collect the data, results of temperature distribution studies, cold spot location within the container, heat penetration tests etc.;
t) F0 achieved by the process; and
u) any other information that is relevant to a particular product and process.

(5) The scheduled process should be based on the worst case scenario likely to be encountered during commercial production, for the given product specifications and equipment capabilities [Codex 7.5.2.2].

(6) Heat penetration tests must be validated in the production retort under commercial operating conditions to confirm the adequacy of the process parameters. This includes provisional schedules that are derived from F0 calculations using data from similar processes or from reference material [Codex 7.5.2.4].

(7) Temperature measuring devices should be inserted into at least 10 containers for each heat penetration test. Where this is not possible, more replicate test runs should be carried out (IFTPS, 2014).

(8) At least 2 confirmatory runs should be carried out to confirm the scheduled process (IFTPS, 2014). This may need to be increased in situations where there is unacceptable variation within and between runs as determined by the qualified person.

(9) Any changes that are made to a critical process or product factor, including the product formulation, container size or retorting must be assessed and where necessary the process revalidated by a qualified person [Codex 7.5.2.8].

(10) If a process is revalidated, it must be independently checked and signed off by a qualified person, prior to implementation [HC Spec 5.2(2)].

(11) If an automatic control system is used to control the process, the system should be validated by the qualified person.

2.4.7 Container closure and handling [Codex 7.4 and CFR 113.60]

(1) All containers must be hermetically sealed.

(2) Every container must be marked with an identifying code (e.g. the premises, product, date and time of closure) [Codex 7.4.10 and CFR 113.60(3)(c)].

Additional information – Coding

When coding product, it is desirable to state the individual retort load and/or production time period. An operator may date a day's production instead of the individual retort load or time period, on the understanding that the whole day's production is involved if a non-compliance occurs. It is also useful to identify the processing line or sealing head.

(3) Procedures should be developed to manage dropped or damaged packaged product that has not been retorted, to ensure that it is not mistaken for fully processed product.

(4) If processing with glass:

a) line design and operation should be managed to minimise the impact of any breakages; and
b) a procedure must be developed to deal with glass breakages.

2.4.8 Container closure evaluation [Codex 7.4.2, Codex 7.4.8 and CFR 113.60]

(1) Container closure evaluation must be conducted at sufficient frequency to ensure the adequacy of the hermetic seal. The intervals must be appropriate to the equipment, line speed and container type [HC Spec 22.4].

(2) The operator should determine the appropriate sample numbers for each sample period.

(3) Containers must be assessed during production and corrective actions taken immediately if there are any critical failures. Corrective actions are likely to include stopping container closure on the affected equipment until control is restored [Codex 7.4.8.1 and CFR 113.60(a)].

(4) In the event of a critical closure failure, all products produced since the last in-specification check must be isolated and assessed by suitably skilled person and appropriate disposition made (e.g. to release with or without restriction, rework or disposal) [Codex 7.4.8.1.4].

(5) Closure evaluation records must be kept [RMP Spec 20, HC Spec 9.2, Codex 7.4.8.1 and CFR 113.60].

2.4.8.1 Can closure evaluation

(1) Table 1: Can closure evaluation describes the checks to be carried out and frequencies for can closures from each head of each filling machine.

Table 1: Can closure evaluation

Evaluation/Check	Frequency	Method
Gross container defects	Regularly	Visual observation
Visual examination	At least every 30 minutes	
Tear-down or optical seam cross section analysis	Intervals not exceeding 4 hours	Micrometer method or analysis using seam scope or projector

(2) Evaluations should also be carried out:

a) at start-up;
b) after work has been done on the seamer;
c) after a prolonged shutdown;
d) after a seamer jam-up; and
e) after changing container size or body and end material.

2.4.8.2. Glass jar closure evaluation

(1) Table 2: Glass jar closure evaluation describes the checks to be carried out and frequencies for jar closures from each head of each filling machine.

Table 2: Glass jar closure evaluation.

Evaluation/Check	Frequency	Method
Gross container defects	Regularly	Visual observation
Visual examination	At least every 30 minutes	
Physical (destructive testing)	Intervals not exceeding 4 hours of continuous operation	As appropriate to the type of closure

(2) Evaluations should also be carried out:

a) at start-up;
b) after a container jam;
c) after machine adjustments;
d) after a prolonged shutdown; and
e) after changing jars or caps.

(3) If using glass containers with vacuum closures, capper efficiency must be checked by measuring the cold water vacuum before filling operations commence.

Additional Information – Glass jar closures

There are many different designs for glass jar closures. The manufacturers recommendations should be followed as well as the guidelines for closure evaluation contained in "Principles of Thermal Process Control, Acidification and Container Closure Evaluation".

2.4.8.3. Semi-rigid and flexible container closure evaluation

Additional Information – Semi-rigid and flexible container closures

When evaluating the seal quality of semi-rigid or flexible containers, the seals will differ between package designs, construction and sealing methods. This requires thorough research. The following documents may provide useful guidance:

- Canned Foods. Guidelines for closure evaluation are contained in Principles of Thermal Process Control, Acidification and Container Closure Evaluation.
- CFIA. 2002. Flexible Retort Pouch Defects Identification and Classification Manual; and
- FDA, Bacteriological Analytical Manual (BAM), Chapter 22C.

(1) Operators should determine the seal tests to be carried out and their frequency by consulting their packaging and sealing equipment suppliers.

(2) Visual and physical tests must be carried out.

(3) Closures must be examined from each sealing or closing head at least every 30 minutes.

Additional Information – Semi-rigid and flexible container closures

When evaluating closures of semi-rigid and flexible containers, the evaluation should assess the entire container not just the seal produced by the processor.

Semi-rigid containers
As a guide, the seals of semi-rigid containers from each head of each filling machine should be evaluated as a minimum at the following frequencies:

- visual examination for defects at least every 15 or 30 minutes; and
- other tests every four hours of continuous production.

Evaluations should also be carried out:

- at start-up;
- after work has been done on the sealer;
- after a prolonged shutdown;
- after a sealer jam-up; and
- after a splice or lot change of the body or lid material.

Table 3: Examples of seal tests for selected packaging types

Test Method	Packaging type		
	Plastic with double seamed metal end	**Semi-rigid sealed lid**	**Paperboard**
Burst test	X		
Compression, squeeze test			X
Dye penetration test		X	X
Electrolytic		X	X
Proximity tester			X
Seam scope projection			X

Sound	X	X	X
Tensile (peel) test		X	
Vacuum testing		X	

Source: Canned Foods. Principles of Thermal Process Control, Acidification and Container Closure Evaluation

Flexible containers
As a guide, pouch seals formed by the processor from each fill tube or sealing lane should be evaluated as a minimum at the following frequencies:

- if possible, 100% inspection of seals;
- visual examination of seals for completeness and a squeeze test at least every 30 minutes; and
- other tests every four hours of continuous production e.g. burst test, tensile (peel) test, drop test, dye penetration test.

Evaluations should also to be carried out:

- at start-up;
- after work has been done on the sealer;
- after a prolonged shutdown;
- after a sealer jam-up;
- for web-fed systems, after every splice; and
- after changes to the sealing temperature, pressure or dwell time.

2.4.9 Container washing [Codex 7.4.11]

(1) When required to remove organic material, containers should be washed after closure using water sprays or a continuous flow water bath, at a temperature that is adequate to ensure the removal of any product scraps.

(2) The wash water may contain an approved maintenance compound.

Additional Information

In the case of cans, extraneous material should not remain on the surface as this will induce corrosion and rusting.

Sealed containers that are dirty should be rinsed to remove protein residues and then washed with hot water and detergent. Washing containers in hot water without pre-rinsing may coagulate soluble proteins making them difficult to remove.

2.4.10 Container handling and retort loading

(1) Containers must be handled on a way that protects the container and seal from damage [Codex 7.4.9].

(2) To ensure that all containers undergo a thermal process, all retort baskets, trolleys or containers must be marked with temperature change indicators (e.g. cards, strips) that change colour permanently if they are heated to a specific temperature, or other effective means to visually indicate whether or not the product has been retorted [Codex 7.5.3.4 and CFR 113.87(b)].

(3) Retort racks must be capable of holding flexible containers (pouches) so that they do not move during the retort process.

Additional information

Edges of the pouches may overlap but the product inside the pouch must not overlap.

(4) Any flexible containers (pouches) that have overlapped or are found to be out of position after the process must be discarded or, if appropriate, reprocessed.

2.4.11 Processing

(1) The process must be operated in accordance with the scheduled process documented in the RMP [RMP Spec 11 and Codex 7.5.3.1].

(2) The scheduled process, including all parameters critical to the retort operation for the product being retorted must be prominently displayed or readily available to the retort operators [Codex 7.5.3 and CFR 113.87(a)].

(3) Retort operators must know the corrective actions to take in the event of a process deviation.

Additional Information – Corrective actions

Retort operators may be informed about the actions to be taken through training and/or written procedures that are readily available.

(4) In accordance with the scheduled process, containers must be filled:

a) with correctly formulated and prepared product, that is maintained at or above the minimum initial temperature (IT) [Codex 7.5.3.5 and CFR 113.87(c)];
b) with the correct weight of product;
c) to the correct level (i.e. sufficient headspace (as applicable) and sufficient vacuum); and
d) ensuring that the maximum residual air is not exceeded for flexible and some semi-rigid packaging.

(5) The initial temperature (IT) of the coldest container(s) in a retort load must be checked and recorded, ensuring that the contents are thoroughly mixed before measuring the temperature. The temperature is measured:

a) for still and discontinuous agitating retorts by:

i) selecting the container that would have been loaded first, or the coldest container from those being loaded into the retort; and
ii) measuring the IT in the selected container after the steam is turned on.

b) for continuous agitating retorts and hydrostatic retorts, periodically selecting a container just before it would enter the retort and measuring the IT.

(6) Despite (4), if the IT is below that specified in the scheduled process and heat processing has started, if appropriate data is available, the process time may be recalculated by the qualified canner based on the new IT and the time of retorting extended as calculated. The procedures in 4.18 Deviation from the Scheduled Process apply.

(7) If pre-programmed controls are used to operate and/or control a process, unauthorised access to the programmed parameters must be prevented [HC Spec 22.3].

2.4.12 Cooling [Codex 7.6.8 and CFR 113.60(3)(b)]

(1) Cooling must take place in accordance with the scheduled process.

