



Guidelines for the Safe Manufacture of Smallgoods

3RD EDITION

24 February 2025

Acknowledgement Statement

*The Australian Meat Industry Council (AMIC) proudly presents the third edition of the **Guidelines for the Safe Manufacture of Smallgoods**. We gratefully acknowledge the significant contributions made by Meat & Livestock Australia (MLA) in the development of previous editions. Their support and expertise have laid a strong foundation for the ongoing advancement of food safety practices within the smallgoods sector.*

This latest edition has been commissioned by AMIC to reflect current industry standards, regulatory requirements, and best practices, ensuring continued excellence in the safe production of smallgoods across Australia.

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It is important to note that the *Guidelines for the Safe Manufacture of Smallgoods – 3rd Edition* are not a regulatory standard, but rather a resource developed to support industry understanding and implementation of food safety principles relevant to smallgoods production.

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The *Guidelines for the Safe Manufacture of Smallgoods – 3rd Edition* are available to the wider industry to support technical capability and promote best practices.

The Annexures to the *Guidelines for the Safe Manufacture of Smallgoods – 3rd Edition* contain proprietary tools, templates, and resources intended exclusively for AMIC members to assist in the implementation and maintenance of robust food safety systems.

These guidelines are an industry resource developed to support consistent and safe manufacturing practices across the smallgoods sector. They have been endorsed by state regulators as a valuable reference but are not intended as a legal or regulatory standard.

The legally binding standards for food safety and composition are set out in the *Australia New Zealand Food Standards Code*, which is a legislative instrument under the *Legislation Act 2003*.

Please note that Food Standards Australia New Zealand (FSANZ) does not provide advice on compliance with the Code. For enforcement and compliance matters, refer to the relevant state or territory agencies and departments (Pg 9 - Section 0.3.2) in the *Guidelines for the Safe Manufacture of Smallgoods – 3rd Edition*.

Each business is responsible for completing and maintaining accurate, current, and relevant documentation applicable to its operations.

This includes, but is not limited to:

- Annexures to the *Guidelines for the Safe Manufacture of Smallgoods – 3rd Edition*
- Food Safety and Quality Policy
- Food Safety Procedures
- Forms and records

Food Safety Programs which incorporate Annexures to the *Guidelines for the Safe Manufacture of Smallgoods – 3rd Edition* must be reviewed annually by the business and updated to reflect any changes in ownership, scope of products and processes, business operations, or applicable legal requirements.

The business must ensure that its Food Safety Program is complete, current, and readily available upon request by any relevant regulatory authority.

Access to the annexures is strictly limited to businesses that are current financial members of AMIC.

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Glossary of Terms and Abbreviations

Ambient temperature	Temperature of the air around you or the product
ACCC	Australian Competition & Consumer Commission
AMIC	Australian Meat Industry Council
Anaerobic	The absence of oxygen, a state which can exist in canned and vacuum-packed products
Australian Standard	The Australian Standard for the <i>Hygienic Production and Transportation of Meat and Meat Products for Human Consumption (AS4696:2023)</i>
<i>C. botulinum</i>	<i>Clostridium botulinum</i>
<i>C. perfringens</i>	<i>Clostridium perfringens</i>
CCP	Critical Control Point. A point, procedure, operation or stage in a process at which a hazard is prevented, eliminated or reduced to an acceptable level
CFM	Cooked Fermented Meats
CFU or cfu	Colony Forming Unit. An estimate of viable number of bacteria
CL	Critical Limit. The limit to which a hazard must be controlled at a CCP to prevent or reduce to an acceptable level the occurrence of the identified food safety hazard
Cold chain	The process of maintaining foods under refrigeration, in either a chilled or frozen state, during storage, distribution and marketing
Comminuted	A meat product which is chopped or minced
Contaminant	Something which may make food unsafe or unwholesome. Examples of contaminants are microorganisms, chemical residues or metal specks
Controlling Authority	The Commonwealth, state or territory authority which is responsible for the enforcement of standards
CP	Control Point
Cured	A product is cured if curing salts have been added at a level which preserves the product. In some regulations a minimum of 2.5% salt on water phase and 100 ppm nitrite in-going
DAFF	Department of Agriculture, Fisheries and Forestry
Decimal reduction time (D)	The time (in minutes or seconds) taken for 90% (1 log) reduction in numbers of a bacterium at a specific temperature (usually written as D65)
<i>E. coli</i>	<i>Escherichia coli</i>
FIFO	First-in-first-out
FSANZ	Food Standards Australia New Zealand
FSP	Food Safety Plan
GMP	Good Manufacturing Practice
HACCP	Hazard Analysis and Critical Control Point is the system which identifies and controls those hazards which pose a significant risk to food safety

Hazard	A biological, chemical or physical agent which may compromise or affect food safety
HPP	High pressure processing
<i>L. monocytogenes</i>	<i>Listeria monocytogenes</i>
Log or log10	Logarithm. Used to express microbial counts e.g. log 2 is 100, log 3 is 1,000 etc
MLA	Meat & Livestock Australia
Microbial count	The number of microorganisms living in or on a food product
Microbiological limits	The maximum number of microorganisms specified for a food product
Microorganisms	Viruses, yeasts, moulds and bacteria
MAP	Modified Atmosphere Packaging. Enclosure of meat in high gas barrier film, in which the gas environment around meat has been changed by removing all the air from pack and flushing it with a gas mixture of varying concentrations of oxygen, carbon dioxide and nitrogen. Vacuum packaging (VP) where most of the air is removed before sealing the pack, is sometimes included in MAP
MPN	Most Probable Number. Method used to determine bacterial numbers based on probability concept instead of counting colonies
NATA	National Association of Testing Authorities
Pathogen	A microorganism which causes illness
pH	A measure of acidity or alkalinity
potable water	Drinking quality water
potentially hazardous food	Food that must be refrigerated to keep it safe
PRP	Prerequisite program
QUAT or QAC	Quaternary ammonium compounds
RI	Refrigeration Index
RTE meats	Ready-to-eat meats are products that are intended to be consumed without further heating or cooking. They include cooked or uncooked fermented meats, pâté, dried meat, slow cured meat, luncheon meat, cooked cured or uncured muscle meat, other RTE meat that is susceptible to the growth of pathogens or the production of toxins.
<i>S. aureus</i>	<i>Staphylococcus aureus</i>
Shelf life	Length of time that a commodity may be stored without becoming unfit for use or consumption, due to loss of quality, the presence of undesirable chemicals, toxins, or growth of pathogens
Shelf stable	Foods that can be kept without refrigeration
Site of microbiological concern	The site on the meat or meat product where microorganisms are likely to be located and be most resistant to treatment (e.g. cooking).
SME	Small and medium enterprise
Spoilage bacteria	Bacteria which limit the shelf life of foods by producing objectionable odours, colours or slime

Spore	A protective coat that some bacteria can form which protects them (especially from heat)
SSOP	Sanitation Standard Operating Procedures
SPC	Standard Plate Count
<i>T. spiralis</i>	<i>Trichinella spiralis</i>
Toxin	A chemical which can cause illness. Toxins may be produced in food by bacteria
UCFM	Uncooked comminuted fermented meats
Validate, validation	The process of obtaining evidence to demonstrate that hazards in a food process are controlled and compliant with standards
VP	Vacuum packaging
Vegetative	Bacteria that form spores also have a vegetative form, which is when they grow
Verify, verification	Means applying methods, procedures, tests and other evaluations in addition to monitoring to determine whether a requirement is complied with, or a matter is met
Water activity (aw)	The water that is available to microorganisms that they need to be able to grow
<i>Y. enterocolitica</i>	<i>Yersinia enterocolitica</i>

0 Introduction

0.1 History of smallgoods manufacture

In Australia, smallgoods manufacture has traditionally belonged to families who came from Europe. They brought the science, technology, and artistry of their trade with them. More recently, smallgoods from Africa, the Middle East and Asia have been manufactured here. Over the past 75 years, supermarkets and the cold-chain have changed the way in which smallgoods have been retailed in Australia and traditional manufacturing methods have had to change as a result. Today smallgoods technology includes both traditional methods, as well as high-tech processes, for example, computer-controlled environments for fermented meats, and sophisticated slicing and packaging machines.

0.2 The Guidelines

In 2001 Meat & Livestock Australia (MLA) assembled a group of industry members, researchers, and regulators responsible for setting food safety standards to draft *Guidelines for the safe manufacture of smallgoods*.

The primary drivers for the *Guidelines* were:

- The Garibaldi smallgoods incident involving mettwurst contaminated with *Escherichia coli* (*E. coli*) O111
- Its aftermath, which led to the mandating of Hazard Analysis and Critical Control Point (HACCP) based Food Safety Plans (FSPs)
- The need for resource materials to help the development of FSPs.

Small outbreaks of illness and recalls of smallgoods have continued since the publication of the original *Guidelines*, and a second edition in 2015, but they have become less frequent, as the industry has become more careful about applying good practices in a consistent way.

Since the publication of the last edition of the *Guidelines*, the Codex Alimentarius Commission has made significant changes to its approach to HACCP in the *General Principles of Food Hygiene*, and the Australia New Zealand *Food Standards Code* has continued to develop food safety requirements.

In response to industry and regulatory changes, the Australian Meat Industry Council (AMIC) has commissioned this 3rd edition of the *Guidelines for the Safe Manufacture of Smallgoods*. A technical advisory panel including both industry, suppliers, and regulatory stakeholders has advised the food safety experts producing the new edition. This new edition takes into account changes in the operating environment, new scientific information, new ingredients, and new products to help manufacturers to keep up with the changing landscape of smallgoods and continue to produce a safe product.

0.3 Regulations

0.3.1 International

Internationally, the Codex Alimentarius Commission is the body of national governments that develops standards and guidelines representing the consensus of these national governments on matters that affect food safety and trade. The standards are particularly important for international trade, but also influence the development of national regulations and standards. The *General Principles of Food Hygiene* were first agreed in 1969 and was most recently revised in 2022¹. Since there were some significant changes to HACCP in the

¹ FAO and WHO. 2023. General Principles of Food Hygiene. Codex Alimentarius Code of Practice, No. CXC 1-1969. Codex Alimentarius Commission. Rome. <https://doi.org/10.4060/cc6125en> [General principles of food hygiene \(fao.org\)](https://www.fao.org/guidelines/food-hygiene/)

2022 revision, we will reference this document, in anticipation of the changes being reflected in national regulations and other standards.

0.3.2 Australian domestic requirements

Food Standards Australia New Zealand (FSANZ) is responsible for the development of the *Food Standards Code*² which has several standards that are relevant to the composition and production of smallgoods products.

The Australian Standard for the *Hygienic Production and Transportation of Meat and Meat Products for Human Consumption* (AS4696:2023) (usually referred to in the industry as the Australian Standard) has requirements that need to be met in 'further processed' meat products. The changes between the 2007 and 2023 versions of this standard do not affect smallgoods manufacturers.

These *Guidelines* reference both the *Food Standards Code* and the *Australian Standard*, but the *Guidelines* do not cover all the requirements for smallgoods manufacture found in these documents. Smallgoods manufacturers need to understand thoroughly how to comply with these legal requirements.

Each state and territory may have different roles in the enforcement of the *Food Standards Code* and the *Australian Standard* when you are manufacturing smallgoods products. The controlling authority has specific requirements for licencing, documentation, audits etc. and sometimes also for technical aspects of your operations. The following table (Table 1) provides a list of state-based controlling authorities.

Table 1: State and territory controlling authorities

NSW	New South Wales Food Authority	Meat & poultry processing plants NSW Food Authority
Qld	Safe Food Production Queensland	Home - Safe Food
Vic	PrimeSafe	https://primesafe.vic.gov.au
Tas	Department of Natural Resources and Environment Tasmania	https://nre.tas.gov.au/biosecurity-tasmania/product-integrity
SA	Department of Primary Industries and Regions, South Australia	Meat - PIRSA
WA	Department of Health	Food (health.wa.gov.au)
ACT	Department of Health	https://www.act.gov.au/health/businesses/food-safety-for-businesses
NT	Department of Primary Industries and Fisheries	https://nt.gov.au/industry/agriculture/meat-industry/domestic-abattoirs-meat-processing

These jurisdictions may also issue guidance documents, which may need to be followed. We have often taken these into account, but we have only addressed the requirements of the *Food Standards Code* and the *Australian Standard* in producing these *Guidelines*.

0.3.3 Export requirements

To export your product, you can expect that your premises will need to be licensed by the Australian Government Department of Agriculture, Fisheries and Forestry (DAFF)³. DAFF will have negotiated the requirements with each importing country, so that the product is considered to be equivalent to the

² [Food Standards Code legislation | Food Standards Australia New Zealand](#)

³ [Exporting meat and meat products - DAFF \(agriculture.gov.au\)](#)

importing country's domestic standards. You will probably have to request a permit to export before sending the product accompanied by the necessary certificates issued by DAFF.

The domestic requirements of the importing country need to be thoroughly understood, because they may be significantly different from Australian requirements.

0.4 What these *Guidelines* help you do

In these *Guidelines* we aim to:

1. Update you on hazards and risks in the products you manufacture
2. Suggest ways you can reduce the risk to your customers
3. Supply scientific backing for your FSP
4. Provide background information so you meet the regulatory requirements for the safe manufacture of all your products.

These *Guidelines* are just that – guidelines about what is safe and what is not. The *Guidelines* (whether here or in a regulation) try to provide conditions (e.g. times, temperatures, pH) to be sure about safety. Other conditions may also be safe, but this needs to be proved (validated) for your circumstances.

If you have a smaller operation, you'll also find useful information in AMIC's *Food Safety and Quality Program* which has been developed to assist Australian retail meat processing businesses such as butcher shops to manage the risks to food safety and quality in their business

0.5 Guide to these *Guidelines*

This section will help you find your way around these *Guidelines* (Figure 1).

The 'central' chapters of these *Guidelines* discuss

- the risks associated with smallgoods products, and how safe products are formulated and produced (Chapter 1)
- how to organise your business to produce a safe product (Chapter 2).

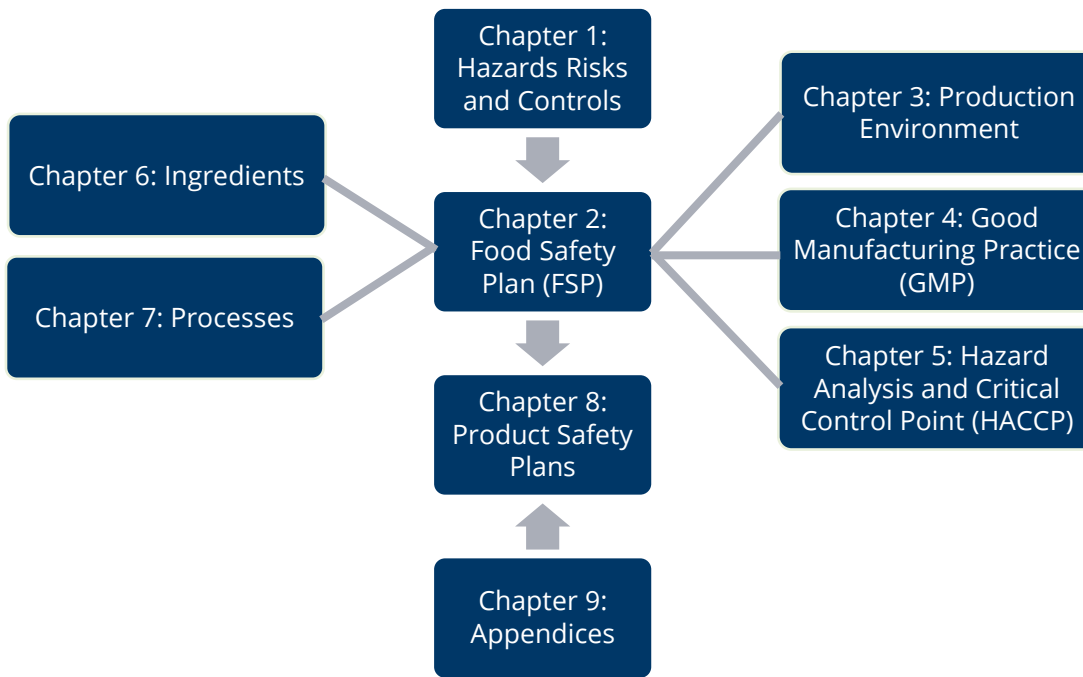
The principles in these chapters are illustrated through a number of sample product safety plans (Chapter 8) covering the standard range of smallgoods products. Your product may differ in formulation or process from these examples, and you will need to change the plan using the supporting information in the *Guidelines*.

These central chapters are supported by:

- reference material on a systematic approach to
 - construction and operation of your production environment (Chapter 3)
 - Good Manufacturing Practices (GMPs) (Chapter 4)
 - HACCP (Chapter 5)
- Reference material on
 - Ingredients (Chapter 6)
 - Processes (Chapter 7)
 - Important foodborne pathogens and how to predict their behaviour (Chapter 9).

If you manufacture a product that does not fit into one of the categories in Chapter 8, the information in the last part of Chapter 8 may help you to identify the hazards and controls that will be most applicable to your product.

Figure 1: Arrangement of chapters in these *Guidelines*



1 Hazards, Risks, and Controls for Smallgoods

1.1 Hazards in smallgoods are a problem

In the meat industry a hazard means a biological, chemical, or physical agent in, or condition of, food with the potential to cause an adverse effect in ('harm to') humans. Given the large range of smallgoods there are many hazards you need to be aware of and control in your business. One way to identify which hazards are the most significant is by looking at:

- Food-borne disease outbreaks from meat
- Recalls of meat and meat products.

1.1.1 Foodborne disease outbreaks involving processed meat

Smallgoods products occasionally have caused food poisoning outbreaks in Australia (Table 2). Table 2 also identifies the hazards which caused the problems, using data collected by state authorities and OzFoodNet.

Table 2: Selected outbreaks of illness associated with meat in Australia

Year	Meat product	Hazard	Number of cases (deaths)
1993	Roast beef	<i>Clostridium perfringens</i> (<i>C. perfringens</i>)	37 (1)
1994	Pork sausage	<i>Salmonella</i>	14
1995	Mettwurst	<i>E. coli</i> O111	173 (1)
1997	Pork rolls	<i>Salmonella</i>	808
1997	Ham, corned beef	<i>Salmonella</i>	25
2005	Corned beef	<i>Listeria monocytogenes</i> (<i>L. monocytogenes</i>)	2-4 (1)
2008	Chicken	<i>Campylobacter</i>	4
2008	Chicken	<i>Staphylococcus aureus</i> (<i>S. aureus</i>)	7
2012	Ham	<i>Salmonella</i>	16
2016	Ham	<i>L. monocytogenes</i>	8
2017	Duck Liver pâté	<i>Campylobacter</i>	1

The examples listed above identify target bacteria – hazards you must control through your FSP. Chapter 9.1 has further information on these target bacteria. Several of the food poisonings occurred in institutions such as aged care facilities and hospitals, underlining the heightened vulnerability of some consumers.

1.1.2 Product recalls

There is a list of all meat recalls on the Australian Competition & Consumer Commission (ACCC) website⁴. From 2013-to 2022 there were 31 recalls of smallgoods:

- Half of all recalls were for the presence of *L. monocytogenes*, especially in cured and cooked products such as hams, and in pâté.
- *Salmonella* and *E. coli* in Uncooked Comminuted Fermented Meats (UCFMs) were responsible for two recalls each.

⁴ <http://www.recalls.gov.au>

- UCFM were also subject to recall for *L. monocytogenes*, poor processing, or failure of records to verify correct processing.
- Incorrect labels were responsible for about 10% of recalls - usually for not labelling the presence of allergens, or for incorrect use-by dates.

These incidents tell us that costly, embarrassing, and potentially harmful events do occur with smallgoods products, even though the record in Australia is better than in the past. It should be remembered that these recalls also tell us that the controls that were supposed to be in place failed for these products. Also, they don't identify the only hazards that need to be managed; other hazards may occur infrequently and still need to be controlled.

1.2 Risks associated with smallgoods

Risk is made up of two factors:

1. The likelihood of being exposed to a hazard
2. The severity of the consequences when exposure occurs, i.e. how serious is the illness.

In 2005 the industry commissioned a comprehensive risk assessment of all meat products: raw, cooked, and fermented⁵. The project included giving a risk rating to various smallgoods products (Table 3)⁶. Some of these risk ratings were revised by other projects in 2009⁷ and 2019⁸. These ratings assume that raw products were properly cooked and that fermented meats were manufactured in accordance with the *Food Standards Code*. Additional steps may be taken to formulate and produce the product that will further reduce the risk. These *Guidelines* will deal with both the basic and more advanced approaches to making a safe product.

The researchers found that the highest risk was associated with cured, cooked meats, especially when these were sliced and vacuum packed⁹ and eaten without further cooking (so-called ready-to-eat (RTE) foods). This risk rating reflects the seriousness of illness caused by *L. monocytogenes* which, though relatively infrequent, results in death in 20-30% of cases.

⁵ Pointon, A., Jenson, I., Jordan, D., Vanderlinde, P., Slade, J., & Sumner, J. (2006). A risk profile of the Australian red meat industry: Approach and management [Article]. *Food Control*, 17(9), 712-718.

<https://doi.org/10.1016/j.foodcont.2005.04.008>

⁶ Sumner, J., Ross, T., Jenson, I., & Pointon, A. (2005). A risk microbiological profile of the Australian red meat industry: Risk ratings of hazard-product pairings [Article]. *Int J Food Microbiol*, 105(2), 221-232.

<https://doi.org/10.1016/j.ijfoodmicro.2005.03.016>

⁷ Ross, T., Rasmussen, S., Fazil, A., Paoli, G., & Sumner, J. (2009). Quantitative risk assessment of *Listeria monocytogenes* in ready-to-eat meats in Australia. *Int J Food Microbiol*, 131(2), 128-137.

<https://doi.org/https://doi.org/10.1016/j.ijfoodmicro.2009.02.007>

⁸ Hernandez-Jover, M., Culley, F., Heller, J., Ward, M. P., & Jenson, I. (2021). Semi-quantitative food safety risk profile of the Australian red meat industry. *Int J Food Microbiol*, 353, 109294.

<https://doi.org/https://doi.org/10.1016/j.ijfoodmicro.2021.109294>

⁹ Ross, T., Rasmussen, S., Fazil, A., Paoli, G., & Sumner, J. (2009). Quantitative risk assessment of *Listeria monocytogenes* in ready-to-eat meats in Australia. *Int J Food Microbiol*, 131(2), 128-137.

<https://doi.org/https://doi.org/10.1016/j.ijfoodmicro.2009.02.007>

Table 3: Risk rating of various meat products

Product type	Risk rating
Fresh sausage ¹	0
Ground products ¹	0
Cooked sausages (franks etc) ²	0
Cooked fermented meats (CFMs)	8
Uncooked fermented meats	8
Slow cured hams (prosciutto)	20
Cooked sausages (franks etc.) eaten raw	38 ³
Roast meats (unsliced)	35-38
Sliced hams	49
Sliced vacuum packed meats	49

¹ assumes cooked thoroughly before eating

² assumes reheated properly before eating

³ ratings above 30 are generally associated with outbreaks of food poisoning

The conclusion for smallgoods manufacturers is clear: you need to control a number of dangerous bacteria, as well as physical and chemical hazards, including allergens, the most difficult of which is *L. monocytogenes*. Cooking is a Critical Control Point (CCP) for the pathogen, but post-process contamination is the danger which may be minimised through changing product formulation and adhering to GMPs. Changing the process or product formulation should result in the risk rating being lower. In these *Guidelines* we focus heavily on controlling handling of cooked meat during slicing and packing.

FSPs are needed for all products – whether the risk is high or low. In general, products that are cooked just before consumption are low risk and, from experience, those that are consumed without cooking just before consumption are considered high risk.

If you feel bulletproof, think again. Here are three tales of woe concerning butchers who made the same products you do.

1.3 Consequences for Australian manufacturers

Hazards in product have resulted in outbreaks of disease, and deaths. They have also had significant impacts on smallgoods businesses, and the industry overall, in Australia.

1.3.1 *E. coli* in mettwurst

An *E. coli* outbreak in 1995 was a defining moment for smallgoods safety in Australia. Mettwurst made in Adelaide was contaminated with a strain of disease-causing *E. coli* O111. Around 170 people became ill, more than 20 of them seriously, and one young girl died. This outbreak led to significant changes in the way meat hygiene and smallgoods manufacture in Australia were regulated. It also provided motivation for writing of the first edition of these *Guidelines*.

The consequences were severe for Garibaldi Smallgoods and its principals. The company closed within days and the principals were charged with manslaughter - later reduced to 'creating a risk of harm' to which they pleaded guilty. The victims' claim for compensation was eventually settled after 16 years, with 23 people receiving compensation for lifelong effects on their health

“The identification of the company’s product and its linkage with the death and severe illness of the children, had a catastrophic effect upon the company’s business, such that it ceased operations on Monday 6 February 1995. This involved the downfall of one of the largest producers of smallgoods in South Australia, the loss of more than 100 jobs and has had a deleterious effect upon several other producers of smallgoods in this State.” Garibaldi Smallgoods: Coroner’s report

1.3.2 *Listeria* in corned beef

In 2005 cold, cooked, corned beef was responsible for an outbreak of *L. monocytogenes* O1 in a South Australian hospital¹⁰. Two of the cases were at the same hospital and had infections from identical *Listeria* bacteria. One of the cases who had complications from diabetes, died. Cold cooked corned beef slices and mixed meat and salad sandwiches from the hospital kitchen were positive for *L. monocytogenes* serotype O1 and were identical to the patients' sample isolates. Food samples from the meat manufacturer that supplied cold meat to the hospital were also positive for *L. monocytogenes*. Two other cases each had isolates of *L. monocytogenes* which were different from the other cases and to isolates from food samples. A smallgoods company issued a consumer level recall for a range of RTE products. The directors of the company were prosecuted.

1.3.3 *Listeria* in ham

In 2016, listeriosis was reported and traced back to ham manufacture.¹¹ Eight cases were reported across three eastern states plus South Australia. All of the patients had an identical strain of *L. monocytogenes* and had eaten cold meat purchased from supermarket deli counters. Food samples and environmental swabs from three supermarkets and the ham manufacturing facility isolated the same *L. monocytogenes* strain. Actions were taken by both the ham production facility to implement further control measures, and by the supermarkets to better clean their facilities to make sure that *L. monocytogenes* couldn't persist in their store.

This outbreak illustrates some important points about the way that foodborne disease detectives work in Australia. While investigations occur separately in each state, the public health laboratories standardise their methods and produce a 'genetic fingerprint' of each strain (not just for *L. monocytogenes*, but other pathogens as well), and they share data with one another. This network of laboratories and investigators is called OzFoodNet and is funded by government. So even a single case in one state or territory, can be linked to cases in other states or territories, and this makes tracking the source of the outbreak more likely. Finding a strain with the same genetic fingerprint at deli counters and the ham manufacturer, makes a clear and compelling case for the ham being the source of the outbreak. There is nowhere to hide from this kind of detective work. The best thing to do is to make sure it doesn't happen to you by designing a good, safe, food production system and making sure that it is always operating correctly.