(2) Cooling water must:

a) not be a source of contamination to the product [AP Reg 6]; and
b) be potable, or of an alternative standard as determined from an analysis of hazards and other risk factors [HC Spec 2.5].

Additional Information

Cooling water should be of consistently low microbial content, e.g. with an aerobic mesophilic count of less than 100 cu/ml at the end of cooling (Codex).

It is generally recommended that aerobic mesophilic count of cooling water is checked at least weekly and coliforms tested for monthly. Any significant variation from the established limits should be investigated and the frequency of sampling increased. The presence of coliforms in any sample indicates the need for immediate investigation.

(3) Chlorinated cooling water must contain a detectable amount of free residual chlorine (usually 0.5 to 2 ppm). The chlorine level must be measured:

a) after each processing batch, or hourly for continuous operations; and
b) at the point after the water has been used for cooling.

(4) If there is no amount of free residual chlorine, the product produced since last compliant result must be reprocessed or disposed of.

(5) Chlorine must have a water contact time of at least 20 minutes at a suitable pH and temperature (Codex).

(6) Retorts that operate using a closed system of re-circulating the same water for both heating and cooling (e.g. "Steriflow", where the water is sterilised as part of the process) do not need chlorinated water for cooling, provided the operator has evidence that the water used is acceptable for cooling.

(7) Alternative methods of water treatment may be used, provided there is evidence that the water is of an acceptable standard for cooling.

(8) Cooling water may be re-used for further cooling purposes provided it is treated to meet the physicochemical and microbiological standards for potable water and is re-chlorinated or otherwise treated to meet the requirements above.

2.4.13 Post–heat treatment handling

(1) After retorting, product must be handled in a manner that prevents recontamination and microbial growth [AP Reg 9, Codex 7.7 and CFR 113.60(3)(d)].

(2) Containers must be rapidly cooled to 40°C or less after retorting and dried quickly before manual handling [Codex 7.6.8 and 7.7].

(3) Containers may be removed from a retort at warmer than 40°C, provided:

a) there are procedures in place to ensure the hygienic cooling and drying of containers; and
b) the hygiene of the container handling and storage environment will not result in contamination or microbial growth in the product.

Additional Information – Container cooling

There is an optimum temperature range for removing cooled containers from a retort. Thermophiles can grow in the range of 35°C-50°C, but excess cooling may mean that containers don't dry. In cans, this may lead to rust formation and degradation.

If cooling failure occurs and containers are removed for cooling at high temperatures, incubation and/or microbiological assessment should be undertaken to determine product disposition.

(4) Containers must not be removed from a retort at a temperature that is likely to result in container distortion as a result of any physical stress [Codex 7.6.8].

(5) Containers must be handled in a manner that will prevent damage to the seal area [Codex 7.7 and CFR 113.60(3)(d)].

(6) Handling of hot and wet containers after retorting must be minimised [Codex 7.7.1].

Additional Information

Manually unloading wet containers can present a risk of contamination from pathogens transferred from the worker's hands into the container via micro-leaks.

Flexible pouches are more susceptible to damage than metal cans and need to be handled carefully to avoid damage.

(7) All conveyors, tracks, belts and bars that the containers may come in contact with must be thoroughly cleaned and sanitised to minimise build-up of microorganisms [Codex 7.7 and CFR 113.60(3)(d)].

(8) Cans must not be washed after retort cooling [Codex 7.4.11.2].

(9) Only single-use sterile wipes may be used for wiping containers.

(10) Personnel access to container cooling areas must be controlled and minimised [Codex 7.7].

(11) The container cooling environment must be protected from sources of contamination [Codex 7.7].

Additional Information – Potential contamination sources

Air flow, presence of water (including condensation) and personnel should be considered when investigating potential contamination sources. Personnel working in areas used for container cooling should be trained about the importance of maintaining good personal hygiene and behaviours appropriate to the area. Access should be limited to people who need to be present to complete the required tasks.

(12) The operator must have a system to monitor the integrity of processed containers (e.g. dud detection equipment, visual inspection programme, teardowns).

(13) Defective containers must be rejected.

2.4.14 Labelling and storage [Codex IX]

(1) Adhesives and labels that do not attract water should be used if the containers could corrode.

(2) Stored product should be kept dry and not subjected to extremes of temperature and humidity.

2.4.15 Incubation

Additional Information - Incubation

Preferably two containers from each retort load should be incubated for 10 days at 37°C. For continuous retorts (chain, carrier, rotational mechanism), at least one container for each processing cycle should be incubated [Codex APP V 4.2.2 and CFR 113.40].

The retort load or lot from which the container was taken should be held in storage until satisfactory incubation tests have been completed. Product may be released prior to completion of the incubation tests if:

- all other records indicate that the product is within specification; and
- it remains under the control of the operator (i.e. is prevented from entering retail sale); and
- it can be effectively withdrawn in the event of an unsatisfactory incubation test results.

The temperature of the incubator should be recorded periodically using a calibrated independent thermometer.

(1) If an incubation test is unsatisfactory, the retort load or lot from which the container(s) came must be disposed of and controls reviewed [AP Reg 6].

Additional Information

“Unsatisfactory“ includes any deviation from the product specification such as gas formation, vacuum change, can leakages or pH changes, at levels which are considered unacceptable for that product as defined by the qualified person.

2.4.16 Records

Additional Information - Records

The critical factors to be checked and recorded will depend on the sterilising system used. Types of sterilising systems and their operation are detailed in “Canned Foods: Principles of Thermal Process Control, Acidification and Container Close Evaluation”. Also detailed in this publication are the requirements for the records to demonstrate control of the process.

(1) Permanent records must be kept for each retort load/operation and all test results must be recorded [Codex 8.1 and CFR 113.100].

(2) Records must be kept for 4 years or the shelf life of the product – whichever is longer. [HC Spec 22.4 and RMP Spec 20].

(3) The information to be recorded at the time of processing (as appropriate to the nature of the process and equipment), includes:

a) business identifier;
b) date;
c) retort identification;
d) product name, product code and/or other identification;
e) container size;
f) approximate number of containers per retort load/operation;
g) product initial temperature (IT);
h) time that steam was turned on for a batch process;
i) time that vents were closed, where appropriate;
j) temperature in the retort when the vents were closed, where appropriate;
k) time that process was started and in the case of a continuous process, the time the first container enters the retort;
l) processing temperature;
m) processing time;
n) water level and water flow rate (if processing in water);
o) temperature reading from the independent temperature measuring device and from the temperature recorder/controller taken at the same time at least once during the process, and in the case of a continuous operation, at least every hour;
p) pressure (if appropriate);
q) speed (chain, carrier, rotational) checked and recorded at the start of operations, and:

i) at least once per load; or
ii) at least once every 4 hours during continuous operations; or
iii) if the speed is changed; or
iv) continuously recorded;

r) time steam was turned off and in the case of a continuous process, the time the last container leaves the retort;
s) water cooling time;
t) chlorine (or other sanitiser) levels;
u) seam check results;
v) cross reference to the automatic temperature record for the cook (record identifies retort number, date, product, batch or lot, retort operator's name and reviewer's name);
w) all other critical factors specified in the scheduled process, at a frequency sufficient to ensure that they remain within the specified limits; and
x) retort operator's signature or other means of providing sign off.

(4) Processing records, including product specification and container closure evaluations must be verified within 24 hours (1 working day) by a suitably skilled person [Codex 8.2.1 and CFR 113.100(b)].

(5) Records must allow traceability of raw materials and final products from the supplier to the next person in the supply chain [AP Reg 18, Codex 8.2.4 and CFR 113.100(f)].

Additional Information

The time within which processing records are verified may be extended to 36 hours if an event occurs which is unforeseen and the required personnel are unavailable. All product must remain under the control of the operator.

2.4.17 Deviation from the scheduled process [Codex 7.8 and CFR 113.89]

(1) Deviations from a scheduled process that may result in under-processed product must be:

a) addressed during processing by adjusting the time and/or temperature of the heat process during the process to ensure the product is made commercially sterile and as agreed to by a qualified person; or
b) assessed by a qualified person after processing if the process is completed without alteration, and either the product is:
    i) immediately reprocessed using the scheduled process; or
    ii) reprocessed using a valid scheduled process, designed for the affected product where it has previously been processed; or
    iii) appropriately disposed of.

Additional Information

If reprocessing is to occur, the thermal process may need to vary from the standard scheduled process. This may be necessary if the original process significantly altered the heat transfer characteristics and/or IT of the product. When determining appropriate reprocessing parameters, the potential for spoilage and growth of pathogens during the product cooling and storage (prior to reprocessing) also needs to be considered.

(2) Any product lot(s) affected by a deviation that may result in under processed product must be identified, segregated, and detained pending the outcome of an assessment by a qualified person.

(3) Assessments of all deviations must be based on detailed information of the conditions during the non-scheduled process and on the heat transfer characteristics of the product, in accordance with procedures adequate to detect any potential hazard to public health.

(4) The impact on public health must be the primary consideration of the qualified person in any decision taken.

(5) A full report of the assessment and corrective actions taken must be prepared by the qualified person, including:

a) date and time of deviation;
b) retort identification;
c) description of the nature and scope of the deviation, including processing records;
d) description of affected product, including any identifiers and quantities involved;
e) corrective action taken, including restoration of control, product disposition and prevention of recurrence;
f) records of the tests undertaken and any reprocessing records; and
g) the name and signature of the qualified person who conducted the assessment.

Additional Information

Product may be disposed of by being:

- reprocessed (subject to any processing constraints) and released for trade;
- released for trade if the applied process was determined by the qualified person to be sufficient to render the product lot(s) commercially sterile; or
- condemned and appropriately disposed of.

If the decision is taken to release product affected by a deviation, consideration should be given to having the assessment reviewed by a qualified person who was independent of the original assessment.

2.5 References

Canadian Food Inspection Agency. (2002). Flexible Retort Pouch Defects Identification and Classification Manual. http://www.inspection.gc.ca/food/fish-and-seafood/manuals/flexible-retort-pouch/eng/1350916942104/1350932698250

Canadian Food Inspection Agency. (2012). Metal Can Defects Manual - Identification and Classification. http://www.inspection.gc.ca/food/fish-and-seafood/manuals/metal-can-defects/eng/1348848316976/1348849127902

Canadian Food Inspection Agency. (2015). Facilities Inspection Manual, Chapter 13. Process Determinations for Thermal Processes http://www.inspection.gc.ca/food/fish-and-seafood/manuals/facilities-inspection-manual/eng/1354209008142/1354209083903

CODEX. (1933). Recommended International Code of Hygienic Practice for Low Acid and Acidified canned foods CAC/RCP 23-1979, Rev 2.