1.4 Hazards in your product – the site of microbiological concern

Biological hazards in finished product, at a level that could cause harm, enter the product from raw materials, and the production environment and process can affect the part of the product that is of concern.

¹⁰ OzFoodNet Working Group (2006) OzFoodNet: enhancing foodborne disease surveillance across Australia: Quarterly report, 1 October to 31 December 2005. Communicable Diseases Intelligence 30(1) 148-153

¹¹ OzFoodNet Working Group. Annual report. Monitoring the incidence and causes of disease potentially transmitted by food in Australia: Annual report of the OzFoodNet network, 2016. Commun. Dis. Intell. (2018) 2021;45 (<https://doi.org/10.33321/cdi.2021.45.52>) Epub 30/9/2021

Animals raised for meat, or harvested as wild game may present a biological hazard when processed as food. FSANZ considered this when it was drafting the Primary Production and Processing Standards.¹² Some hazards may be eliminated or well controlled, whereas others may not be sufficiently well controlled when this meat is used for smallgoods manufacture. Raw meat is almost inevitably contaminated with microorganisms during processing, and these microorganisms may grow during chilling, storage and transportation to your production facility. Meat processed in Australia has a reputation around the world for its low levels of contamination and high levels of safety, but we still need to act as though these hazards are present. The hazards that need to be considered in raw meat (even if they are rarely found) are:

- *Salmonella*
- Pathogenic *E. coli* (particularly in ruminants; beef and sheep meat)
- *S. aureus*
- *L. monocytogenes*
- *C. perfringens*
- *Clostridium botulinum* (*C. botulinum*)
- *Yersinia enterocolitica* (*Y. enterocolitica*) (in pork)
- *Campylobacter* (in chicken)
- *Trichinella spiralis* (*T. spiralis*) (a parasite).

There are two characteristics of the bacteria that are important in smallgoods production. Some bacteria form spores, which are resistant to heat and allow the bacteria to survive cooking. These bacteria may also be in a 'vegetative' state which allows them to grow, and they are then sensitive to heat. The other characteristic is that some bacteria produce toxins, which can cause illness, even if the bacteria are destroyed; some are very resistant to heat, so once they are produced by the bacteria, they will stay in the product (Table 4).

Table 4: Characteristics of hazardous bacteria relevant to smallgoods processing

	Do not form spores	Form spores
Do not produce toxins	<i>Salmonella</i> <i>E. coli</i> <i>L. monocytogenes</i> <i>Y. enterocolitica</i> <i>Campylobacter</i>	
Produce toxins	<i>S. aureus</i>	<i>C. perfringens</i> <i>C. botulinum</i>

Some other raw materials may also contain these hazards. For example, any protein source (including dried plant-derived ingredients) may contain *Salmonella*, and spices often contain spore forming bacteria such as *C. perfringens*.

S. aureus ("golden Staph") can be found in raw meat, but it is also found in the noses, and on the hands of humans very frequently, and you must be alert to the possibility of this hazard entering your product via workers.

L. monocytogenes is probably the most frequent cause of concern in RTE smallgoods products. It can be found in raw meat, but problems come because it can be found in the production environment and on equipment,

¹² Food Standards Australia New Zealand. Proposal P1014 - Primary Production & Processing Standard for Meat & Meat Products | Food Standards Australia New Zealand

and it enters the product after cooking. When it contaminates the product after cooking it may grow to dangerous levels in product during its shelf life because it can grow at even good refrigeration temperatures.

The location of these hazards in product can be very important when we consider how to make product safe. We call this **'the site of microbiological concern'**. We should always consider the site on the meat or meat product where microorganisms are likely to be located. Usually, the surface of the meat is the site of microbiological concern. However, if a piece of meat is injected, then the injection needles can move contamination from the surface of the meat into the centre, which is then the site of microbiological concern. If the meat is marinated, then the contamination remains on the surface, and this is the site of microbiological concern. When cooking and cooling, the site of microbiological concern is the thermal centre of the product, unless we can be sure that the contamination is only on the surface.

Chemical hazards generally come through raw materials and the way those raw materials are used. Chemical contaminants – unwanted chemicals in the raw materials – are a possible source of chemical hazards. Raw meat is considered to have chemical contamination very under control and have very low risk.¹³ Cleaning chemicals and sanitizers can be hazardous if used at the wrong level or are left on equipment when they should not be. A major hazard may occur from mixing up chemicals that look alike, or have similar names, and using the wrong amount. Several chemicals that are used in smallgoods manufacture are necessary to produce a safe product but may be a hazard if used at the wrong level.

Allergens can be considered to be chemical hazards. Raw meat is not considered to be a major allergen (though some people can have an allergy to some meat proteins). Allergens are hazards that may be present in the raw materials we use (e.g. sulphites, soy protein, peanut proteins in satay sauce) or may contaminate the non-allergenic raw materials we use.

Radiological hazards are another kind of chemical hazard, though rarely encountered. Radioactive chemicals may be found in food or water if there has been some accidental release from a nuclear facility or in areas where there is naturally a high level of radioactivity.

Unexpected mould on product can result in a chemical hazard because some moulds produce mycotoxins which can be harmful in the long term to human health.

Physical hazards may arise from raw materials or the production environment. Physical objects such pieces of bone or metal or glass shards from broken bottles or lights, may cause injury to consumers if allowed to remain in raw materials or enter the production process.

1.5 Vulnerable consumers

Not all consumers are equally likely to be injured when consuming a food containing a food safety hazard.

Vulnerable people have a greater risk of getting sick because their immune system is weakened (or still developing). These people include pregnant women, their unborn and newborn babies, young children, the elderly and people whose immune systems have been weakened by illness or drugs (for example: cancer patients, organ transplant recipients, and people on drugs like cortisone). This is why public health authorities provide advice to these consumers about not eating RTE smallgoods unless they are freshly cooked or reheated thoroughly. Very small children, and the elderly/infirm are more likely to suffer from choking (physical) hazards.

When planning how to make your product safely, you may consider only the 'general' population and rely on education of vulnerable consumers to ensure they consume only foods that are appropriate for their increased risk.

¹³ Food Standards Australia New Zealand. Proposal P1014 - Primary Production & Processing Standard for Meat & Meat Products | Food Standards Australia New Zealand

However, if you produce, and supply specifically to vulnerable consumers (e.g. hospital or aged care homes, or their food services) you may be required to comply with additional requirements imposed by your controlling authority. In other words, if your intended consumers include people in these more susceptible categories, you must be extra vigilant and develop a HACCP plan/use GMPs that provide extra protection to those consumers.

1.6 What makes a product safe?

This chapter has suggested that nearly all smallgoods products can be produced safely, though recalls and outbreaks tell us that the processes for producing a safe product are not always followed. So, what is it that makes products safe?

Meat is very nutritious, but just as it is nutritious for us, it is also an excellent source of food for microorganisms: in fact, many bacteria (one kind of microorganism) are better able to metabolise the nutrients in meat than even we are.

Edible animal tissues (meat, many offals) are sterile (not contaminated with microorganisms) in the live animal, but processing the animal to convert it into meat and food, inevitably contaminates the meat with microorganisms to a greater or lesser extent. For this reason, we take many actions to try to minimise the level of contamination, to increase its microbiological safety and quality and shelf life.

As well as excellent slaughter hygiene, other strategies involve taking actions to reduce the microbial load (number of microorganisms) on the finished product, essentially by killing as many of the microorganisms as possible on the finished product, and actions to minimise the potential for growth of the surviving microorganisms, or any introduced after the processing. The time between production and consumption contributes to the level of risk because some bacterial and fungal pathogens can grow in products, and modern supply chains call for a long shelf life. We can use refrigeration, added salt, added organic acid salts (e.g. lactate, di-acetate), modified atmosphere packaging (MAP), or vacuum packaging (VP) or potentially so-called 'active packaging'. These actions individually or in combination reduce the growth rate of bacteria. Collectively, we use the term 'hurdles' to describe actions we take that slow down, or stop, microbial growth in foods. The more hurdles, the safer and longer lasting the product will be. However, there is a balance to be reached between product quality (flavour, appearance, texture, etc.) and safety and shelf life.

When we talk about growth of bacteria we don't mean an increase in *size*, but an increase in their *numbers*. Food safety and quality and shelf life are largely dictated by the growth of undesirable bacteria (or moulds) and, when they get to levels more than a few thousands of bacterial cells per gram, problems can begin to become noticeable.

There are many different kinds of bacteria that are important as hazards to the safety, quality, and shelf life of smallgoods. In general, we group the various types of bacteria of relevance to food into two categories: 'pathogens' and 'spoilors' (spoilage bacteria). Pathogens are those bacteria that can cause illness. Spoilers are the ones that lead to loss of quality.

Because the pathogens each respond somewhat differently to temperature (heat or cold), saltiness, oxygen availability, acidity, and so on, we need to understand those responses reasonably well to optimise our treatments to achieve safe, quality food with good shelf life, while not wasting energy and chemicals, and in a way that also satisfies consumer expectations for only the minimum amount of processing and preservatives necessary.

In general, higher temperatures (usually at above 65°C) are most effective at killing bacteria. The higher the temperature, the faster the bacteria will be killed. The longer the time, the more bacteria will be killed. The lower the temperature, the more slowly the bacteria will grow. The more salt added, the slower the growth of most bacteria. The less oxygen (and/or more carbon dioxide, i.e., VP and MAP), the slower the growth of most

bacteria, and the lower the pH (and particular in the presence of salts of lactic or acetic acids), the lower the rate of increase of most bacteria.

While these general responses of bacteria to changes in the environmental conditions brought about by smallgoods processing have been understood qualitatively for a very long time, it is only in the last few decades that specific quantitative knowledge of the responses of bacteria of relevance to food have been developed and described, including interactions between those factors. With this knowledge it is now possible to fine-tune processing times and temperatures and product formulations to achieve a safe, but quality, product reliably.

An example of using technologies (hurdles) to make a safe product

UCFM (i.e. salami-style products) are a very good example of the manipulation of the microbial ecology of foods to achieve a safe, long shelf-life product that does not require refrigeration. The stability of the product relies initially on bacteria using sugars added to the batter and turning it into lactic acid, which increases acidity (lowers pH). These lactic acid bacteria that are added to the batter ensure rapid and reliable fermentation. (Lactic acid bacteria, even at high numbers, do not cause spoilage of the meat, but help to preserve it through their metabolic activity). In addition, salt is added. The salt helps to cause shrinking of the muscle pieces in the batter (termed 'syneresis') that, in the process, squeezes out water, further drying the fermenting products and improving the texture. The squeezing of the batter into a casing also expels most of the oxygen. The salt and low oxygen levels encourage the growth of the lactic acid bacteria, which rapidly consume the residual oxygen, convert simple sugars to lactic acid, increase the acidity and in doing so, suppress the growth of less desirable bacteria, increasing the overall safety and stability of the product. Sodium nitrite is also added to the batter, specifically to inhibit the growth of spore forming bacteria such as *C. botulinum*, a very severe hazard. The addition of a small amount of simple sugars and control of fermentation temperatures encourage the rapid growth and metabolism of the lactic acid bacteria. The maturation of the product occurs at much lower temperatures and under controlled relative humidity – further allowing water to be removed from the maturing batter and increasing the effective salt content. After a few days the combined salt and acidity and organic acid levels are sufficient to prevent the growth of pathogens of concern, as well as spoilage organisms – as long as the initial fermentation is successful, i.e., that acidification occurs relatively rapidly. If not, pathogens can grow to dangerous levels during the warm and nutritious environment during the fermentation. The acidification is the first step in a process of induced changes in the microbial ecology of fermented meats using various hurdles, that eventually both improve the taste, safety, and shelf stability. Ideally, the combined acidity, salt content and low oxygen create an environment that precludes growth of undesirable bacteria and, when bacteria can't grow, the pathogens of concern will tend to die. Under these conditions, the rate of death is faster at warmer temperatures, but temperatures that are too warm can reduce the quality of the product due to changes in the fat composition and distribution in the product.

1.7 Product specifications

The steps toward making a safe product depend not only on the raw materials, hazards, processes, and consumers of the product, but also on the characteristics of the finished product itself.

These questions need to be answered:

- Are there regulatory requirements for the composition of the product (e.g. preservative levels)?
- How will the product be packed?
- Will the product be shelf stable, that is, able to be stored without refrigeration?
- Will pathogens be able to grow in the packed product at intended storage conditions during its shelf life?

Answers to these questions will determine the shelf life of the product and how it needs to be labelled to manage the safety of the product and will be discussed in the following sections.

1.8 Shelf life

The shelf life is the length of time after manufacture before a product either becomes unsafe to eat or significantly deteriorates in quality. Shelf life is always determined at realistic storage conditions. Generally, that means whether or not the product needs to be kept refrigerated.

There are two things to consider with shelf life determination:

- Growth of pathogenic bacteria and, depending on the species of bacterium, the production of toxins
- Growth of spoilage microorganisms and deterioration of product quality (appearance, odour, flavour, texture, etc.).

1.8.1 Pathogens and shelf stability

Shelf stable means that the product can be stored without the need for refrigeration. Shelf stable foods can be defined based on their acidity (measured by pH) and availability of water for bacteria to grow (measured as water activity, a_w). On the other hand, the *Food Standards Code* defines a potentially hazardous food as 'food that has to be kept at certain temperatures to minimise the growth of any pathogenic microorganisms that may be present in the food or to prevent the formation of toxins in the food'. The following discussion about shelf stability and the need for refrigeration considers only foodborne pathogens (i.e. product safety), rather than potential spoilage of the product.