GMA Science and Education Foundation. (2015). Canned Foods: Principles of Thermal Process Control, Acidification and Container Closure Evaluation. National Food Processors Association. The Food Processors Institute, Washington D.C.

Institute for Thermal Processing Specialists. (2014) Guidelines for Conducting Thermal Processing Studies.

http://iftps.org/wp-content/uploads/2017/12/Retort-Processing-Guidelines-02-13-14.pdf

United States Food and Drug Administration Requirements for Thermally Processed Low-acid Foods Packaged in Hermetically Sealed Containers, 21 CFR Part 113; and Acidified Foods 21 CFR Part 114

3 High Pressure Processing

3.1 Purpose

High pressure processing (HPP), also known as high hydrostatic pressure or ultra-high pressure processing, is the process of applying pressures, usually between 100 and 600 MPa to packaged or unpackaged liquid or solid foods, to achieve a particular technological effect, make them safe and/or to extend shelf life. It is a non-thermal technique with a typical pressurisation time of a few seconds to over 20 minutes.

As bacterial spores are resistant to HPP applied at ambient (or colder) temperatures, products produced using HPP are often high acid and are stored chilled. Although there is evidence to support the ability of HPP applied with high heat (known as Pressure Assisted Thermal Sterilisation (PATS) or HPP with heat), to achieve significant reductions in spore formers, this requires the HPP unit to be able to withstand these higher temperatures, and to be equipped to control the temperature during processing. The availability of commercial units capable of achieving this is limited, and so this technique is not addressed in this guidance.

Increasingly, processors are looking to use HPP as an alternative to thermal pasteurisation. However, there is limited published information that describes validated parameters for HPP, such as is available for thermal processing. As a result, processors often need to carry out their own validation to demonstrate that the product will be safe, both immediately after processing, and for its shelf life.

This section focuses on HPP where it is applied to eliminate or reduce vegetative bacteria to acceptable levels to:

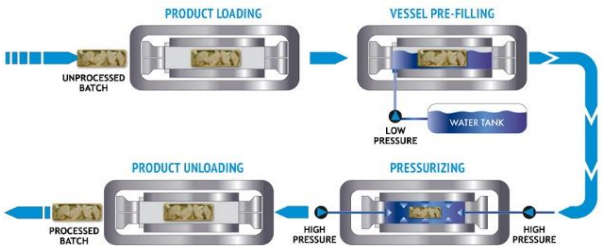
- extend shelf life; and/or
- replace traditional thermal pasteurisation processes to make foods safe.

When developing and validating a HPP process, processors need to also consider other risk factors such as chemical and physical hazards.

Additional Information - HPP

HPP systems consist of a pressure vessel, a pressure-generating device (high pressure pump), and loading and unloading conveyors. Generally, products are treated in their final package. The process initiates with loading product into HPP carrier baskets. The baskets are then inserted into the pressure vessel. The vessel is sealed and filled with pressure transmitting fluid (usually water) at low pressure. A high pressure pump compresses the fluid inside the vessel until the target pressure is reached. This pressure is held for a period of time and finally, depressurisation occurs, and the product is unloaded.

Figure 1: Diagram of operation of a HPP unit (http://www.hiperbaric.com/en/high-pressure)



3.2 Layout of section

This section has been written to align with the activities carried out as you develop, validate and operate a HP process.

3.3 Definitions

In this Guidance Document, unless the context otherwise requires:

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

headspace means the air or empty space left above the food contents in a sealed package

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, 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)

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 people

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

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

sub-lethally injured cell means a microorganism that is stressed or injured by HPP, which given favourable conditions and time can become functionally normal again

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

surrogate organisms means non-pathogenic species and strains that respond to HPP in a manner equivalent to a pathogenic species and strain

validation means a process by which evidence is obtained to demonstrate the process operating at defined parameters, is consistently capable of producing animal products that meet the requirements to be fit for its intended 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: $a_w = p/p_o$

3.4 High Pressure Processing Procedures

3.4.1 General requirements

(1) When operating a HPP, you must:

a) document and meet any regulatory limits applicable to the product [RMP Spec 7 & 11];
b) establish operator-defined limits that are appropriate for the product and have evidence to justify their selection [RMP Spec 7 & 11]; and
c) demonstrate that the process is capable of consistently achieving the regulatory and/or operator-defined limits [RMP Spec 18].

Additional Information – Operator-defined limits

Operator-defined limits are measurable limits that are established by you, the operator, and are not defined in legislation. Examples include:

- microbiological limits for products not currently addressed in the FSC;
- a specified $\log_{10}$ reduction of a target pathogen; or
- HPP parameters.

They may be sourced from reputable codes of practice or guidance documents, peer-reviewed scientific information, predictive models, scientific information from people or organisations known to be competent, other regulatory authorities or developed from trials and experiments. In setting operator-defined limits, you should consider aspects such as the product's intended use, intended consumer, and the handling it is likely to receive during its shelf life.

(2) HP processes should be developed and validated[15] by suitably skilled persons.

Additional Information – Suitably skilled persons

Suitably skilled people who develop and validate HP processes should have a good working knowledge of factors that are critical to the process. It is recommended that they have knowledge of:

a) the capabilities and limitations of HP processing and the HPP unit;
b) product and packaging characteristics;
c) pathogens of concern and their response to pressure;
d) validation techniques for HPP (e.g. challenge trials and shelf life studies);
e) analysis of validation data; and
f) dealing with process deviations.

You are responsible for ensuring that people with the appropriate knowledge and skills are used to develop and validate your RMP.

If you are looking for consultants to assist with this work, a good starting point is the NZ Food Innovation Network.

(3) People carrying out key tasks (such as monitoring or verification) must be identified in the RMP, and any required competencies specified [RMP Spec 15].

(4) Training records must be kept [HC Spec 9.3 and RMP Spec 15].

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

Additional Information – Training

If a processing step is a CCP, training expectations are heightened. The training should cover the operation, control, and monitoring of that step.

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

(6) The validation report must be kept while the product is in production.

(7) If the validation report is replaced, the obsolete report must be kept for 4 years or the shelf life of the product, whichever is longer [RMP Spec 20].

Additional Information – Contents of validation report

The validation report should include the documentation recommended in section 5.2.5 of the Risk Management Programme Manual.

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

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

(10) All equipment used for critical measurements must meet HC Spec 6.2.

3.5 Equipment

(1) HPP units should be fitted with a control system that can generate permanent process records, and that enables you to identify process deviations.

Additional Information – Equipment

The following table is an example of the transducers recommended by the Food and Drug Administration (2000), their precision, accuracy, and appropriate location in the vessel.

Table 1: Recommended transducers

Measuring Transducer	Accuracy/Precision	Location in HPP System
Pressure Gauge (Electronic)	+/- 1/2% / 3.4 MPa	Anywhere in HPP system
Pressure Gauge (Dial Display)	+/- 1% / 6.8 MPa	Anywhere in HPP system
Time (Recorder)	+/- 1% / one second	(not applicable)
Temperature (Thermocouple)	+/- 1/2% / 0.5^{0}C	Incoming low-pressure transmitting fluid line*

* Personal communication

(2) Equipment should be installed, commissioned, and maintained by suitably skilled persons, according to the manufacturer's specifications.

3.6 Raw Materials

(1) Raw materials must comply with the requirements of the FSC.

(2) Raw materials must be protected from contamination, handled hygienically, and stored in a manner that will minimise deterioration [AP Reg 9].

Additional Information – Raw materials

Information about the microbiological quality of your raw materials may be obtained:

a) from certificates of analysis from suppliers;
b) from the MPI National Microbiological Database (NMD) for some meat types;
c) by testing the raw materials; or
d) using knowledge you have gained about any previous processing steps applied to that material.

The capability of your process, the intended use of the product, and any further processing that the product receives and/or preparation prior to consumption should be considered when determining the microbiological quality of your raw materials.

You should have procedures to ensure that raw materials are not changed in a formulation (including supplier, type, or addition rate) without input from a suitably skilled person, to determine whether the validated process will still be effective.

3.7 Packaging and Labelling

(1) Packaging must be:

a) used in accordance with the manufacturer's specifications;
b) appropriate to the intended use, and the filling and sealing equipment used [HC Spec 7.2(1)]; and
c) clean and sound before filling [HC Spec 7.2(2)].

(2) Packaging must be stored in a way that prevents it from being contaminated. It should be wrapped and stored off the floor until it is used in production [AP Reg 16 and HC Spec 7.2(2)].

(3) The barrier properties of the packaging such as the permeability (water, oxygen, or carbon dioxide) should not significantly change due to HPP.

(4) Where necessary to ensure the safety of the product, procedures should be implemented to check the packaging seal or closure integrity.

(5) Any materials used for sealing product must be controlled to ensure that it is not a source of physical contamination to the product [AP Reg 6].

(6) Product must be labelled in accordance with the requirements of the FSC, including any "Directions for Storage and Use".

(7) You must have procedures to ensure that all information printed on the label or on packaging is accurate, and that the correct label is applied to the product [APA s 17, RMP Spec 11].

Additional Information

Packaging

As the volume of the product reduces during HPP, the packaging needs to have a degree of flexibility. The compression and decompression means that the packaging should be capable of withstanding up to a 15% reduction in volume without losing seal integrity or barrier properties (USFDA, 2000).

Head space should be kept to a minimum to ensure that pressure is well transferred to the product, to help minimise deformation of packaging, and to make the most of the space inside the pressure vessel. Where a larger headspace is desirable (such as modified atmosphere packaging), the packaging may need a more robust design. Entrapped air should also be minimised to avoid potential packaging damage during the decompression.

Packaging should be obtained from reputable suppliers who can provide technical support, including specifications for package sealing parameters, design recommendations and food contact compliance for HPP processes. The most common packaging materials are polyethylene terephthalate (PET) bottles and

trays, polypropylene (PP) tubs and trays, polyester tubes, polyethylene (PE) pouches, trays and tubs, and nylon cast polypropylene pouches. For barrier materials, ethylene-vinyl alcohol (EVOH) is commonly used. Packaging seal or closure integrity checks may include visual or physical testing such as checking that complete seals are being formed, and there is no cracking, wrinkling, delamination, or blistering. Seal checks should be carried out on products after HPP, on randomly selected packs (i.e. not on empty packs).