Shelf stability and the potential growth of pathogens is just as important for smallgoods products that will be cooked prior to consumption. Some pathogens (e.g. *S. aureus*, *C. perfringens*) cause illness through the production of toxins, which can be produced in food and still cause illness after the food is cooked.

Guidance has been developed that is useful for most products, but there may be exceptions relating to certain bacteria, product formulations or processes.¹⁴

Foods that have been heat treated to destroy vegetative cells (e.g. *Salmonella*, *E. coli*, *S. aureus*, *L. monocytogenes*) have already taken a significant step towards being shelf stable, because only the heat resistant bacteria able to form spores (*C. perfringens*, *C. botulinum*) will survive. Cooking, as defined by the *Australian Standard* (65°C for 10 minutes, or equivalent) can be expected to kill the significant vegetative foodborne pathogens in the product. If these products are packaged to protect them from re-contamination, then the characteristics in Table 5 define their shelf stability.

¹⁴ [Institute of Food Technologists Scientific and Technical Panel] 2003. Current and Proposed Definitions of "Potentially Hazardous Foods". 31 December 2001. *Comprehensive Reviews in Food Science and Food Safety* vol 2 supplement, 1-109.

Table 5: Product treated to control vegetative cells and protected from recontamination. pH and a_w for shelf stability. Not PHF = Not potentially hazardous food, ? = product evaluation required

a_w	pH				
	<4.2	4.2-4.6	>4,6-5.0	>5.0-5.6	>5.6
<0.85	Not PHF	Not PHF	Not PHF	Not PHF	Not PHF
>0.85- <0.88	Not PHF	Not PHF	Not PHF	Not PHF	Not PHF
0.88-0.90	Not PHF	Not PHF	Not PHF	Not PHF	Not PHF
>0.90 – 0.92	Not PHF	Not PHF	Not PHF	Not PHF	Not PHF
>0.92 – 0.95	Not PHF	Not PHF	Not PHF	Not PHF	?
>0.95	Not PHF	Not PHF	?	?	?

Foods that have not been heat treated to control vegetative cells are more susceptible to growth of pathogenic bacteria, because a wider range of them could potentially be present in the product. If these products are produced, then Table 6 defines their shelf stability.

Table 6: Product not treated to control vegetative cells or treated but not protected from recontamination. pH and a_w for shelf stability. Not PHF = Not potentially hazardous food, ? = product evaluation required

a_w	pH				
	<4.2	4.2-4.6	>4,6-5.0	>5.0-5.6	>5.6
<0.85	Not PHF	Not PHF	Not PHF	Not PHF	Not PHF
>0.85- <0.88	Not PHF	Not PHF	Not PHF	Not PHF	Not PHF
0.88-0.90	Not PHF	Not PHF	Not PHF	?	?
>0.90 – 0.92	Not PHF	Not PHF	?	?	?
>0.92 – 0.95	Not PHF	?	?	?	?
>0.95	Not PHF	?	?	?	?

If a product assessment is required, that means either:

- performing a challenge test (adding pathogens to your product and seeing whether they can grow to unsafe levels under the recommended storage conditions and desired shelf life), or
- using predictive models, or
- finding a scientific paper that describes your product and its shelf stability.

You will need some expert advice whichever method is chosen. Challenge tests can be expensive and time consuming. The use of a predictive model can be faster and less expensive, but validated models are needed to provide confidence about the answer they provide. The University of Wisconsin has produced a validated model, which is accepted by the US regulator to support decisions about shelf stability for fermented, salt-cured, or dried meat and poultry products.¹⁵

1.8.2 Shelf life considering growth of *L. monocytogenes*

L. monocytogenes is a bacterium that is able to grow at low temperatures, even below 0°C if the other characteristics of the food are favourable. It contaminates and grows in many RTE smallgoods products and

¹⁵ University of Wisconsin Shelf-Stability Predictor available at: https://meathaccp.wisc.edu/ST_calc.html.

therefore knowing whether a product allows the growth of *L. monocytogenes*, and how much it can grow, is an important part of making a safe product. It also determines the possible shelf life of the product.

L. monocytogenes will not grow in a RTE food if it has:

- a pH less than 4.4 regardless of water activity, or
- a water activity less than 0.92 regardless of pH, or
- a pH less than 5.0 in combination with a water activity of less than 0.94.

and therefore, the shelf life is determined by the factors previously discussed.

The *Food Standards Code* considers product with a refrigerated shelf life no greater than five days, no matter what its pH or water activity, to not support the growth of *L. monocytogenes*.

If your product does not meet any of these characteristics there is an option of validating that the level of *L. monocytogenes* will not increase by greater than 0.5 log cfu/g over the shelf life of the food. You can do this by challenge testing or by the use of a predictive model, and in either case, some expert advice will be needed. Using a predictive model, it is possible to determine the lag phase (number of days before *L. monocytogenes* will start to grow) and growth rate (how fast it will grow) and you can then set the shelf life according to the number of days that the model indicates the product will be in compliance with the *Food Standards Code*. You can find out more about this approach in Chapter 9.2.

It is also possible to change the way that you produce the product, for example by the addition of ingredients (acids, smoke, protective cultures) that will make it more difficult for *L. monocytogenes* to grow. The effects of these ingredients can also be included in the predictive model (Chapter 9.2).

1.8.3 Spoilage

Product may spoil due to the actions of bacteria or fungi that do not cause disease but are able to grow in the product. These spoilage microorganisms are often able to grow in a wider range of conditions than pathogens. Additionally, product may deteriorate over time and change colour, odour, taste or texture, so that it becomes unacceptable, or not the quality that you want to present to your customers.

Using the information for pathogens as a guide, you should store typical product (more than one batch, measuring parameters such as pH and a_w) under conditions likely to be found in the supply chain (refrigerated or unrefrigerated) to determine whether the product deteriorates. It is possible that some spoilage microorganism may grow and cause the product to become unsuitable for sale. Or it may slowly deteriorate chemically, and change appearance, texture or flavour. You can only find out by storing for a lengthy period. It is sometimes recommended that you store the product for 1.3x the desired shelf life (i.e. eight weeks for a product with a six week shelf life) but may be less (e.g. 1.2x) for longer shelf life products.

Some retail customers have detailed requirements for shelf life testing. It is worth obtaining expert advice before starting a shelf life study to make sure that you will get the right answer.

1.8.4 Date marking

Two types of date marking are used in Australia: use-by dates and best-before dates.

Foods that must be eaten before a certain time for safety reasons should be marked with a **use-by date**. Foods should not be eaten after the use-by date and can't legally be sold after this date because they may pose a safety risk.

The **best-before date** indicates that the product will be safe but may have lost some quality. Foods that have a best-before date can legally be sold after that date provided the food is fit for human consumption.

If specific storage conditions are needed in order for a product to keep until its best-before or use-by date, suppliers must include this information on the label, e.g. 'This product should be kept refrigerated'.

1.9 Making a safe product - using these *Guidelines*

These *Guidelines* are about understanding the important hazards and how to control them. These *Guidelines* are just that – guidelines about what is safe and what is not. The guidelines (whether here or in a regulation) try to provide conditions (e.g. times, temperatures, pH) to be sure about safety, but other conditions may also be safe, but this needs to be proved (validated) for your circumstances.

Systems are extremely important to good control. You need to be able to assess the risks, decide how to control them and be certain that those controls are in place for every batch of product you produce. That requires a systematic approach. In these *Guidelines* we present:

- How to prepare a FSP (Chapter 2)
- How to design and control your production environment (Chapter 3)
- The GMPs that you should implement for all your production (Chapter 4)
- How to implement a HACCP system to ensure safe products (Chapter 5).

Technical details of product and production are important too, which is why in these *Guidelines* we present:

- Information about the ingredients you may use and how they can affect product safety (Chapter 6)
- The processes you perform and how to control them well (Chapter 7)
- For each kind of product, a description of the hazards and how to control them in sample HACCP plans which identify likely CCPs and important GMPs (Chapter 8).

1.10 The role of microbiological testing in managing food safety

Sometimes customers or regulators, and even senior managers, demand a 'Certificate of Analysis' to present the results of microbiological testing. It is very tempting to believe that these results tell us with great certainty about the safety of the product. But microbiological testing is a poor way of determining whether product is safe unless many, many samples are taken and tested, because finding a harmful bacterium in a product is more difficult than finding a 'needle in a haystack' and does not even begin to tell us about whether a toxin might be present.

Laboratories often report whether a pathogen is 'detected' or 'not detected' in the 'sample received by the laboratory' because they want to tell you what the laboratory has done to the best of their ability. Bacteria are often distributed unevenly through product, so the sample tested by the laboratory may not contain the bacteria of concern. This is why repeated sampling is so critical to obtaining a good understanding of the quality of a lot of product and why there is often a requirement to send multiple samples of product to the laboratory.

When a process is being validated it is necessary to conduct microbiological tests on raw materials, process samples, and finished product, and multiple samples are collected, so that an accurate assessment of the capability of the process can be determined. Testing for other parameters (temperature, pH, a_w , % solids, etc.) can help to detect variations in the process that can lead to poor microbiological quality. The use of multiple samples increases the chance of finding a problem. It is tempting to ignore the occasional bad result, but you should never do this because it indicates some problem that needs to be investigated.

The inability of microbiological testing of finished product to demonstrate that product is safe is the reason why so much emphasis is placed on the reliability of the process of production, and therefore, on GMP and HACCP. Microbiological testing can be used as part of validating that a process is safe and, therefore that the individual products coming out of the process are most likely safe too. If the process is correctly designed and is 'under control', then the product will almost certainly conform with the microbiological specifications.

If you do send samples to the laboratory to test for pathogens, it is good practice to hold that lot of product until the test results are available. That way, you avoid having to conduct a recall if a pathogen is detected.

Regulators may be interested in verification through testing because they cannot audit every aspect of the process. When investigating foodborne illness, testing is essential to determine the pathogen responsible, and to start the process of tracing back to the production establishment. Often sophisticated 'genetic fingerprinting' is used as part of the investigation.

There are two main applications in smallgoods production where microbiological testing is an important part of the control: *E. coli* in UCFM and *L. monocytogenes* in RTE products because the health consequences for consumers who ingest those bacteria in foods can be very severe and, in some cases, fatal.

The process for UCFM manufacture has no single step that will eliminate the *E. coli* that may be found in raw materials, but rather several that, in combination, reduce the *E. coli* concentration to very low levels or even the probability of being present at all. Therefore, it is important to know the number of *E. coli* that may be found in raw materials (which may be established by your supplier and their process control). Since the reduction in *E. coli* concentration depends on the time and temperature of the process, and may not always be fully-controlled, verification that *E. coli* concentration in the finished product is very low or absent is needed, because of the risk of this bacterium to public health.

L. monocytogenes can sometimes be found in RTE products because it can contaminate product *after* cooking, often during slicing and packaging. *Listeria* often come from the packaging environment, or slicers, or can be found there, which is why stringent environmental controls are important GMPs for RTE products. Despite how thorough cleaning and sanitation practices are, there is no easy way to be sure that the practices have been effective, thus environmental testing for the presence of *Listeria* is an important added practice. There are several species of *Listeria*, but only *L. monocytogenes* causes illness in humans. The practice in testing is to look for any *Listeria* species, because if one species can survive in the environment, then *L. monocytogenes* could also be present.

2 Food Safety Plan (FSP)

2.1 Introduction

Producing a safe product, all the time and every time, requires you to do more than follow someone's instructions on how to make the product. It requires you to

- plan how to make the product safely
- be sure that everything has been done correctly
- rely on the people doing the job.

Of course, you need to meet the requirements of the *Food Standards Code*, the *Australian Standard*, and the registration/licencing requirements of the controlling authority in your state/territory.

This chapter will take you through all the aspects of producing a safe product, starting with people.

2.2 Food safety culture

Food safety culture is about attitudes, behaviours and the priority that managers and staff have for food safety. It can be summed up by the phrase, "It's how we do things here". In a food business, it is how everyone (owners, managers, employees) thinks and acts in their daily job to make sure the food they make is safe. It doesn't need to be complicated, particularly in a small business.

In Australia, people expect to enjoy their food with the assurance it is safe to eat. A good food safety culture is the foundation for protecting:

- consumers from harm, illnesses and death from unsafe food
- your brand's reputation
- your business from financial loss.

The *Food Standards Code* is also concerned with the production of safe food and tells you what you need to achieve. The requirements will be mentioned several times in this chapter and other chapters of the *Guidelines*. A strong food safety culture in the business is the start of preventing problems from occurring and makes it easier to be sure that you are meeting the requirements of regulations.

People are the key to food safety systems working properly. Your business needs to focus on people as well as processes. After all, it's people who make the decisions, handle the food, use and maintain equipment and clean things up.

In a strong food safety culture, people take responsibility, pride and care in producing safe food. They understand the importance of making safe food and the consequences of things going wrong. People have the right knowledge and skills and a genuine commitment to doing things the right way, every time.

Food safety culture starts at the top but needs support from everyone across the business. It includes not only food handlers, but also people involved in cleaning, maintenance, purchasing, and other activities, so that they understand how they contribute to food safety.

FSANZ has developed helpful materials for assessing the food safety culture of your business and suggesting how you can improve it.¹⁶

¹⁶ Food safety culture | Food Standards Australia New Zealand

2.3 Training

When staff are working in a business with a good food safety culture, it is easier to train staff to follow all of the requirements to produce a safe product. The following sections of this chapter outline all of the actions that need to be taken to make sure that your product is safe - and they all require people to do the right thing.

The *Food Standards Code* requires that people handling food, and their supervisors, have the skills and knowledge required to undertake their tasks.