Package handling should be minimised, including when loading into the unit, to reduce the potential for damage from pinching, tearing or crushing. Packages should be dried as soon as possible after the process.

Packaging requires its own validation to ensure that it will consistently meet product specifications and will not adversely affect the HP process. Where possible, worst case packaging conditions should be tested such as greater headspace and lower seal strength.

Labelling
There is no requirement to include a statement on the label that the product has undergone an HPP process. Labelling procedures should cover identification, storage, inventory and use of labels, and disposing or obsolete or incorrect labels.

3.8 Outcome of High Pressure Processing

Additional Information
Example validation templates are in Appendix 1.

(1) HPP applied for the purpose of food safety 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., *Escherichia coli* O157:H7, *Campylobacter* spp., *Listeria monocytogenes*, *Staphylococcus aureus*, *Vibrio parahaemolyticus*, *Clostridium* spp, *Bacillus cereus*, and *Cronobacter* spp.);
   b) viruses (e.g. Norovirus, Hepatitis A); and
   c) parasites (e.g. *Toxoplasma gondii*, *Trichinella spiralis, Anisakis simplex)* [AP Reg 6].

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

Additional Information – Biological hazards

The application of HACCP principles will identify those pathogens that are reasonably likely to occur and that need to be controlled by your HPP. The MPI Hazard Database and model HACCP plans can be used to assist with hazard identification and analysis.

As an example, Table 2 identifies the pathogens of concern and the level of inactivation that is expected when developing and validating a HPP as a key control when applied to raw milk, instead of using thermal pasteurisation.

Table 2: Target pathogens and level of inactivation when applying HPP to raw milk

Pathogen	Log_{10} reduction in product to be sold in NZ	Log_{10} reduction to achieve a standard similar to thermal pasteurisation (export product should meet at least this standard)
Campylobacter spp.	5	>7
Listeria monocytogenes	5	>7
Shiga toxin-producing Escherichia coli (STEC)	5	>7
Salmonella spp.	5	>7
Staphylococcus aureus	5	>7
Mycobacterium avium sub spp *paratuberculosis (MAP)*[a]	6[b]	Estimate >7, may need data on *M. bovis*
Bacillus cereus	No growth	No data available[c]

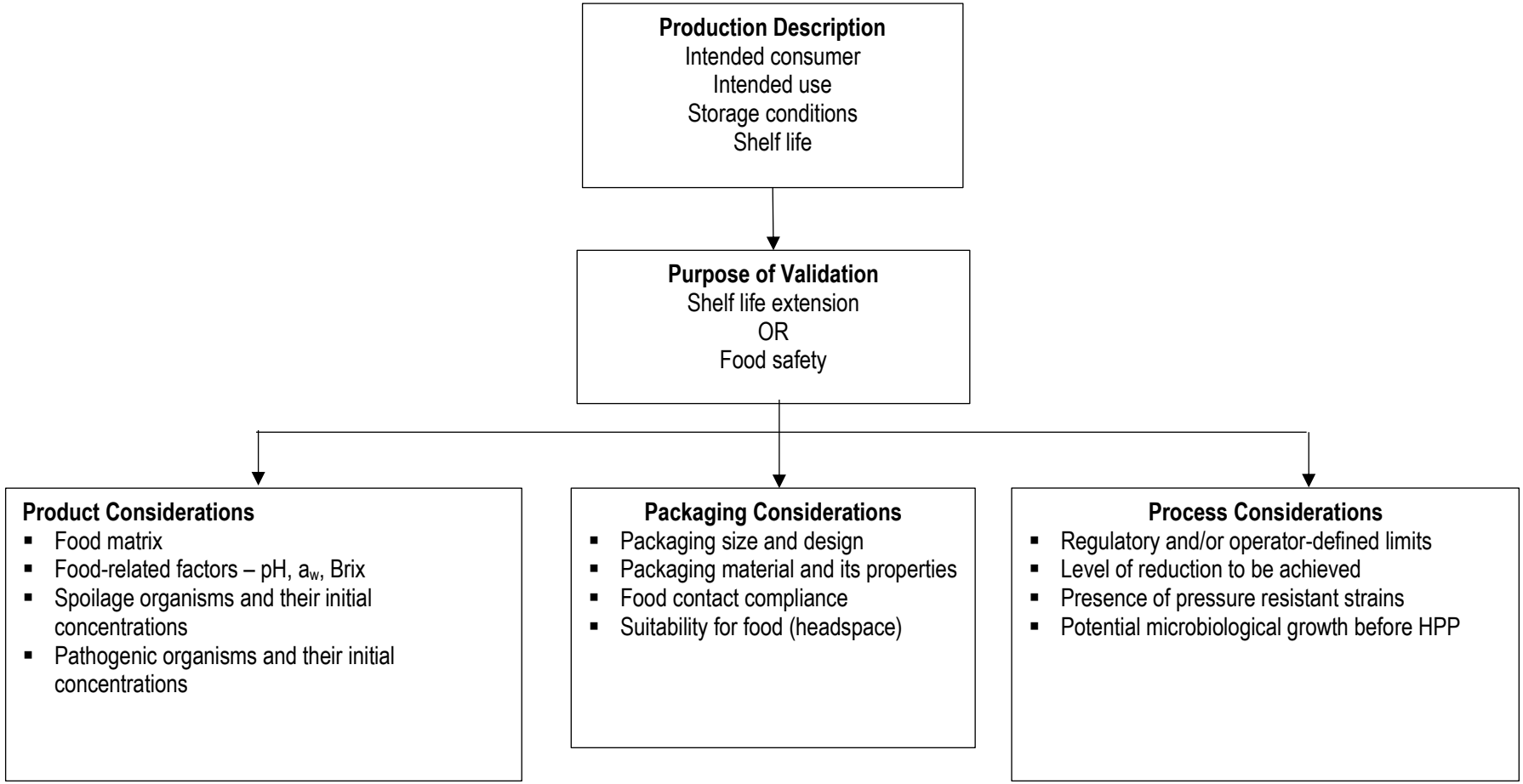
[a]The inclusion of MAP is as a surrogate for *M.bovis*. The requirement to eliminate *M. bovis* is based on the current NZ TB status.
[b]An additional 1 log_{10} reduction has been applied to allow for the possibility that *M. bovis* inactivation under HPP may differ to MAP.
[c]Comparison cannot be made as pasteurisation does not inactivate spores.

3.9 Development and Validation of a High Pressure Process

(1) When determining appropriate HPP parameters to apply to your product (such as holding times and target pressure), you should consider the following factors:

a) purpose of applying the HPP process (e.g. shelf life extension, food safety);
b) pathogens of concern as identified during the application of HACCP principles and their initial concentration in the raw materials;
c) presence of pressure resistant strains of any pathogens of concern;
d) spoilage organisms and their initial concentrations;
e) food matrix;
f) food-related factors (pH, a_w, Brix etc);
g) packaging size and design;
h) packaging material and its mechanical and thermal properties (strength and barrier properties);
i) potential microbiological growth before HPP, including during any product hold steps;
j) regulatory and/or operator-defined limits;
k) level of pathogen or spoilage organism reduction to be achieved by the process; and
l) intended use and consumer of the product, storage conditions and shelf life.

Figure 1: Validation study – factors to consider



Additional Information – Validation considerations

To assist with understanding the factors that are critical to HPP, New Zealand Food Safety commissioned the report "Review of the High Pressure Processes applied as an alternative to thermal process pasteurisation". The following information is taken from that report.

HPP for shelf life extension

Shelf life extension trials aim to demonstrate that HPP is able to eliminate or reduce spoilage microorganisms in the food to acceptable levels and thereby extend its shelf life. The results of testing HP treated product is compared with untreated product to identify if there is a delay in the growth of spoilage microorganisms during the proposed shelf life.

HPP for food safety

HPP is capable of eliminating or reducing foodborne pathogens to acceptable levels for the shelf life of the product. However, the effectiveness of a HP process depends on a number of intrinsic factors (growth phase, cell membrane,) and extrinsic factors (pH, a_w).

The HP process should be designed and validated to ensure the elimination or reduction to acceptable levels of the most pressure resistant strains of the pathogen(s) likely to occur in the product. If spore forming microorganisms are likely to occur in the product, other control measures will need to be in place.

Inactivation of pathogens

Different bacterial strains of the same species can be reduced by significantly different amounts when subject to the same HP process. Often pathogens that are susceptible to heat are not more susceptible to pressure. In most cases, trials and experimentation will be needed.

Use of high pressure (>550MPa), with an elevated pre-pressurisation product temperature (>50^0C) for more than 5 minutes, has achieved a 5 $\log_{10}$ reduction of most non-spore forming foodborne bacterial pathogens in NZ. However, achieving these temperatures using standard HPP units may be difficult.

Product composition

The composition of the product can affect the level of microbial inactivation achieved by a HP process. Parameters such as pH, a_w, and fat content need to be considered. In general, HPP is more effective when the a_w of the product is above 0.87 or the pH is more acidic. Due to the significant influence that these factors have on the inactivation that can be achieved by HPP, it is important that the validation is carried out using the product as formulated for commercial production.

Product packaging and size

As packaging may affect the temperature and pressure within the product during HPP, wherever possible, the packaging should be the same material as used in the commercial production. If this is not possible, consider whether this impacts on the inactivation achieved by the process.

Challenge trials

When carrying out microbial challenge trials, a cocktail of strains of the target pathogen(s) is inoculated into the product and then processed to determine whether the required pathogen reduction is achieved. Cells in the stationary phase are more pressure resistant than actively growing cells. Therefore, when carrying out trials, cells should be in this growth phase. Acid and/or cold adaptation of the pathogens prior to inoculation can also greatly influence their ability to survive when inoculated into the product.

Surrogate organisms

Challenge trials involving microbial pathogens should not be carried out in the commercial processing environment. Surrogates can be useful as they can allow validation of a HPP without introducing pathogens into a processing area. The choice of surrogate used for HP process validation needs to be justified. Surrogates need to have comparable pressure resistance to the pathogens they are representing, in an equivalent product matrix. Validating a surrogate is not a simple task and currently there are limited

validated surrogates that are recommended for use for HPP validation. The ESR report includes a review of available HPP surrogates.