Everyone must be aware of their role and responsibility to make a safe product. They need to have the knowledge and skills to manufacture product hygienically. Staff who handle cleaning chemicals or other potentially hazardous ingredients and chemicals should be instructed in proper use to prevent unsafe food. Keeping records of qualifications and training for each person helps you to make sure that you have enough staff trained in each task and it's something that your auditors will want to see.

Training programmes should also consider the knowledge and skill levels of the personnel being trained. Topics to be considered for training programmes could include:

- the principles of food hygiene
- the measures that are used to prevent contaminants in food
- the importance of good personal hygiene, including proper hand washing and wearing appropriate clothing, for food safety
- the GMPs applicable to the food business
- appropriate actions to take when food hygiene problems are observed.

2.4 Quality Systems

A Quality System, or a Quality Management System, is a formal system, including the policies, processes, documented procedures, which determines how your company will create and deliver the products that your customers desire.

The ISO 9001:2015 standard, from the International Organization for Standardization, is the best known definition of requirements for a quality management system that can apply to any kind of organisation. The ISO 22000:2018 Food safety management systems is similar in structure and purpose to the ISO 9001 standard but is specific about achieving food safety.

These standards tell you what you need to achieve, not how to do it. Specific food regulations and *Guidelines*, such as we are presenting here, helps you to make the product safely; meeting these standards helps you to achieve the right result every time, and makes sure you take the correct actions if you don't.

Many businesses will implement aspects of these standards as part of their routine way of working. Regulations may require more aspects to be implemented. But compliance with the standards goes beyond what businesses think of doing and regulators require. These standards really make you think about all aspects of your business and continually improve what you deliver to your customers.

If you supply, or want to supply, large retailers, and other large customers, they may have their own standards, which you need to follow. Some may require ISO 9001 and/or ISO 22000, or you may follow them because they help you to be a successful business. An example of a popular standard is the Brand Reputation Compliance Global Standard (BRCGS). Any business can obtain copies of the standards and implement the requirements, but there is a lot of value in becoming certified as following these standards by an external auditor.

One of the cornerstones of quality systems is the documentation of “Work instructions”. These are simple instructions that are specific to your business, formulations, equipment, etc., that tell staff exactly how product should be produced. Work instructions are the way that your culture is written down for the person doing the job and the FSP is converted into the tasks that are performed.

2.5 Construction and production zones

In this section we cover the design and construction of the premises.

It doesn't matter whether you run a smallgoods factory or make smallgoods in the back of a butcher's shop, you must work in clean premises and use equipment and techniques which supply safe products.

The requirements in the *Food Standards Code* Standard 3.2.3 – Food Premises and Equipment will need to be followed. FSANZ also publishes a guide to the food safety standards.¹⁷

The *Australian Standard* details how premises should be designed and built. This Standard has requirements that must be met. It has a section on premises, equipment and essential services.

You need to design and build your plant to make it easier to manufacture safe products. These ideas are based on industry experience and best practices and are mentioned in some regulatory guidance¹⁸ and in some industry standards.¹⁹ They are good ideas for everyone, and particularly those producing products that can be a risk for *L. monocytogenes*. These recommended practices are based on the idea of dividing your premises into zones.

Food process operations can be divided into four zones based on the level of risk of contamination that each is exposed to. Food contact surfaces, called Zone 1 surfaces, are at the highest risk for product contamination while non-food-contact surfaces that are farthest from the product are designated Zone 4. The zones work a little bit like layers of an onion: you want to prevent pathogens getting from the outside, into the most sensitive part of your operation; these areas need to be protected with layers of physical barriers (walls, closing doors, airlocks etc.) and operational barriers (cleaning, clothing, sanitising).

There are two basic ideas about zones:

- You prevent the entry of dangerous pathogens, such as *L. monocytogenes*, into the zones where you conduct the activities that are at risk
- You make sure that there are no places where these dangerous pathogens can hide (sometimes called, harbours) and grow and move around on people and equipment.²⁰

Production zones are discussed in more detail in Chapter 3.

2.6 The Food Safety Plan (FSP)

The FSP is a document that explains how you will ensure that the food product you manufacture will not cause adverse health effects (e.g. food poisoning or illness) to the consumer when it is prepared and eaten as intended. In the *Food Standards Code* (Standard 3.2.1) it is called a ‘food safety program’.

The *Australian Standard* (clauses 3.3 to 3.11) requires that all meat businesses have, implement and review HACCP which is the central part of a FSP.

¹⁷ Safe Food Australia - A guide to the Food Safety Standards | Food Standards Australia New Zealand

¹⁸ Australian Meat Regulators Group (2019) Standard 4.2.3 – Guidelines for the Management of Listeria

¹⁹ BRCGS Global Standard Food Safety (2022) issue 9 Appendix 2

²⁰ Holah, J. (2022). A 5-Point Listeria Control Plan: A European Perspective Food Protection Trends, 42(5), 383-395.

The *Food Standards Code (4.2.3 Production and Processing Standard for meat)* requires that all producers of RTE meat have a written plan documenting:

- all stages of production
- compliance with the requirements of clauses 3.3 to 3.10 of the *Australian Standard*
- a HACCP plan
- compliance with the requirements of *Food Standards Code Standard 3.2.2(Food safety practices and general requirements)*.

It is also necessary to follow any other aspects of a food safety management system required by your state or territory's controlling authority.

Depending on where you are, and who you are preparing the document for, there may be different requirements for what is included in the document, including:

- Staff training (how are your staff trained to do a particular job? Are special qualifications needed for some jobs?)
- Traceability of product (how can you find and control poor quality product on your premises, and after they are shipped?)
- Your raw materials
- The risks associated with the product
- How those risks are controlled
- Manufacturing practices that will ensure the likelihood of a problem is very low
- Particular processes that must be controlled carefully, and records kept demonstrating that the product will be safe.

While your controlling authority and customers/auditors may have certain expectations about what you include in your documentation, you are also writing it for you and your own staff. You need to be sure that it will help everyone do the job right.

In these *Guidelines*, we will discuss each type of product, the usual ingredients and processes, and the hazards (Hazard Analysis) that need to be controlled. We will point out the important GMPs (sometimes called Good Hygienic Practices, GHPs) and how to control the critical points in the process (CCPs).

GMPs alone may be sufficient to manage the hazards. However, it may be necessary to place greater attention on some GMPs that are particularly important for food safety. Hazards that occur or are present at levels such that GMPs are not sufficient to provide safe food should be managed by an appropriate combination of control measures that are developed through the HACCP plan.

GMPs including sanitation, and other practices such as training and traceability establish the foundation for implementing good control of hazards. Sometimes, cleaning and sanitation are called Sanitation Standard Operating Procedures (SSOPs) and kept separate because these procedures often occur during hours when you are not manufacturing and are often performed by different people.

The prerequisite programs (PRPs) need to be in place before CCPs can be expected to effectively control the hazards found through Hazard Analysis.

The interrelation between the elements of a FSP is shown in Figure 2.

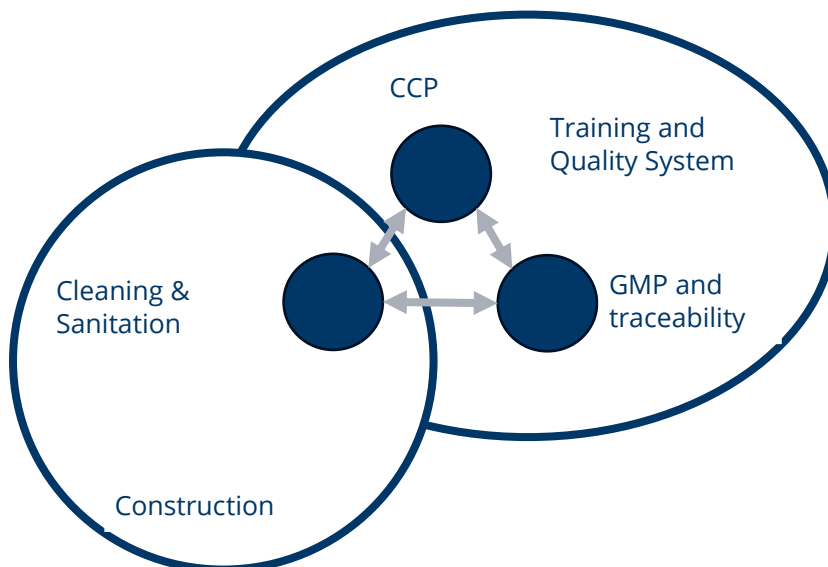


Figure 2: Elements of a FSP

2.7 Cleaning and sanitation

When the processing of a product ends, and at the end of the processing day, the food plant needs a major clean down. Thanks to modern equipment, applying cleaning solutions to working surfaces is a straightforward process.

The cleaning crew needs a plan. They need to be trained in how to carry it out and be given sufficient time to do the job. Chemical safety is also important:

- Chemicals need to be stored in a locked room or caged area which is protected by bunds (low walls) to contain leaks
- Staff need to be trained in how to use cleaning chemicals safely and what to do if they have an accident.

The cleaning plan needs to form part of your premises' SSOPs.

Cleaning and sanitation are discussed in more detail in Chapter 3.

2.8 Good Manufacturing Practices (GMPs)

GMPs are the foundation of any effective control of hazards associated with smallgoods manufacture.²¹

There are some fundamental GMPs that must be addressed in all products. These include:

- Having a safe (potable) water supply and one which supplies sufficient for all your plant needs
- Maintaining food contact surfaces in good, clean condition
- Preventing cross-contamination from one part of the process/building to another

²¹ FAO and WHO. 2023. General Principles of Food Hygiene. Codex Alimentarius Code of Practice, No. CXC 1-1969. Codex Alimentarius Commission. Rome. <https://doi.org/10.4060/cc6125en> General principles of food hygiene (fao.org)

- Maintaining hand washing, hand sanitising and toilet facilities
- Protecting food, food packaging materials and food contact surfaces from adulteration with lubricants, fuel, pesticides, cleaning compounds, sanitising agents, condensate and other chemical, physical and biological contaminants
- Labelling, storing, and using toxic compounds in a safe manner
- Controlling employee health
- Excluding pests
- Confining and removing wastes.

For some products, effective implementation of GMPs will be sufficient to address food safety. The sufficiency of the implemented GMPs to address food safety could be determined through conducting a hazard analysis and determining how to control identified hazards (see following sections).

All GMPs are important, but some GMPs have a greater impact on food safety. Thus, for some GMPs, based on safety concerns, greater attention may be needed to provide safe food.

For example, the cleaning of equipment and surfaces which come into contact with RTE food should receive greater attention than other areas such as the cleaning of walls and ceilings, because if food contact surfaces are not properly cleaned, this could lead to direct contamination of food. Greater attention may include a higher frequency of application, of monitoring and of verification.

In some circumstances, the implementation of GMPs may not be sufficient to ensure food safety due to the complexity of the food operation and/or specific hazards associated with the product or process. In such cases, when there are significant hazards found through hazard analysis as not being controlled by GMPs, they should be addressed in the HACCP plan.

An important GMP is traceability. This means being able to trace all of your raw materials and which products (and batches of product) they were used for and also being able to trace back from a batch of product and find out which others used the same ingredients or were produced in the same way. Traceability is important because, if there was a problem with a raw material (e.g. contained a toxic chemical), or with a process (e.g. not cooked properly) you will want to be able to identify all product that have the problem and make sure that they aren't sold, or if they have been, that they are recalled. Having good traceability reduces the size of the recall if something goes wrong.

GMPs are discussed in more detail in Chapter 4.

2.9 Hazard Analysis and Critical Control Point (HACCP)

The HACCP system identifies specific hazards and measures for their control to ensure the safety of food. HACCP is a tool to assess hazards and establish control systems that focus on control measures for significant hazards along the food chain. A significant hazard is one identified as reasonably likely to occur at an unacceptable level in the absence of control, and for which control is essential given the intended use of the food.²²

The HACCP plan is a document, prepared following the principles of HACCP, to ensure control of significant hazards in food products.

The HACCP system then ensures implementation of the procedures in the plan.

²² FAO and WHO. 2023. General Principles of Food Hygiene. Codex Alimentarius Code of Practice, No. CXC 1-1969. Codex Alimentarius Commission. Rome. <https://doi.org/10.4060/cc6125en> General principles of food hygiene (fao.org)

In these *Guidelines* we will identify the significant hazards for the raw materials and ingredients, and process described, based on a study of the scientific literature as well as public health experience described in Chapter 1. You must make sure that the guidance corresponds with the methods of production and activities in your establishment and ensure all relevant hazards are controlled.

The HACCP system is described in more detail in Chapter 5.

2.10 Validation and verification of the FSP

Before the HACCP plan can be implemented, it needs to be **validated**. Validation consists of collecting evidence that the controls described in the HACCP plan work the way they are described and are capable of ensuring control of the significant hazards relevant to the product. Where a HACCP plan has been developed by external experts, instead of the local HACCP team, or critical limits (CLs) from these *Guidelines* are used, care should be taken to ensure that the your plan describes the product you are producing (e.g. ingredients, moisture, etc.), the process you use (e.g. times, temperatures) and CLs fully apply to the specific operation, product, or groups of products that you make.

During the initial implementation of the HACCP system, evidence should be obtained to demonstrate that control can be achieved consistently under production conditions. Also, you need to know that the product will meet regulatory requirements. The verification activities listed below may all be used for validation with more intense monitoring and testing. Any changes having a potential impact on food safety should require a review of the HACCP system, and when necessary, a revalidation of the HACCP plan.