Bacterial injury
HPP can result in sub-lethally injured bacterial cells, that are able to recover and grow during storage. Because of this, it is important that samples are stored for longer than the intended shelf life to confirm (or otherwise) that the process has fully inactivated the target micro-organisms. When validating a HP process, the microbiological method should be able to detect stressed or injured cells.

Pre-compression temperature
The temperature of the product prior to HPP used during the validation work should cover the range likely to be encountered during commercial processing. Unlike thermal processing, the least inactivation is not necessarily achieved using the lowest pre-compression temperature (i.e. sometimes higher pre-compression temperatures result in lower levels of inactivation). The pre-compression product temperature should homogeneous with no cold spots.

Holding time
The length of the holding time at the target pressure is not necessarily proportional to the level of microbial inactivation. Therefore, inactivation data from validation studies should not be extrapolated between or beyond the holding times tested. Also, consider that cyclic pressurisation or pulsed HPP can achieve greater inactivation of pathogens. This treatment involves series of pressure cycles with full decompression between each cycle.

HPP units
Laboratory scale HPP units are likely to have different temperature profiles than industrial scale equipment, as smaller units lose or gain heat faster than larger systems during HPP, due to the larger surface area to volume ratio. HPP units used for validation trials should provide a comparable pressure, temperature and time profile as the commercial equipment.

Trials
Validation trials should be comprehensive and include minimum of testing over three batches to ensure confidence in the results. Your laboratory should assist in developing a sampling plan, with understanding as to when the product should be sampled after the HP process, and carry out the microbiological validation trial (Refer Template 1C for more details).

(2) Where possible, worst case process conditions (larger headspace, higher pH, lower a_w) should be included in the validation trials.

(3) Once validated, process and product parameters that are critical to food safety and shelf life should be identified in the RMP and managed, including identifying those that would require revalidation if changed.

Additional Information – Product testing
Trials carried out to validate a HP process should be repeated if a change is made that could impact on food safety, such as, to the ingredient supply, formulation, pre-HPP steps, packaging or the HP process.

3.10 Pressure-transmitting fluid

(1) Water, when used as a pressure-transmitting fluid, that comes into direct contact or indirect contact with the product, must be suitable water [HC Spec 2.5.1].

(2) The pressure-transmitting fluid should be monitored and changed frequently.

(3) In the event of a burst package, the HPP unit should be inspected, cleaned and sanitised, and the pressure-transmitting fluid should be replaced.

Additional Information – Pressure-transmitting fluid

Water is the most commonly used pressure-transmitting fluid in commercial equipment. As the product does not come into direct contact with the water it can be recycled. Most microorganisms in the water are eliminated when it is subject to high pressures (e.g. 600MPa). However, pressure resistant microorganisms can potentially build up, which may then contaminate the product or attach to the packaging and contaminate the product when opened.

3.11 Routine processing

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

(2) HPP should commence promptly after product preparation. Any delays or holding between product preparation and HPP treatment must be in accordance with the RMP [RMP Spec 11].

Additional Information – Holds or delays

The maximum time from product preparation to HPP should be specified in the RMP, taking into account conditions that may permit microbial growth and toxin production. Ideally, the time should not exceed 2 hours.

(3) Handle raw materials and products to avoid any contamination or deterioration that the process is not designed to eliminate [AP Reg 9].

(4) If pre-programmed controls are used to operate the HPP unit, unauthorised access to the programmed parameters must be prevented [HC Spec 22.3].

(5) Procedures should be put in place to ensure that product cannot bypass the HPP process.

Additional Information – Preventing bypass

The procedures may include physical barriers, appropriate labelling and/or storage between pre- and post-processed product, or suitable pressure sensitive process indicators located with the packages or on the package itself.

(6) The process must be monitored and results recorded for every batch [HC Spec 9, RMP Spec 20].

Additional Information – Product release

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

(7) Permanent records must be kept for each product batch for 4 years or the shelf life of the product, whichever is longer [HC Spec 9.3 (2)(b), RMP Spec 20].

(8) Records must allow traceability of raw materials and final products from the supplier to the next person in the supply chain [HC Spec 28.2].

Additional Information – Process records

Process records may include:

- processing date and time;
- product name, code and/or other identification;
- formulation;
- pack size;
- product parameters (pH, a_w, product composition etc.);
- approximate number of containers in the load;
- pre-compression product temperature;
- pressure transmitting fluid (water)
- pre-compression temperature;
- compression time;
- target pressure;
- holding time;
- decompression time;
- results of seal checks;
- results of final product testing; and
- water suitability checks.

(9) Periodically, verify any parameters that had been managed when validating the process but are not routinely monitored during processing, to ensure that the process continues to operate within those parameters.

(10) Implement operator verification procedures, including ensuring that regulatory and operator-defined limits are met [RMP Spec 16].

3.12 Pre- and Post-process Handling

(1) Product must be handled in a manner that prevents recontamination and deterioration [AP Reg 9].

3.13 Deviation from the Validated Process

(1) Take immediate action if there is a process deviation that could impact on food safety, wholesomeness or labelling, including if any regulatory or operator-defined limit is not met [RMP Spec 8].

(2) Any product lot(s) affected by a deviation that could impact on food safety should be identified and detained pending the outcome of an assessment by a suitably skilled person.

(3) A record of the assessment and corrective actions taken must be prepared by the suitably skilled person [HC Spec 27.2]. The record kept should be appropriate to the nature of the deviation and include:

a) date and time of deviation;
b) description of the deviation, including the processing records;
c) description of affected product, including batch identifiers and quantity;
d) corrective action taken, including restoring control, product disposition and preventing recurrence;
e) records of any tests or checks carried out; and
f) the name and signature of the suitably skilled person who carried out the assessment [RMP Spec 20].

Additional Information – Alternative processes

If a corrective action such as extending the pressurised holding time is used, you would need to have evidence that the alternative process will deliver safe product.

3.14 Shelf life

(1) You must have evidence to support the shelf life of your product. [FSC standard 1.2.5, APA s17(2)(b), AP Reg 6]

Additional Information – Chilled storage temperatures
When selecting storage temperatures at which to carry out shelf life trials, the maximum chilled storage temperature at retail required under the Food Act 2014 is 5°C. Refer to the MPI Guidance document "How to Determine the Shelf Life of Food" for further guidance.

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3.16 Appendix 1: Microbiological Validation Templates

1A: Shelf Life Extension

1B: Challenge Trials

1C: Guidance for laboratories carrying out HPP validation trials

1.1 Background

The following templates have been developed to assist you to validate a HP process. The templates are generic and can be applied to all product types. They will be amended over time as more information becomes available. Also provided, is a basic guide for laboratories carrying out the microbiological aspects of validation work.

1.2 What is validation?

Validation is the work carried out to demonstrate that your HP process will produce safe and wholesome product. Section 18 of RMP Spec provides the legal underpinning for validation. Validation should be carried out to confirm that HPP parameters such as the target pressure and holding time are effective at reducing the microorganisms of concern to an acceptable level when applied to your product.

Validation may be carried out to demonstrate that the following parameters, will produce safe and wholesome product:

- parameters that you have previously validated on very similar products;
- parameters from reference material, reputable scientific literature, codes of practice, or international standards and that are directly applicable to your product;
- parameters from equipment suppliers and/or others with expertise in HPP that are directly applicable to your product; and
- parameters that you are developing for products or applications that have not previously been validated.

Challenge trials are likely to be needed if the HPP step is being applied to inactivate pathogens, for example, to replace a thermal pasteurisation process, and the parameters have not previously been validated as effective for your particular product and process.

1.3 Who should use these templates?

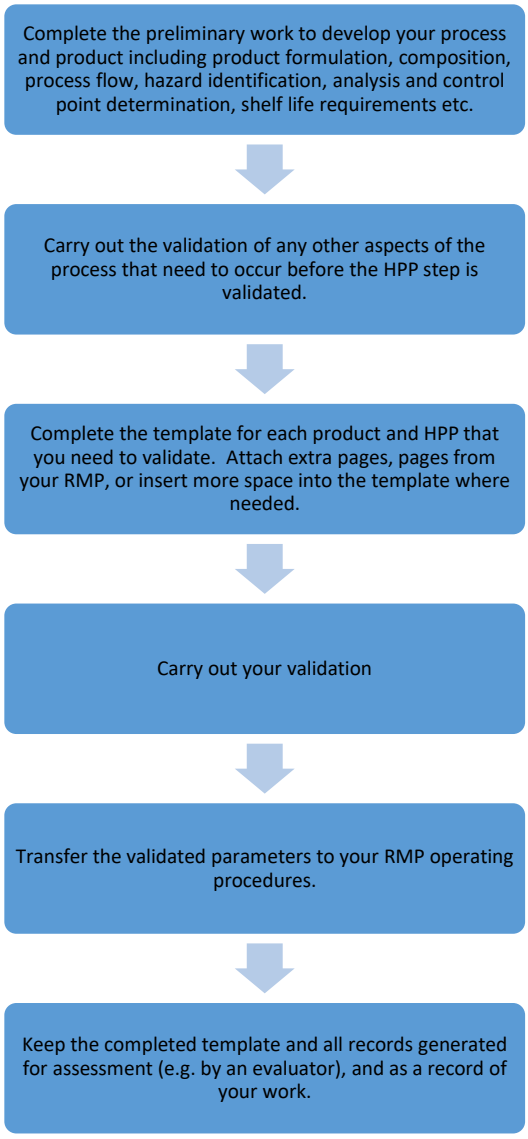
These templates should be used if you are validating a HP process that is being applied for the purpose of:

- shelf life extension, i.e. ensuring that the product remains microbiologically suitable for the duration of its shelf life; and/or
- food safety, i.e. reducing the vegetative pathogenic microorganisms of concern by a known amount and maintaining its safety for the duration of its shelf life.

This template does not need to be used if the HPP step is being applied for a technological or physical effect only, such as the shucking of shellfish or the removal of meat from crustaceans.

1.4 How to use the templates

Figure 1 describes the steps to be carried out when validating your process using this template:



Often your product will be subject to processing steps (hurdles) prior to HPP and you will need to have evidence that these other steps are effective. However, validation of these steps is not covered by this template. For example, if applying HPP to retail ready-to-eat sliced ham or to a pasta salad, validation of the ham or pasta manufacture process is not covered. You can expand the template to include all aspects of the validation so that you have all the information in one place.

Your process flow diagram, and HACCP plan should include all process steps used to process the product, including steps prior to HPP. Control points and limits for the pre-HPP steps should be provided. This will then inform about the hazards that have been identified and where and how they will be controlled. It will clarify the hazards that remain to be addressed by HPP and for which this validation information will be needed.

Remember:

- Plan thoroughly and get technical help if needed;
- Keep good records so that the process can be reproduced by someone with no prior knowledge;
- If data is not recorded, the impact of changing a parameter on food safety or shelf life may not be known and the value of the work will be lost.

1.5 Records

(1) As part of the validation work, the records to be kept should include:

a) name of the person or group of people who developed the process, and their responsibilities;
b) date of development;
c) product name, formulation, composition and product parameters (pH, a_w, brix);
d) product preparation, packaging and closure;
e) microbiological hazards and spoilage organisms associated with the raw materials and their loadings;
f) log reduction of target pathogen(s) and/or spoilage organism(s);
g) product intended use, storage conditions and shelf life.
h) all trial conditions used when validating the process, including the data acquisition system, raw data and laboratory information;
i) critical process parameters such as:
    i) pre-compression product temperature;
    ii) pre-compression temperature of pressure transmitting fluid;
    iii) compression profile;
    iv) target pressure;
    v) holding time;
    vi) in the case of pulsed processes: number of pulses, pause time-interval between pulses, pause pressure, product temperature and holding time for each pulse;
    vii) decompression profile;
    viii) final product temperature; and
    ix) final temperature of pressure transmitting fluid.

3.16.1 Template 1A: Shelf life Extension

This template should be used if validation is to demonstrate that HPP will extend the shelf life of a product beyond that which would be achieved if the product was not HPP treated. These trials will provide justification for setting the product shelf life in relation to microbiological spoilage of the product. This template does not address loss of shelf life due to other quality issues or deterioration due to chemical factors.

Shelf life studies should not be undertaken without a review of potential pathogens. A process to extend shelf life may give rise to hazards as a consequence of pathogens that survive the process. See the MPI Guide: How to Determine the Shelf life of Food, for further detail.

The most common way to perform a trial to demonstrate shelf life extension using HPP is to compare microbiological results from products that have been HPP treated against untreated controls. Untreated samples are tested at the start of the validation. Treated samples are tested immediately after the HPP step and the remaining product is held under controlled storage conditions and tested at various times up to and beyond the proposed shelf life.

During trials:

- product should be stored, and microbiological testing should be continued beyond expected shelf life;
- the variability between ingredient batches, product batches, processing days, staff, storage and transport conditions should be taken into account by testing a number of batches; and
- consider the product's intended use, intended consumer, and whether the product will be consumed in one sitting or over a period of time when deciding on the storage conditions to be tested.

The areas in white in the template need to be filled in.

A: Product information

Product details	Name or other identifier:	Weight/volume:
Microbiological regulatory or operator-defined limits to be met in the product.	Microorganism	Limit
Any microbiological limits to be met prior to the HPP step *This may be in individual ingredients or the formulated product just prior to the HPP step.*	Microorganism	Limit
Product formulation *List ingredients, amounts added and form (e.g. dried, fresh etc).*	*Write the complete recipe here or attach from your RMP:*	
Product characteristics *If these characteristics don't apply to your product, delete and replace with more appropriate characteristics. You can also add more rows.*	pH:	a_w:
	Salt/sugar content:	Protein content:
	Fat content:	Other *(list)*:
	Preservative(s)/Antimicrobial agent(s):	
Product packaging to be used *Remember, you will need evidence of compliance with HC spec Part 7.*	Type and form of packaging: Confirmed compliance with HC Spec? Yes [ ]	Is the packaging appropriate for use in the HPP and capable of forming a hermetic seal? Yes [ ] No [ ] Can the material withstand the loading and unloading into/from the unit? Yes [ ] No [ ]

	Is the same packaging to be used during the trials? Yes [ ] No [ ] Is same pack size to be used during the trial? Yes [ ] No [ ] If no, you will need evidence that the results will be applicable when using the commercial packaging.	What is the gas composition inside the product packaging/headspace e.g. vacuum, composition of modified atmosphere: Is the same gas composition to be applied to the trial samples: Yes [ ] No [ ] If no, you will need evidence that the results will be applicable when using the commercial packaging.
Intended shelf life and would product be used in one sitting or consumed over time?	Months/Weeks/Days: Single use/multiple use:	Storage conditions:

B: Process information

Full process details *Include preparation, filling, closing, holding, HPP, cooling, storage etc.*	Attach details, including all processing parameters and limits. This may be provided as a process flow.	
HACCP plan or equivalent RMP documentation	Attach for the entire process.	
Proposed HPP test parameters *There may be a number of process variations to be tested.* *If these parameters don't apply to your product, delete and replace with more parameters. Add more rows if needed.*	Pre-compression product temperature:	Holding time(s) at target pressure (state mins/sec etc, also if pulses applied):
	Target pressure (give units e.g. MPa, bar):	Compression and decompression profile (e.g. pressure increase/decrease vs time):
	Pre-compression temperature of pressure transmitting fluid:	Other (e.g. number of cycles):
Source of proposed HPP parameters *This may be peer reviewed research, a person with expertise in HPP, the equipment supplier etc. If possible, provide an electronic link to the source.*	State how the proposed HPP parameters have been determined, or the source from which they have been taken:	

C: Trial Information

Date(s) of validation work		
Suitably skilled person(s) involved in the validation trials *You may have one or more.*	Name: Evidence of competency:	Name: Evidence of competency:
How is trial product to be disposed of?	Product disposition:	Confirmation that product from the trials was disposed of as stated:
Name and contact details of laboratory carrying out testing. *Some testing **must be** carried out by a laboratory with accreditation to ISO 17025, for example if testing for Listeria monocytogenes in ready-to-*		

eat animal products. Check if this is a requirement for your product. Check that the laboratory has the competency and capability to conduct your validation trials – this can be a complex area.		
Compatibility of food matrix and test methods.	Are the laboratory test methods appropriate for food matrix and pathogen(s)? Yes [ ] No [ ]	
Enumeration method(s) for target microorganisms *Ensure these methods are capable of detecting sub-lethally injured cells It is recommended that you obtain this information from the laboratory and attach it to this template.*	Microorganism	Enumeration method
Details of the HPP equipment used for the trials	Premises where HPP is located and equipment details (e.g. make, model, size):	Evidence viewed that instrumentation calibrated: Yes [ ]
Is this the same HPP unit that will be used for commercial production?	Yes [ ] No [ ] If no, you will need evidence that the results will be applicable when used on the commercial unit. (If the results cannot be applied to the commercial unit, these trials will need to be repeated using an appropriate unit).	
Microorganisms of concern and limits to be met *Confirming that these limits will be met is the purpose of this validation.*	Microorganism	Limit
Processing conditions.	*As provided in **Section B.** Product should be processed under worst case conditions.*	
Sample storage conditions during the trial. *Examples:* *Optimum e.g. storage as on the label for entire shelf life;* *Realistic e.g. repeated short periods of elevated temperatures;* *Worst case e.g. poor temperature control in a domestic refrigerator or variable temperature control.*	Set of storage conditions (1):	Set of storage conditions 2 *(add more rows if more sets of conditions are used)*:
Number of batches to be tested (N_B). *It is recommended that three batches are tested so that batch to batch variability can be detected.*	Number:	

Total number of samples needed for the shelf life trials from each test batch. *Sufficient samples should be stored so that testing can be carried out beyond the stated shelf life, to ensure that any surviving cells that may grow during the shelf life are detected.* *A full set of samples will be needed for each storage condition tested. Determine the number needed from*	If your sampling programme requires you to test non-HPP treated controls throughout the shelf life, you will also need to store a sufficient number of these as identified in your sampling programme. Number of samples: Batch 1: Controls (non-HPP treated) [ ] HPP treated [ ] Batch 2: Controls (non-HPP treated) [ ] HPP treated [ ] Batch 3:

<table>
<tr><td>your sampling programme plus a few spares.</td><td colspan="5">Controls (non-HPP treated) [ ] HPP treated [ ]</td></tr>
<tr><td rowspan="9">Sampling programme for shelf life trial:

An example sampling programme is provided here. This should be deleted and replaced with your own programme or attach your sampling programme to this template.

The information includes the dates of testing and number of samples tested at each sampling period.

Studies should be repeated on at least three batches to identify variability within and between batches. Ideally, these will be on different dates with different ingredients, batches, etc. A sampling programme should be prepared for each batch tested.

Further trials will be needed if the shelf life is not met, or the shelf life reduced to that which is achieved.

At each testing period it is recommended that 3-5 replicate samples are tested.</td><td colspan="5">Batch ID: X Batch number: 1 Date of Manufacture: 2.10.20</td></tr>
<tr><td>Sample description</td><td>Sample date (N_p)</td><td>Sampling points</td><td>Number of samples tested (N_R)</td><td>Testing required (e.g. yeasts, moulds, bacteria, pH etc):</td></tr>
<tr><td>Green juice, untreated control</td><td>2.10.20</td><td>Take sample immediately before HPP step</td><td>5</td><td>Y, M, APC, pH, a_w, temp</td></tr>
<tr><td>Green juice, HPP treated</td><td>2.10.20</td><td>Take sample immediately after HPP step</td><td>5</td><td>Y, M, APC, pH, a_w, temp</td></tr>
<tr><td>Green juice, HPP, untreated control</td><td>9.10.20</td><td>Condition 1: 4°C/After week 1</td><td>5</td><td>Y, M, APC, pH, a_w, temp</td></tr>
<tr><td>Green juice, HPP treated</td><td>9.10.20</td><td>Condition 1: 4°C/After week 1</td><td>5</td><td>Y, M, APC, pH, a_w, temp</td></tr>
<tr><td>Green juice, HPP untreated control</td><td>9.10.20</td><td>Condition 2: 8°C/After week 1</td><td>5</td><td>Y, M, APC, pH, a_w, temp</td></tr>
<tr><td>Green juice, HPP treated</td><td>9.10.20</td><td>Condition 2: 8°C/After week 1</td><td>5</td><td>Y, M, APC, pH, a_w, temp</td></tr>
<tr><td>Etc</td><td></td><td></td><td></td><td></td></tr>
<tr><td colspan="6">Data collected when processing the samples for shelf life testing</td></tr>
<tr><td rowspan="6">Data collected on product prior to entering the HPP:

It is recommended that at least 5 samples are tested for each parameter (n=5). If product is not homogeneous more samples will need to be tested.