After the HACCP system has been implemented, procedures should be established to confirm that the HACCP system is working effectively. These include procedures to **verify** that the HACCP plan is being followed and controlling hazards on an ongoing basis, as well as procedures that show the control measures are effectively controlling the hazards as intended. Verification also includes reviewing the adequacy of the HACCP system periodically and when changes occur.

Verification activities should be performed on an ongoing basis to ensure the HACCP system functions as intended and continues to operate effectively.

Examples of verification activities include:

- reviewing monitoring records to confirm that CCPs are kept under control
- reviewing corrective action records, including specific deviations, product disposition and any analysis to determine the root cause of the deviation
- calibrating or checking the accuracy of instruments used for monitoring and/or verification;
- observing that control measures are being conducted in accordance with the HACCP plan
- sampling and testing, e.g. for microorganisms (pathogens or their indicators), chemical hazards such as mycotoxins, or physical hazards such as metal fragments, to verify product safety
- sampling and testing the environment for microbial contaminants and their indicators, such as *Listeria*
- reviewing the HACCP system, including the hazard analysis and the HACCP plan (e.g. internal and/or third-party audits).

Verification should be carried out by someone other than the person who is responsible for performing the monitoring and corrective actions. The frequency of verification activities should be sufficient to confirm that the HACCP system is working effectively. This review can be carried out by individuals within a food business or by external experts. The review should include confirmation that various verification activities have been executed as intended.

3 The Production Environment

Looking after the production environment so that you are ready to produce a safe product is an extremely important task. If you have constructed your plant (Chapter 2.5) well, you will find it easier to maintain a safe production environment.

Maintaining the production environment ready to produce a safe product is particularly important for products that can support the growth of *L. monocytogenes*, because this bacterium is good at persisting in the environment and hiding in places that are wet and cold - sometimes for years.

Some aspects, such as cleaning and sanitation, are part of GMP, but we deal with the topic separately here because it is something that you do before you start manufacturing, and it is important.

3.1 Zoning in your plant

Food process operations can be divided into four zones based on the level of risk of contamination that each is exposed to. Food contact surfaces, called Zone 1 surfaces, are at the highest risk for product contamination while non-food-contact surfaces that are farthest from the product are designated Zone 4. The zones work a little bit like layers of an onion: you want to prevent pathogens getting from the outside, into the most sensitive part of your operation; these areas need to be protected with layers of physical barriers (walls, closing doors, airlocks etc.) and operational barriers (cleaning, clothing, sanitising). Even a piece of equipment (e.g. slicing machine) can be divided into zones.

Zone 1 refers to all direct food contact surfaces (e.g. slicers, mixers, conveyors, utensils, racks, work tables, etc.). Even within zone 1 you may have areas where you need to give the product even higher levels of protection, for example, when you handle unwrapped, cooked RTE product such as in slicing machines.

Zone 2 encompasses the areas directly next to Zone 1. In a small production room, Zone 2 includes all non-food contact surfaces in the processing area (e.g. exterior of equipment, framework, food carts, equipment housing, gears, ventilation/air handling equipment, floors, etc.). In a larger room, Zone 2 is the area around the exposed product in which a pathway to product contamination could exist.

Zone 3 is the area surrounding Zone 2. Zone 3, if contaminated with a pathogen, could lead to contamination of Zone 2 via actions of humans or movement of machinery. Zone 3 could include hallways and doorways leading into food production areas or, in a large production room, areas further away from food handling equipment than typical Zone 2 areas.

Zone 4 is the area surrounding Zone 3, which, if contaminated with a pathogen, could lead to contamination of Zone 3 via the actions of humans or machinery. Examples include an employee locker room that is not adjacent to food production rooms, dry goods storage warehouse, finished product warehouse, cafeterias, hallways, and loading dock area.

You design and operate your zones so that you can

- **Prevent entry** of *Listeria* into high hygiene food manufacturing areas using effective barriers
- Ensure that the high hygiene manufacturing infrastructure (building structure, equipment, and utensils) **cannot harbor and/or allow the growth** of *Listeria* (*Listeria* sources)
- Ensure that high hygiene GMPs **limit the cross-contamination** vectors that can carry *Listeria* from sources to product or product-contact surfaces.²³

An example of the zoning concept working in practice, is that the batching of ingredients and thawing/tempering of raw meat may occur in zone 3, the chopping, extruding, filling of casings and entrance

²³ Holah, J. (2022). A 5-Point *Listeria* Control Plan: A European Perspective *Food Protection Trends*, 42(5), 383-395.

to the cooker may be in zone 2, and the post cooking-cooling, storage, slicing and packing occurs in zone 1. Movement of product and people is carefully controlled. Handwashing and changing clothes may be required between zones (especially entering zone 1). The air conditioning system ensures that the highest pressure is in zone 1 so that the air flows from the cleanest to less clean areas. More than one piece of some equipment may be required so that it is not moved between zones. In a small operation, it may not be possible to rebuild the plant to accommodate every desirable aspect, but compensation can be made by careful procedures, conducting steps requiring high attention to hygiene before those that have lower hygiene, thorough cleaning between activities etc.

For the purpose of environmental testing, your controlling authority may apply slightly different definitions of Zone 1 and Zone 2.²⁴

3.2 Cleaning and sanitation

Cleaning your plant to remove all signs of left over, and half-made product from the previous batch and then sanitising to destroy the bacteria that you can't see are basic activities required to be ready to manufacture a safe product.

You must follow *Food Standards Code* (3.2.2 Food safety practices and general requirements)²⁵ and document how you will do that. Implementing these recommendations on cleaning and sanitation along with GMPs (Chapter 6) will help you to meet this requirement.

Your equipment should be in good condition; worn equipment is more difficult to clean. Surfaces that are scored or pitted can make effective cleaning and sanitation almost impossible - even something as innocuous as a whiteboard. *L. monocytogenes* is known to become part of a slime, or sticky, layer of bacteria and their products (biofilms) that attach to a surface. They are commonly found in places such as closed systems, areas where moisture accumulates and between close fitting materials. These biofilms are surrounded by a protective sheath of proteins and sugars that make them harder to remove.

It is important to plan the cleaning process, especially in a small plant; you don't want water flowing from low risk to high risk areas or splashing water around and spreading water droplets from the floor onto equipment. In a small plant you may want to sanitise the high risk area last so that cleaning activities in other areas don't spread contamination into your recently sanitised area.

The notes here are general; there are many specific activities that may be required, depending on your plant, equipment, and what products you are making. Many products are susceptible to being contaminated with *L. monocytogenes*, so there is specific advice on how to manage this bacterium.

3.2.1 Soils

'Soils' is the term used to describe the build-up which is left on the food plant when production ceases. In smallgoods factories the main soils are fat and protein, and in areas where the water is hard, calcium and magnesium are additional soils.

The soils which need to be removed have to be identified so the correct detergent can be used.

3.2.2 Cleaning

The removal of soils like waste, dirt, grease, food scraps and blood from equipment and premises is termed cleaning. Some materials can be collected and swept or scooped, and others can be removed by rinsing. A

²⁴ Australian Meat Regulators Group (2019) Standard 4.2.3 – Guidelines for the Management of Listeria

²⁵ Federal Register of Legislation - Australia New Zealand Food Standards Code - Standard 3.2.2 - Food Safety Practices and General Requirements (Australia Only)

detergent that has been designed to remove these specific soils so they can be rinsed away with water will be required. Cleaning must be done properly so equipment and surfaces are visibly free from soils and deposits.

The quality of the water is important as very often under the influence of the alkaline cleaner insoluble scale or salts will be precipitated onto the surface. For this reason, a good cleaner will have adequate levels of sequestering (a chemical that prevents insoluble scale from forming) to compensate for the hardness in the water.

The chemicals used are generally alkaline in nature and have a surfactant (a chemical that makes it easier for the water to wet the surface). So, the pH is over 8 and sometimes a lot higher. The alkaline part will solubilise the protein and fat and allow it to be carried away by the water. The surfactant part will also assist in making the fat and protein soluble so it can be washed away.

Neutral and acid cleaners may also be used. Neutral cleaners have pH 6-8 and are used for most general cleaning. Acid cleaner has a pH less than 6 and is used to remove scale and alkaline soils.

3.2.3 Detergents

All detergents are formulated to remove fat and protein from the food plant. They typically have alkali (which removes fat) and chlorine (which removes protein), but the concentration of chlorine and alkali will vary according to the soil loading. For example, cleaning a grinder that's been working all day takes a heavy-duty chlorinated alkali detergent. You may need to scrub equipment to remove the fat and protein deposits that build up. Warm water is helpful for removing fat, but you don't want the temperature to be so hot that it causes proteins to stick to a surface.

Detergents are also formulated to take into account the hardness of water, and reputable chemical suppliers won't sell you a detergent until they've tested your water supply.

3.2.4 Sanitisers

As well as being soil-free, the cleaned surfaces of food plants must also have extremely low bacterial levels (<5 cfu/cm²). The role of the sanitiser is to destroy any bacteria remaining on the surface. Sanitising can be achieved by heat or by chemical means. Typical chemical sanitisers include quaternary ammonium compounds (QACs), sodium hypochlorite, hydrogen peroxide and peroxyacetic acid containing products.

Traditionally, hypochlorite has been the most widely used sanitiser, but it's corrosive and other forms of chlorine, such as chlorine dioxide, are available. QACs have also been used for many years and continue to be effective as no-rinse sanitisers when used at the correct concentrations, as is peroxyacetic acid. Some sanitisers have detergency built in making them a 'one-stop' cleaner/sanitiser. You may need to swap one sanitiser for another periodically to make sure that bacteria don't become resistant to the one you are using.

Products that seem more natural, but may also be effective, include electrolysed, or oxidised water. These products are based on using electrical current to modify (activate) salt water to produce hypochlorous acid, which is an effective sanitiser that has benefits over the use of traditional chlorine products

3.2.5 Applying cleaning solutions

Applying cleaning solutions is usually done with low pressure and low volume foaming wands – high-pressure pumps only blast solutions all over the plant. Typically, detergents are foamed onto surfaces and left (contact time) while the chemical reactions take place so that all the soil reacts with the detergent. Sanitisers are also foamed and left for the correct contact time (recommended by your chemical suppliers) needed for bacterial inactivation.

The ideal application system is a central chemical store where bulk cleaning solutions are piped around the factory in a ring main. At key locations around the factory are drop points where low pressure foam units are

plugged in. The ring main supplies detergent and sanitiser at the correct concentration and the cleaning crew applies solutions according to their work instructions.

Other application systems include portable foam units with automatic mixing of water and solution.

3.2.6 Sanitising spaces

Whole spaces, such as rooms, may be sanitised using fogging, gases or UV light. Fogging a chemical requires spraying it into a fine mist, high in the space, so that it fills the space, and chemicals land on all the equipment, including hard to reach spaces. The same idea applies to using gases (such as chlorine dioxide). In both cases, you need to obtain advice from suppliers who know what they are doing; chemicals that are suitable for applying to surfaces are not always suitable for spraying because they may not be safe for staff. Ultraviolet (UV) light may also be useful for sanitising surfaces or air, but it works over limited distances (that is, the UV light source needs to be close to the surface), and the light sources have limited life (UV light is invisible, so you can't look at the light to see if it is working).

With all of these treatments you should expect to see evidence from the supplier that the system works in other food manufacturers and agree on how they will demonstrate that it is effective on your site.

3.2.7 Choosing systems and cleaning solutions

Reputable suppliers of cleaning chemicals are as much concerned with setting their customers up properly as they are with selling drums of soap. Manufacturers can expect a number of 'add-ons' from chemical supplier such as:

- Training the cleaning crew, both in technique and Work Health and Safety (WHS) (concentrated cleaning chemicals are dangerous)
- Trialling cleaning solutions and reporting on their effectiveness
- Providing work instructions on how to clean different equipment and areas
- Undertaking verification of chemical concentration, and microbiological monitoring
- Working out a cleaning budget.

3.2.8 Costs of cleaning

The major costs for cleaning food factories are labour, cleaning chemicals and hot water. Far and away the major cost is labour so, if the aim is to reduce the overall cost of cleaning, a priority is to supply cleaning solutions and application systems which shorten the task of the cleaning crew. While one particular detergent may be cheaper it might also lengthen the time needed to clean, so ends up costing more in labour.

3.2.9 Where to clean and how often

The overriding priority in cleaning rests with the priority one sites – those surfaces and pieces of equipment which come into contact with final product. These will need cleaning and sanitising during the working day between one batch and another or at a break to reduce any contamination (and reduce batch sizes). Cleaning will need to be done while keeping the equipment dry because *Listeria* thrives if there is moisture around.

Table 7 lists priority 1, 2 and 3 sites and suggests ways of cleaning and sanitising them. This is only a template designed to be used as a guide and will need to be customised for individual operations.

In addition to daily cleaning of all equipment, weekend 'blitzes' need to be scheduled to clean and sanitise drains, cool rooms, and difficult-to-clean equipment such as slicers and equipment which are hard to access.

Table 7: Cleaning and sanitising priority 1,2 and 3 sites

	Pre-operation	In process cleaning	End-of-day cleaning
<p>Priority 1 sites</p> <p>Slicers, dicers, bandsaws, de-skinners etc.</p> <p>Hoppers which feed them</p> <p>Conveyors/ trolleys for cooked product</p> <p>Tables, benches on which product is portioned or packed.</p> <p>PPE such as aprons, gloves</p>	<p>Inspect and re-clean if necessary and dry with paper towels.</p> <p>Spray a no-rinse sanitiser and allow contact time.</p> <p>Wipe dry with squeegees before start-up</p>	<p>In each work break or product change:</p> <p>Remove scraps of meat.</p> <p>Spray a no-rinse sanitiser and allow contact time.</p> <p>Wipe dry with paper towel before start-up</p>	<p>Develop detailed work instruction</p>
<p>Priority 2 sites</p> <p>Chiller doors</p> <p>Switches</p> <p>Hand forklift controls and wheels.</p> <p>Cleaning equipment; squeegees, rubbish bins, shovels, dustpan brooms.</p> <p>Storage tubs.</p> <p>Tables including underneath surface and legs</p>	<p>Inspect and re-clean if necessary and dry with paper towels.</p> <p>Spray a no-rinse sanitiser and allow contact time.</p> <p>Wipe dry with paper towel before start-up</p>	<p>As necessary if gross contamination occurs:</p> <p>Wash with brush and cleaning solution</p> <p>Mop up moisture</p> <p>Spray a no-rinse sanitiser and allow contact time.</p> <p>Wipe dry with paper towel</p>	<p>Develop detailed work instruction</p>
<p>Air vents, blower units and drip trays in cooked product areas</p>			<p>Weekly on weekends: develop work instructions. Fog a sanitiser through the air conveying system</p>
<p>Priority 3 sites</p> <p>Equipment for handling packed product (lazy susan, roller conveyors)</p> <p>Motor housings</p>	<p>Inspect and re-clean if necessary and dry with paper towels.</p> <p>Spray a no-rinse sanitiser and allow contact time.</p> <p>Wipe dry with paper towel before start-up</p>	<p>As necessary if gross contamination occurs:</p> <p>Wash with brush and cleaning solution</p> <p>Mop up moisture</p> <p>Spray a no-rinse sanitiser and allow contact time.</p> <p>Wipe dry with paper towel</p>	
<p>Floors, drains, walls</p>	<p>Inspect and re-clean if necessary and dry with a squeegee</p>		

3.2.10 Work instructions

A work instruction must be documented for each area to be cleaned, with a focus on those areas that are critical to supporting product safety. A typical work instruction explains, sometimes with photographs, how to:

- Remove food scraps (called dry cleaning)
- Dismantle equipment
- Rinse with water
- Apply detergent and leave it in contact for the correct time. Scrub contact surfaces with scourers and/or brushes that are in good condition.
- Rinse the detergent with water, then allow to drain
- Apply sanitiser and leave for required contact time
- Rinse if needed
- Reassemble and leave equipment so it's dry at production start-up.

All these steps can be combined into a one-page work instruction which can also include WHS instructions, where needed, and give the cleaner an idea of the time needed to clean the equipment.

3.2.11 Some do's and don'ts

- Don't use porous and absorbent items like rags or wooden handled tools - they harbour bacteria.
- Do use separate brushes for product and non-product surfaces, and high risk and low risk areas, to minimise chances of cross contamination - colour-coded is good e.g. red means only use for floor waste, green is used for product only. You don't want *L. monocytogenes* to move around your plant through cleaning equipment.
- Do sanitise brushes and store them correctly between use.
- Do dry equipment after cleaning and sanitising.
- Do use low pressure cleaning systems to minimise splashing and aerosols.
- Do store hoses off the ground on reels or racks.
- Do clean shelving inside chillers about twice a week and door handles daily.
- Do have a look up at the blowers in the cool room – if they are covered in dust, or are dripping water, that's bad news for everything underneath. Chillers need regular cleaning and it's easier to schedule that if the room is managed properly (first-in-first-out (FIFO)) and having everything on shelves.
- Do maintain door seals in good condition – they can harbour *Listeria*.
- Always do a 'pre-op' inspection with the aid of a torch before work is started. Have a good look to see surfaces and equipment are clean and, if they aren't, do a clean down and sanitise. This will slow operations, so if this is the case, find out why it wasn't done properly first time around.

3.3 Environmental monitoring and microbiological verification

It is important to make sure that your cleaning and sanitising process works, and that your production environment is not harbouring bacteria that may cause you problems. *L. monocytogenes* is the bacterium we usually think of because it survives well in cold and damp places and has been known to take up residence in food production plants for years and to cause infections in consumers.

Visual inspection to check that all scraps and residues are removed is the first step. Metal surfaces should look shiny, and water should run smoothly over the surface because there is no residual fat. Looking for pooling of water on tables or floors; remove excess water so that everything dries quickly and easily. Looking in out-of-the-way and hard-to-clean places, and around joins, and seals is also important. It is possible to run some quick 'swab' tests that look for the presence of protein on the surface or the presence of ATP which is found in all living organisms.

Collecting samples, and running tests for *Listeria* species, is a direct way of monitoring. There are many species of *Listeria*, not just *L. monocytogenes*. The others don't cause disease, but if one species is able to survive, then it tells us that it's possible that *L. monocytogenes* is there also, or that it could be there.

Your state controlling authority has requirements for environmental monitoring for the presence of *Listeria* in your production environment, concentrating on zone 1 and zone 2 samples.²⁶ A minimal testing program requires five environmental samples once per month. You are encouraged to collect samples from the places *Listeria* is most likely to be, so that you can find, and eliminate the *Listeria* risk to your product. Your regulator has documented how samples should be collected and tested.

3.4 Keeping control of *Listeria*

Keeping *Listeria* out of food plants is almost impossible, which means you need to:

- Think about the zoning of production areas and how they operate
- Be vigilant with plant hygiene.

In addition to these routines, you may consider additional actions like the ones mentioned here:

3.4.1 Preventing people and equipment moving *Listeria* around the factory

One key to controlling *Listeria* is to keep slicing and packing rooms dry. However, there is always the possibility of leaks from equipment (shrink tunnels are a common source) and people or trolley wheels transferring the pathogen. In North America it is common to use a quaternary ammonium (QUAT) sanitiser in crystalline form, so-called 'crunchy QUAT', on the floors of the slicing and packing areas. Moisture is absorbed by the QUAT and a dry, sanitised environment is maintained.

3.4.2 Heating chillers to eliminate *Listeria*

MLA commissioned an investigation of *Listeria* in chillers at three large, processed meat facilities in south-east Queensland. In one facility *Listeria* was isolated from many of the sites sampled: door frames (11.5% positive), door seals (40.9%), doors and hinges (8.7%), floors (7.4%) and walls (3.6%).

The researchers placed heaters in chillers to dry them and to raise their temperature. Small chillers were heated at 50°C for two hours and large chillers to 37°C for 36 hours.

After heating, *Listeria* was isolated from 1.7% of sites (reduced from 10.6% pre-heating): door frames (3.8%), seals (4.5%) and hinges (4.3%).

Trials in Australia²⁷ showed that heating chillers as a routine intervention to break the *Listeria* cycle is effective. You can also take the opportunity to fill the chillers with other equipment such as racks or crates during the heating process to remove any possible contamination from these items.

²⁶ Australian Meat Regulators Group (2019) Standard 4.2.3 - Guidelines for the Management of *Listeria*.

²⁷ Eglezos, S., & Dykes, G. A. (2011). Application of Heat in Postcook Meat Chillers Reduces *Listeria*. *J Food Prot*, 74(6), 999-1002. <https://doi.org/https://doi.org/10.4315/0362-028X.JFP-10-532>

Eglezos, S., Thygesen, S., Huang, B., & Dykes, G. A. (2010). A simple method to reduce *Listeria* in blast and holding chillers. *Food Protection Trends*, 30(8), 472-476.

You should clean and sanitise any floor drains in the chillers just before, or simultaneously with this heat treatment, because the heating inside the chiller will not penetrate into the drain and leave it as a potential source of *Listeria*.

3.4.3 Heating equipment which can be moved into cookers

The idea of heating pieces of equipment in smokehouses is now routinely practiced in North American plants. On weekends, equipment which can be moved is taken to the smokehouse and 'cooked' to 70-80°C for one to two hours.

3.4.4 'Tenting' large scale equipment and heating with steam

For large pieces of equipment which cannot be moved e.g. form-fill packing machines or large slicing machines, companies in North America routinely use in-place steaming. The principle involves shrouding the slicer in polyethylene sheet and using steam (35 psi) to bring the equipment to 70-80°C for one to two hours. The challenge is to protect heat and moisture sensitive parts from the steaming process and to protect operators.

This process requires considerable expertise to set up but, once done, it takes only two to three hours to free the equipment of *Listeria* in those parts which cannot be accessed by routine cleaning.

3.4.5 Anti-*Listeria* bacteriophages

Bacteriophage (or, phage, for short) are viruses that attack and kill bacteria; they tend to be very specific and only attack a single species or a few strains of a species. A suspension of them in water can be sprayed in areas of the plant after routine cleaning and sanitation. Certain bacteriophage products are approved for use in Australia as processing aids.

You need to take care to follow the supplier's advice on how to use these products. It is possible to select for *Listeria* that are resistant to the bacteriophage, so careful monitoring and testing for *Listeria* at the sites where the bacteriophage product is used should be performed regularly.

3.4.6 Bioprotective cultures

Specific strains of lactic acid bacteria can protect against *Listeria* growth in the environment. Evidence also suggests bioprotective cultures are able to breakdown biofilms. Commercial bioprotective cultures are typically supplied freeze dried, then dispersed in water and can be fogged for greater coverage, or hand sprayed for specific hot spot areas as an addition to standard GMP.

4 Good Manufacturing Practices (GMPs)

GMPs are basic way to set up your production and processes to supply safe products. When we add practices such as training and traceability to this list, we have all of the basic environmental and operating conditions that set the foundation for implementation of a HACCP system.

Earlier chapters have already discussed design and construction of your plant (Chapter 2) and maintenance of the plant through cleaning and sanitation (Chapter 3).

You must comply with *Food Standards Code* (3.2.2 Food safety practices and general requirements) and document how you will do that. Implementing these GMPs, along with cleaning and sanitation (Chapter 3) will help you to meet this requirement.

This chapter discusses GMPs that are general to manufacturing processes.

4.1 GMPs and HACCP

It is possible that the application of GMPs alone is sufficient to manage some or all of the hazards, identified through Hazard Analysis, associated with the operation through control of their sources, such as:

- control of food handler practices and hygiene – prevents many potential communicable diseases that could be foodborne
- control of food contact surfaces by cleaning – removes bacterial contaminants, including foodborne pathogens, and allergens.²⁸

However, it may be necessary to place greater attention on some GMPs that are particularly important for food safety (e.g. wearing of clean clothing and washing hands is important in all production areas but may be more important in areas where product is being sliced and packed after cooking).

Most smallgoods production processes will have hazards that occur or are present at levels such that GMPs are not sufficient to provide safe food and therefore must be managed by the right combination of control measures that are capable of preventing occurrence of hazards or eliminating or reducing them to an acceptable level. The control measures can be identified in one or more steps throughout the production process. Where significant hazards are identified that need to be controlled after the implementation of GMPs, it will be necessary to develop and implement a HACCP system.

4.2 Personal hygiene

The hygiene of your staff is important so that you can produce a safe product. Everyone who comes into contact with food (either directly, or indirectly) needs to:

- maintain appropriate personal health
- maintain an appropriate degree of personal cleanliness
- behave and work in an appropriate manner.

The health of your staff is very important. Food handlers who have a symptom (diarrhoea, fever, vomiting, sore throat with fever, or jaundice - unless they know that it is caused by something not related to foodborne disease) should not handle food. National guidelines for the management of gastroenteritis outbreaks recommend that food handlers should not return to their usual duties until they have been symptom free for 48 hours. Further information and advice on the requirements can be obtained from the *Food Standard Code*²⁹ and the FSANZ publication, *Safe Food Australia*³⁰.

The business must provide staff with space to store their belongings, so they are not put on bench tops or other places where they could contaminate food. You want to keep all unnecessary ('foreign') objects out of production areas.

Even if your staff are healthy, you will want to separate your staff from the product. Wearing special clothing, hair nets, beard nets (snoods), gloves in production areas may be required depending on the zone and on the tasks they are performing. If staff work in areas where raw meat is handled, and then work in an area requiring high hygiene (e.g. product slicing and packing) they will need to change their clothing, including boots. In some high risk areas all outer clothing is disposable.

Washing hands properly before working, when returning from a break, and when changing tasks is critical to make sure that human pathogens don't enter the work area and are not moved from one place to another.

²⁸ FAO and WHO. 2023. General Principles of Food Hygiene. Codex Alimentarius Code of Practice, No. CXC 1-1969. Codex Alimentarius Commission. Rome. <https://doi.org/10.4060/cc6125en> General principles of food hygiene (fao.org)

²⁹ Food Standards Code 3.2.2

³⁰ FSANZ Safe Food Australia - A guide to the Food Safety Standards | Food Standards Australia New Zealand

Gloves may be useful, but hand washing still needs to occur first. And people sometimes think that because they are wearing gloves, everything they touch is safe, which is not true.

Washing of personal protective equipment such as sleeves, gloves, and aprons is also required.

4.3 Control of raw materials

A range of ingredients are used in smallgoods operations, including chilled and frozen pork, beef, sheep and poultry meat, offal, fat and a variety of other ingredients.

When purchasing meat, it is important to choose the cut (or manufacturing meat etc.) that is suitable for the product you are making. Good microbiological quality is especially important for products that will not be cooked. When meat is received it must be inspected for wholesomeness, and specifications such as temperature must be checked (no warmer than 5°C for cartoned meats and 7°C for carcasses). Receival and storage temperatures are regulated under the *Australian Standard* and there is no tolerance for temperatures warmer than those stipulated, except under an approved program which has specified corrective actions according to the risk.

Other raw materials and ingredients should be inspected to make sure that they are in good condition and conform to your purchasing specifications. Any ingredient that does not 'look right' needs to be inspected more closely.

Records must be kept so if there's a problem the cause can be identified. Having records and traceability shows your compliance with requirements and protects your business.