These parameters are suggestions only. Generally, pH, a_w (unless liquids with an a_w close to 1), and pre-compression temperature is expected.

Make sure these parameters are the same as will occur during commercial operations.</td><td colspan="3">pH:</td><td colspan="2">a_w:</td></tr>
<tr><td colspan="3">Salt/sugar:</td><td colspan="2">Fat content:</td></tr>
<tr><td colspan="3">Pre-compression temperature of product (hold samples of the product and measure the temperature just before the HPP step starts):</td><td colspan="2">Pre-compression temperature of pressure transmitting fluid (e.g. water):</td></tr>
<tr><td colspan="3">Target Pressure (give units e.g. MPa, bar):</td><td colspan="2">Holding time at target pressure (state mins/sec etc):</td></tr>
<tr><td colspan="3">Compression and decompression profile (e.g. pressure increase/decrease vs time):</td><td colspan="2">Final temperature of pressure transmitting fluid (e.g. water):</td></tr>
<tr><td colspan="3">Final product temperature immediately after the HPP step:</td><td colspan="2">Other important parameters (list):</td></tr>
<tr><td colspan="6">Raw data and analysis</td></tr>
<tr><td>Data collected and its analysis:</td><td colspan="3">Product temperature during storage and times</td><td colspan="2">Microbiological results tabulated and analysed</td></tr>
</table>

Attach the tables of raw data and its analysis for all batches to this template and tick the boxes to indicate that this has been done (add more rows if needed).	Yes [ ]	Yes [ ]
	Product characteristic test results tabulated and analysed Yes [ ]	Other (list):
Results		
Were the results as expected?	Yes [ ] Explain:	No [ ] See next row.
Were there any unusual or unexpected results? *Unexpected result should be investigated and explained.* *Examples include, high growth levels in some samples when most are not detected, results that are much higher or lower than expected, large variations.*	Explain unexpected results	
Shelf life achieved. *This should be the earliest time at which spoilage or other limiting factor occurs as determined from these trials.*	Shelf life: months/weeks/days	
Validated parameters		
Validated HPP parameters transferred to the RMP operating procedures, including procedures to ensure correct shelf life is applied.	Yes [ ]	No [ ]
Validation report is filed after use.	Yes [ ]	No [ ]

3.16.2 Template 1B: Challenge trials

This template should be used if validation is to demonstrate that the HPP will inactivate vegetative pathogenic microorganisms. Inoculation of products with known quantities of target pathogenic microorganisms can be used for two purposes:

- to assess the growth potential of the pathogen in product under specific circumstances; and
- to assess the efficiency of an inactivation process.

Depending of HPP parameters used (e.g. target pressure, time and temperature) combined with the characteristics of the product (e.g. a_w, pH, salt/sugar/fat content), the effect on inactivation can vary. Some pathogenic cells may not be completely killed, but only injured. These cells may not be detected/enumerated through the analyses performed just after the HPP treatment, especially when selective media is used, but the conditions of storage during shelf-life may allow the recovery of these injured cells and therefore, their detection at some stage during the shelf life.

It is important to consider - do the product characteristics and storage conditions allow the recovery and growth of the target microorganism during the shelf life? If the answer is no, assessment of the $\log_{10}$ reduction in the concentration of the pathogen just after the HPP treatment may be sufficient. If the answer is yes, the $\log_{10}$ reduction needs to be assessed at the end of the product's shelf life.

Given this, it is likely that you will need to demonstrate that the pathogens remain at an acceptable level for the shelf life of the product, so sufficient samples need to be produced and stored for at least the product shelf life.

Additional Information

The following factors are critical for HPP challenge trials:

- Inoculum for each pathogen of concern should be a cocktail of strains including human related and pressure resistant strains;
- If spore forming bacteria are pathogens of concern, these should be included as one of the microorganisms in the trial;
- The inoculum should be in a stationary growth phase;
- The enumeration method should be appropriate to detect stressed or injured cells;
- The commercial product formulation needs to be used;
- If possible, the packaging should be the same as to be used in the commercial production;
- The HPP unit should provide a comparable target pressure and temperature against time profile as the commercial unit;
- Post HPP storage conditions should be comparable to commercial storage conditions; and
- A change in ingredients, product formulation, pre-HPP steps, packaging or the HPP process is likely to require further validation trials.

The areas in white in the template need to be filled in.

A: Product information

Product details	Name or other identifier:	Weight/volume:
Microbiological regulatory or operator-defined limits to be met in the product.	Microorganism	Limit
Any microbiological limits to be met prior to the HPP step. *This may be in individual ingredients or the formulated product just prior to the HPP step.*	Microorganism	Limit
Product formulation *List ingredients, amounts added, and form (e.g. dried, fresh etc).*	*Write the complete recipe here or attach from your RMP:*	
Product characteristics *If these characteristics don't apply to your product, delete and replace with more appropriate characteristics.*	pH:	a_w:
	Salt/sugar:	Protein content:
	Fat content:	Other (list):
	Preservative(s)/Antimicrobial agent(s):	
Product packaging to be used *Remember, you will need evidence of compliance with HC spec Part 7.*	Type and form of packaging: Confirmed compliance with HC Spec? Yes [ ]	Is the packaging appropriate for use in the HPP and capable of forming a hermetic seal? Yes [ ] No [ ] Can the material withstand the loading and unloading into the unit? Yes [ ] No [ ]
	Is the same packaging to be used during the trials? Yes [ ] No [ ] Is same pack size to be used during the trial? Yes [ ] No [ ] If no, you will need evidence that the results will be applicable when using commercial packaging.	What is the gas composition inside the product packaging/headspace e.g. vacuum, composition of modified atmosphere: Is the same gas composition to be applied to the trial samples: Yes [ ] No [ ] If no, you will need evidence that the results will be applicable when using commercial packaging.
Intended shelf life and would product be used in one sitting or consumed over time?	Months/Weeks/Days: Single use/multiple use:	Storage conditions:

B: Process information

Full process details *Include preparation, filling, closing, holding, HPP, cooling, storage etc.*	Attach details, including all processing parameters and limits. This may be provided as a process flow.	
HACCP plan or equivalent RMP documentation	Attach for the entire process.	
Proposed HPP test parameters	Pre-compression product temperature:	Holding time at target pressure (state mins/sec etc, also if pulses applied):

There may be a number of process variations to be tested. *If these parameters don't apply to your product, delete and replace with more parameters. Add more rows if needed.*	Target Pressure (give units e.g. MPa, bar):	Compression and decompression profile (e.g. pressure increase/decreased vs time):
	Pre-compression temperature of pressure transmitting fluid (e.g. water):	Other (e.g. number of cycles):
Source of proposed HPP parameters List of technical references used to support the HPP parameters selected e.g. literature, international standards. *If possible, provide an electronic link to the source.* *This may be peer reviewed research, a person with expertise in HPP, the equipment supplier etc.*	State how the proposed HPP parameters have been determined, or the source from which they have been taken:	

C: Trial Information

Date(s) of validation work		
Suitably skilled person(s) involved in the validation trials *You may have one or more.*	Name: Evidence of competency:	Name: Evidence of competency:
How trial product is to be disposed of.	Product disposition:	Confirmation that product from the trials is disposed of as stated:
Name and contact details of laboratory carrying out testing. *Some testing **must be** carried out by a laboratory with accreditation to ISO 17025, for example if testing for Listeria monocytogenes in ready-to-eat animal products. Check if this is a requirement for your product.* *Check that the laboratory has the competency and capability to conduct your validation trials – this can be a complex area.*		
Compatibility of food matrix and test methods.	Are the laboratory test methods appropriate for food matrix and pathogen(s)? Yes [ ] No [ ]	
Enumeration method(s) for target microorganisms. *Ensure these methods are capable of detecting sub-lethally injured cells. It is recommended that you obtain this information from the laboratory and attached it to this template.*	Microorganism	Enumeration method
Details of the HPP equipment used for the trials. *Note it is generally unacceptable to introduce pathogens into your processing site. A laboratory or pilot plant with the appropriate facilities is likely to be needed for challenge trials unless an approved procedure*	Premises where HPP is located and equipment details (e.g. make, model, size):	Evidence viewed that instrumentation calibrated: Yes [ ]

is in place or validated surrogate(s) are used.		
Is this the same HPP that will be used for commercial production?	Yes [ ] No [ ] If no, you will need evidence that the results will be applicable when used on the commercial unit. (If the results cannot be applied to the commercial unit, these trials will need to be repeated using an appropriate unit).	
Microbial pathogens to be inactivated by the HPP and the reduction to be achieved and/or limits to be met. *These are the biological hazards identified in your hazard identification and analysis that are to be inactivated by the HPP step. Confirming that these limits will be met is the purpose of this validation.*	Target pathogenic microorganism	Limit and/or target log_{10} reduction to be achieved by the HPP step
Cocktail of microbiological strains used for each pathogen and justification for their selection. *The strains should be relevant to the product (those isolated from similar products), include a reference strain, human related strains and also pressure-resistant strains.*	Cocktail of strains and justification for each target pathogen: *For details of what is needed, see Template 1C: MPI guidance for laboratories carrying out validation trials. This information should be provided by your laboratory.* *Organism/Cocktail 1:* *Organism/Cocktail 2:* *Organism/Cocktail 3:* *Etc*	
Sample inoculation. *Inoculum preparation etc should be managed by the laboratory. Information needed here should be provided by the laboratory.*	Level of inoculation into product samples for each cocktail: Are all inocula are in stationary growth phase: Yes [ ]	
Sampling programme for the duration of the trial. *This information includes the dates and number of samples tested at each sampling period. Details may be written here or attach the sampling programme to this template.* *Studies should be repeated on more than one batch to identify variability within and between batches. Ideally these will be on different dates with different ingredient batches etc.* *Further trials will be needed if the required reduction is not achieved or the stated shelf life is not met.* *A sampling programme should be prepared for each batch tested.* *At each testing period it is recommended that at least 3-5 replicate samples are tested.*	*See example of sampling programme provided in template 1A.Sampling Programme for Shelf Life Trial.*	
Processing conditions.	*As provided in **Section B**. Product should be processed under worst case conditions.*	
Sample storage conditions during the trial. *Examples:* *Optimum e.g. storage as on the label for entire shelf life;*	Set of storage conditions (1):	Set of storage conditions (2) *(add more rows if more conditions are used)*:

Realistic e.g. repeated short periods of elevated temperatures; *Worst case e.g. poor temperature control in a domestic refrigerator or variable temperature control.*		
Number of batches to be tested (N_B): *It is recommended that more than one batch is tested so that batch to batch variability can be detected*	Number:	
Total number of samples needed for the trials from each test batch. *Sufficient samples should be produced and stored so that testing can be carried out beyond the stated shelf life e.g. to ensure that any surviving cells that may grow during the shelf life are detected.* *A full set of samples will be needed for each pathogen and storage condition tested. Determine the number needed from your sampling programme plus a few spares.*	Total number of inoculated controls needed: [ ] Total number of inoculated but non-HPP treated control samples for each pathogen tested *(these are tested at the start and end of the shelf life)*. Total number of inoculated HPP treated samples to be produced for each pathogen tested *(these are tested straight after the HPP step and then at various times until after the end of the shelf life)*. Number of samples: Batch 1: Controls (non-HPP treated) [ ] HPP treated per pathogen [ ] Batch 2: Controls (non-HPP treated) [ ] HPP treated per pathogen [ ] Batch 3: Controls (non-HPP treated) [ ] HPP treated per pathogen [ ]	
Data collected when processing the samples for Challenge trial		
Data collected by you on **product prior to entering the HPP:** *It is recommended that at least 5 samples are tested for each variable (n=5). If product is not homogeneous more samples will need to be tested.* *These parameters are suggestions only. Generally, pH, a_w (unless liquids with an a_w close to 1), and initial temperature is expected.* *Make sure these parameters are the same as will occur during commercial operations.* *Note: when you test intrinsic product characteristics this does not need to be carried out on inoculated product.*	pH:	a_w:
	Salt/sugar content:	Protein content
	Fat content:	Other (list):
	Preservative(s)/Antimicrobial agent(s)::	
	Pre-compression temperature of product *(hold samples of the product and measure the temperature just before the HPP step starts):*	Pressure transmitting fluid (e.g. water) pre-compression temperature:
	Target pressure (give units e.g. MPa, bar):	Holding time at target pressure (state mins/sec etc):
	Compression and decompression profile (e.g. pressure increase/decrease vs time):	Final temperature of pressure transmitting fluid (e.g. water):
	Final product temperature immediately after the HPP step:	Other important parameters *(list)*:
Raw data and its analysis		
Data collected and its analysis*:* *Attach the tables of raw data and its analysis for all batches to this template and tick the boxes to*	Product temperatures during storage and times: Yes [ ]	Microbiological test results tabulated and analysed: Yes [ ]

indicate that this has been done (add more rows if needed).	Product characteristic results tabulated and analysed: Yes [ ]	Other (list):
Results		
Were the results as expected?	Yes [ ] Explain:	No [ ] See next row.
Were there any unusual or unexpected results? *Unexpected result should be investigated and explained.* *Examples include high growth levels in some samples when most are not detected, results that are much higher or lower than expected, large variations.*	Explained unexpected results:	
Log count reduction (LCR) of the target organisms achieved by the process: *Attach the data and calculations used to determine the LCR.* *See the guide for laboratories for an example of how this should be calculated.*	LCR=$\log_{10}$ cfu/ml non-HPP treated control (average) – $\log_{10}$ cfu/ml HPP treated (average) Log count reduction achieved:	
Shelf life achieved.	Shelf life: months/weeks/days	
Validated parameters		
Validated HPP parameters transferred to the RMP operating procedures.	Yes [ ]	No [ ]
Validation report is filed after use.	Yes [ ]	No [ ]

3.16.3 Template 1C: Guidance for laboratories carrying out HPP validation trials

This template should be completed by the laboratory carrying out microbiological validation trials. Add more space if needed.

<table>
<tr><th>Step</th><th colspan="3">Information</th><th>Comments</th></tr>
<tr><td rowspan="2">Target microorganisms</td><td>Cocktail 1 /Organism:</td><td>Strains:

-

-

-

-</td><td>Origin:

-

-

-

-</td><td rowspan="2">• Rationale for the choice of target microorganism(s)

• A cocktail of about 3-5 strains for each microorganism genus is needed (although the exact number is under the laboratory responsibility, provided they give a rationale to their choice)

• Different species should not be mixed in the same cocktail (for example. Salmonella and Listeria)

• For each strain: provide the origin of the strain: reference strain from a collection (ex ATCC), environmental strain obtained from environment/ water/food, clinical strain obtained from human cases.

• When possible, include strains with known high pressure resistance

• Surrogates can be used but they should be validated, and their choice should be justified (references needed).</td></tr>
<tr><td>Cocktail 2 /Organism:</td><td>-

-

-

-</td><td>-

-

-

-</td></tr>
<tr><td rowspan="5">Inoculum preparation</td><td colspan="3">Media used:</td><td rowspan="5">• Describe the complete protocol for the growth and preparation of the inoculation cocktail

• Indicate if there is a pre-adaptation step: for example, adaptation to cold.

• Growth phase: the target microorganisms should be in stationary phase because they are more pressure resistant than bacteria in exponential phase</td></tr>
<tr><td rowspan="2">Incubation</td><td>Temperature:</td><td></td></tr>
<tr><td>Duration:</td><td></td></tr>
<tr><td colspan="3">Number sub-cultivation steps:</td></tr>
<tr><td colspan="3">Pre-adaptation:</td></tr>
<tr><td colspan="3">Growth phase:</td></tr>
</table>

<table>
<tr><td rowspan="2">Inoculation level</td><td colspan="3">Number CFU/g or CFU/ml in the cocktail and /or in the food sample:</td><td rowspan="2">• The inoculation level should be high enough (e.g. 10^6-10^7 cfu/g) to demonstrate the level of inactivation if HPP is intended to replace a heat treatment (a minimum of 5 $\log_{10}$ reductions).
• If the HPP treatment is intended to be used as a post lethality treatment (for example for cooked RTE products after slicing), this level can be reduced, as it is expected that the main pathogen reduction is performed by other inactivation treatments. Therefore, the inoculum level can be lower than 10^6 cfu/g.
• Indicate how you control the final inoculation level in the product</td></tr>
<tr><td colspan="3">Volume of inoculation:</td></tr>
<tr><td>Inoculation methodology</td><td colspan="3"></td><td>• Indicate how the microorganism cocktail is inoculated to the food sample: surface, in deep, how long is the waiting time after inoculation, if there is mixing of the food sample</td></tr>
<tr><td rowspan="7">Duration of the study</td><td>Intended shelf-life:</td><td colspan="2">…… days / weeks / months</td><td rowspan="7">• Frequency of testing: no less than once a week if shelf life in weeks.

Minimum: just after HPP treatment, half the shelf life, end of shelf life, and eventually beyond shelf life. However, if the main purpose of the challenge study is the process inactivation assessment, the number of sampling points may be reduced to 2 (just after HPP treatment and at the end of shelf life).</td></tr>
<tr><td colspan="2">Number of sampling points (N_P)</td><td>N_P =</td></tr>
<tr><td rowspan="5">Sampling points

T=time</td><td>HPP = T0</td><td></td></tr>
<tr><td>T1</td><td>HPP + …….</td></tr>
<tr><td>T2</td><td>HPP +……</td></tr>
<tr><td>T3</td><td>HPP + ……</td></tr>
<tr><td>T4</td><td>HPP + ….</td></tr>
<tr><td rowspan="4">Number of samples</td><td colspan="2">Number of replicates per sampling point (N_R):</td><td>N_R =</td><td rowspan="4">• Number of replicates per sampling point for each batch: minimum of 3 replicates
• Number of batches: batches should be processed at different times with different ingredients. The number of batches tested can be reduced if the low inter-batch variability is demonstrated (stable intrinsic characteristics such as pH, a_w, etc).
• NS = NR x NP
• Un-inoculated control samples should be analysed. It is prudent to perform these analyses for each sampling point to determine the behaviour of background flora.</td></tr>
<tr><td colspan="2">Number of batches (N_B):</td><td>N_B =</td></tr>
<tr><td colspan="2">Total number of inoculated samples (N_S):</td><td>N_S =</td></tr>
<tr><td colspan="3">Number and nature of controls:</td></tr>
</table>

<table>
<tr><td rowspan="2">Product storage conditions</td><td colspan="2">Storage temperature:</td><td rowspan="2">Indicate if temperature abuse is considered and how.</td></tr>
<tr><td colspan="2">Temperature abuse? Yes [ ] No [ ]</td></tr>
<tr><td rowspan="6">Analyses</td><td>Parameter:</td><td>Method:</td><td rowspan="6">Parameters to be analysed: microbiological and non-microbiological, with the corresponding methods.
It is better to use normalised methods, accredited by IANZ.
If no normalized methods are used, justify this choice and describe extensively the method: media, incubation time and temperature.
Indicate if recovery of injured cells will be assessed and how: medium and protocol used.</td></tr>
<tr><td></td><td></td></tr>
<tr><td></td><td></td></tr>
<tr><td></td><td></td></tr>
<tr><td colspan="2">Recovery: injured cells? Yes [ ] No [ ]</td></tr>
<tr><td colspan="2">Method</td></tr>
<tr><td rowspan="4">Data treatment</td><td colspan="2">Control validation: Yes [ ] No [ ]</td><td rowspan="4">All the raw data and calculated results should be provided in the separate table.
Colony counts and identification should comply with the corresponding normalized methods.
Controls: assessment of controls => do they validate the test? (no pathogen detection in un-inoculated samples).
For technical replicates within a batch, it is necessary to calculate the average or median with the confidence interval or SD.
log reduction calculation ➔ log initial inoculum level (non HPP treated)– log final count (HPP treated at the end of shelf life).
Calculation of separate Log reductions for each batch.
Log reduction between each batch will be compared and discussed: the final log reduction to be taken should be the worst case scenario (the least log reduction).</td></tr>
<tr><td>Results:</td><td></td></tr>
<tr><td>Log reduction for this challenge test:</td><td></td></tr>
</table>

To read Section 4 to Section 7 refer to the following link: **Further Processing Code of Practice Chapter 2: Good Operating Practice**

4 Hurdle Technology

5 Smoking

6 Acidification

7 Concentration and Drying