Returned goods should be clearly identified and stored in a designated area.

Once accepted, raw materials should be:

- moved to storage or directed to processing as soon as possible
- maintained at the right temperatures for safety and quality
- protected against contamination or damage
- stored in their own, or in clean containers on racks or shelves to ensure no contact with the floor
- used on a FIFO basis

Packaging materials and packaging practice used for smallgoods should be purchased from a reputable supplier which sells product that meets international standards. Store packaging in a dust and vermin proof room, on racks above the floor so that it is easy to clean underneath. Records of the packaging code and batch number need to be kept ensuring affected product can be traced if a problem occurs – all part of traceability.

4.4 Weighing and adding ingredients

Many chemicals such as nitrite and sulphite are toxic or poisonous when too much is ingested. The quantity of ingredients added is crucial to the health of consumers. For example, if sodium nitrite and sodium chloride are mixed up and nitrite is added at the amount meant for sodium chloride, the dose could be lethal. If the product isn't made to the correct formula (e.g. salt concentration is too low) then unwanted bacteria could grow and the product could become unsafe.

A fail-safe system of batching up ingredients and additives is needed. Consider buying a premix with the amount you need pre-weighed so that the entire bag is added to a batch. Or set up a specific area where one or two trained people follow carefully designed procedures to make sure that everything is weighed out and labelled correctly. And, of course, make sure that the amount of meat in the batch is correct; don't add something extra that is 'left over'

4.5 Allergen management

An allergen is a component of food that causes a person's immune system to react. Food allergies can be life threatening. For people who have a food allergy the only way to manage the allergy is to avoid the food allergen. For this reason, there are laws in place, for example, mandatory labelling, to help people who have a food allergy avoid food allergens.

The Allergen Bureau (www.allergenbureau.net) estimates more than 8% of children and 2% of adults in countries like Australia have a food allergy.

Food containing allergens must be labelled. In addition to allergens, gluten (from wheat, rye, barley, or oats) and added sulphites (present at 10mg/kg or higher) are included in labelling requirements due to their potential to cause non-allergic, hypersensitivity reactions. Food containing bee pollen, propolis, or royal jelly must be labelled with either a warning or advisory statement.

The *Food Standards Code* (Standard 1.2.3 Information Requirements - warning statement, advisory statements and declarations) requires the following foods and ingredients to be declared (using these names):

- wheat
- fish
- crustacean
- mollusc
- egg
- milk
- lupin
- peanut
- soy, soya, soybean
- sesame
- almond
- Brazil nut
- cashew
- hazelnut
- macadamia
- pecan
- pistachio
- pine nut
- walnut
- barley*
- oats*
- rye*
- sulphites**.

* Barley, oats, and rye must be declared if they contain gluten.

** Sulphites must be declared when added in amounts equal to or more than 10 milligrams per kilogram of food.

There are some limited exemptions from labelling in the *Food Standards Code* for ingredients derived from the above products.

Manufacturers need to include the segregation of these foods and ingredients in their GMPs and assess the risks in their HACCP plan. You need to regularly check package labels to identify any ingredient changes in raw materials and ingredients. You need to demand that suppliers inform you of formulation changes before releasing products that could put consumers and businesses at risk.

To minimise the potential for incidental contamination of products, allergens must be used so that they don't contaminate products that don't have the appropriate warning labelling. This includes storing them in a separate area when there is a chance of contamination and using interventions such as wash-down between manufacturing of products which do, or do not, contain allergens. Allergen products can be controlled by:

1. Starting with an effective end-of-day cleaning program verified by the pre-op inspection
2. Making allergen-free products first while equipment is clean
3. Washing all equipment, food contact surfaces and utensils between batches
4. Labelling each product if it contains an allergen, e.g. some marinades contain peanuts (satay sauce)
5. Labelling product if it is allergen-free e.g. if you make gluten-free sausages.

Key sources of information about allergen control and labelling are:

- the FSANZ Allergen Portal³¹
- The Allergen Bureau³².

The VITAL (Voluntary Incidental Trace Allergen Labelling) tool, which is used to calculate potential cross contamination, can be found at the Allergen Bureau website.

4.6 Equipment calibration

All equipment used to monitor a process must be checked for accuracy and calibrated regularly or the process may be out of control. The first step is to identify every piece of equipment which needs calibrating, such as:

- thermometers
- gauges on cool rooms
- gauges on cookers
- salinometers
- pH meter
- water activity meters
- scales
- metal detectors
- fat testers.

³¹ <https://www.foodstandards.gov.au/consumer/foodallergies/food-allergen-portal>

³² <https://allergenbureau.net/>

The next step is to make a schedule for calibrating all the equipment on the list.

Thermometers need to be calibrated regularly. How often depends on the type of thermometer. FSANZ recommends that the thermometer supplier's advice should be followed. It also recommends that thermometers are calibrated at least once every 12 months. The calibration of thermometers may best be performed (at least periodically) by the thermometer's supplier or by an accredited laboratory.

The National Association of Testing Authorities (NATA) gives general guidance on setting up a program for equipment assurance³³ including advice on calibration of thermometers³⁴ when used in laboratory testing, and these guidelines may be useful to set your own calibration and checking schedule. For digital thermometers NATA recommends calibration every two years with a check at an operating temperature every six months against a reference thermometer and for liquid-in-glass thermometers, calibration every five years with a check at an operating temperature every six months. Most medium and large-size premises have a reference thermometer calibrated by a NATA accredited laboratory. This is used only for calibrating working thermometers. The reference thermometer is calibrated by a service company accredited by NATA to perform the calibration.

It is relatively easy to check the calibration at 0 and 100°C but you could also check at a temperature close to the range where the thermometer is routinely being used (e.g. refrigeration or cooking). Some thermometers have a calibration test device, which gives an indication of whether the thermometer is working correctly. However, this test may only check the readout and not the temperature probe. The CSIRO Meat Research Newsletter, Number 91/2 "Thermometers" also has useful information on calibration.³⁵ Oven and cool room probes can't be easily removed so calibrate them in-place, using a calibrated thermometer at least once a month.

Scales are calibrated according to the manufacturer's requirements and checked at intervals by an approved calibration service.

A number of instruments like pH meters and metal detectors are calibrated according to the manufacturer's requirements. Advice can also be found on the NATA website, or from your external laboratory.

4.7 Physical contamination - and foreign body detection

Metal can enter smallgoods during a number of operations. You certainly hear it if a piece of metal breaks off and is bouncing around in the bowl chopper. Sometimes when the grinder is dismantled for cleaning a fractured blade can be found. A broken needle might be noticed at the end of injecting. Pitting on equipment means that small pieces of metal have worn off. In each case, metal ends up in the product. Ingesting metal can cause damage from breaking a tooth or from becoming stuck in the throat or gut. It is a serious hazard.

If you have manual injectors, you will notice it immediately and put the affected product to one side to remove the needle for rework. If brine injection is an in-line process the defect should be picked up by routine check-weighing of the product or when the injectors are inspected. Either way the needle must be found and then the under-injected product may be re-worked if it is certain there is no metal left in the product. Large manufacturers of emulsified products usually have detectors on the fillers, so metal is detected as it enters the casing. There are two possible sources of metal in emulsified, cooked sausage – worn mincer plates/cutter blade fracture or a clip from the filler. Smaller manufacturers of emulsified

³³ NATA (2019) General Accreditation Criteria: Equipment assurance, in-house calibration and equipment verification. <https://nata.com.au/files/2021/05/Equipment-assurance-in-house-calibration-and-equipment-verification.pdf>

³⁴ NATA (2023) General accreditation guidance: General equipment table. <https://nata.com.au/files/2021/05/General-Equipment-Table.pdf>

³⁵ http://www.meatupdate.csiro.au/data/MEAT_RESEARCH_NEWS_LETTER_91-2.pdf.

sausage may not find out until late in the day, when the grinder is being cleaned, that the grinder blade has shed some metal.

Large operations have metal detectors at one or more points to control this hazard. If you don't have a metal detector the options are:

- Hiring a detector if the product has no metal clips, such as fresh sausage
- Examining and reworking product which has been clipped, such as UCFM
- Dumping suspect product
- Reworking the batch by removing the sausage emulsion and spreading it over a cleaned bench for a visual search.

The best practice is to prevent suspect product being filled into the casings. In a small operation you will be nearby when the meat is going through the mincer, and you will be able to hear the noise as the metal goes through the plate. You can stop the mincer and discard product which might be affected by metal. You can also remove product, wash down the mincer and replace the broken blade.

4.8 Reprocessing smallgoods

Sometimes goods are returned by customers because they are getting close to their use-by dates. DO NOT be tempted to repack this product. The risk to your consumers and your business is high. You may be liable for criminal charges if a consumer is badly hurt. The best policy is to dump, or discard returned product. If a finished product has not left the premises, the risk is much lower because you have full knowledge of the history of the product. You can decide whether to recook to full specifications and repack, or to discard the product.

4.9 Documentation and records

Having good documentation of how you run your business is important, especially if there is a problem. Having documented product specifications, raw material specifications, manufacturing methods, cleaning methods and calibration methods, all help to prevent a problem from occurring.

You need to have records that show what you have done right; if something goes wrong these records will limit your product losses and help to reduce how much product you may need to recall. If some part of your production is a requirement in the *Food Standards Code* or the *Australian Standard*, then you will need some way of proving to your auditor or controlling authority that you have been doing the right things.

4.10 Product traceability and recall

If you need to remove unsafe food from distribution and sale you are conducting a food recall. You must be able to quickly remove food from the marketplace to protect public health and safety. FSANZ coordinates and monitors food recalls in Australia. State or territory authorities can order or force a recall. However, most recalls are initiated by food businesses.

You must have a written food recall plan so that you are ready to act immediately when you become aware of a problem. This is a requirement of the *Food Standards Code*.

FSANZ provides a Food Industry Food Recall Protocol³⁶ and templates³⁷ to help you meet this requirement and be prepared to act quickly.

³⁶ Food Industry Food Recall Protocol_September 2024 [1MB].pdf (foodstandards.gov.au)

³⁷ Recall templates | Food Standards Australia New Zealand

Being able to track food through all stages of production, processing and distribution will make it easier and quicker for you to recall it if something goes wrong. The *Food Standards Code* requires you to identify and label your product.

You should be able to trace all the inputs you use (including all ingredients, packaging, etc.) and the customers that receive your product. Have a strong traceability system that includes:

- procedures for identifying producers, suppliers, customers and products
- contact details of your suppliers and a list of what they supply
- contact details of your customers and a list of what you supply them
- dates of transactions and deliveries
- batch numbers or lot identifiers
- quantities of products supplied or received
- any other records relating to production that are relevant to your business.

You may conduct a mock recall to see whether the process that you have documented is working as expected.

5 Hazard Analysis and Critical Control Point (HACCP) System

The *Australian Standard* requires that all meat businesses have, implement, and review a FSP, employing HACCPs (*Australian Standard* clauses 3.3 to 3.11).

The *Food Standards Code* (4.2.3 *Production and Processing Standard for meat*) requires that all producers of RTE meat have a written plan documenting:

- all stages of production
- compliance with the requirements of clauses 3.3 to 3.10 of the *Australian Standard*
- a HACCP plan
- compliance with the requirements of *Food Standards Code* Standard 3.2.2 (*Food safety practices and general requirements*).

In this chapter we discuss the concepts of HACCP and how it works together with the other parts of your FSP. It is based on the internationally accepted, Codex Alimentarius *General Principles of Food Hygiene*.³⁸

GMPs (Chapter 4) including sanitation (Chapter 3), and other practices such as training (Chapter 2) and traceability (Chapter 4) set up the foundation for implementing good control of hazards. These are called PRPs.

5.1 GMPs and HACCP

GMPs alone may be sufficient to manage some or all of the hazards, identified through Hazard Analysis, associated with the operation through control of their sources, such as:

- control of food handler practices and hygiene – prevents many potential communicable diseases that could be foodborne
- control of food contact surfaces by cleaning – removes bacterial contaminants, including foodborne pathogens, and allergens.

However, it may be necessary to place greater attention on some GMPs that are particularly important for food safety (e.g. wearing of clean clothing and washing hands is important in all production areas but may be more important in areas where product is being sliced and packed after cooking).

Most smallgoods production processes will have hazards that occur or are present at levels such that GMPs are not sufficient to provide safe food and therefore must be managed by the right combination of control measures that are capable of preventing occurrence of hazards or eliminating or reducing them to an acceptable level. The control measures can be identified in one or more steps throughout the production process. Where significant hazards are identified that need to be controlled after the implementation of GMPs, it will be necessary to develop and implement a HACCP system.

5.2 HACCP system

The HACCP system identifies and evaluates hazards (Hazard Analysis) and controls those hazards at CCPs. The HACCP system, which is science-based and systematic, identifies specific hazards and measures for their

³⁸ FAO and WHO. 2023. General Principles of Food Hygiene. Codex Alimentarius Code of Practice, No. CXC 1-1969. Codex Alimentarius Commission. Rome. <https://doi.org/10.4060/cc6125en> General principles of food hygiene (fao.org)

control to ensure the safety of food. HACCP is a tool to assess hazards and set up control systems that focus on prevention.

Development of a HACCP system may show the need for changes in:

- processing parameters
- processing steps
- manufacturing technology
- end product characteristics
- method of distribution
- the intended use or
- the GMPs applied.

Making a change will help you to produce a safe product.

The HACCP system requires the development of a HACCP plan and the implementation of that plan.

5.3 Principles and steps to developing a HACCP system

The HACCP plan is based on a series of steps, implementing principles set out by the Codex Alimentarius Commission. The principles are closely related to the steps as shown in Figure 3 and Table 8.

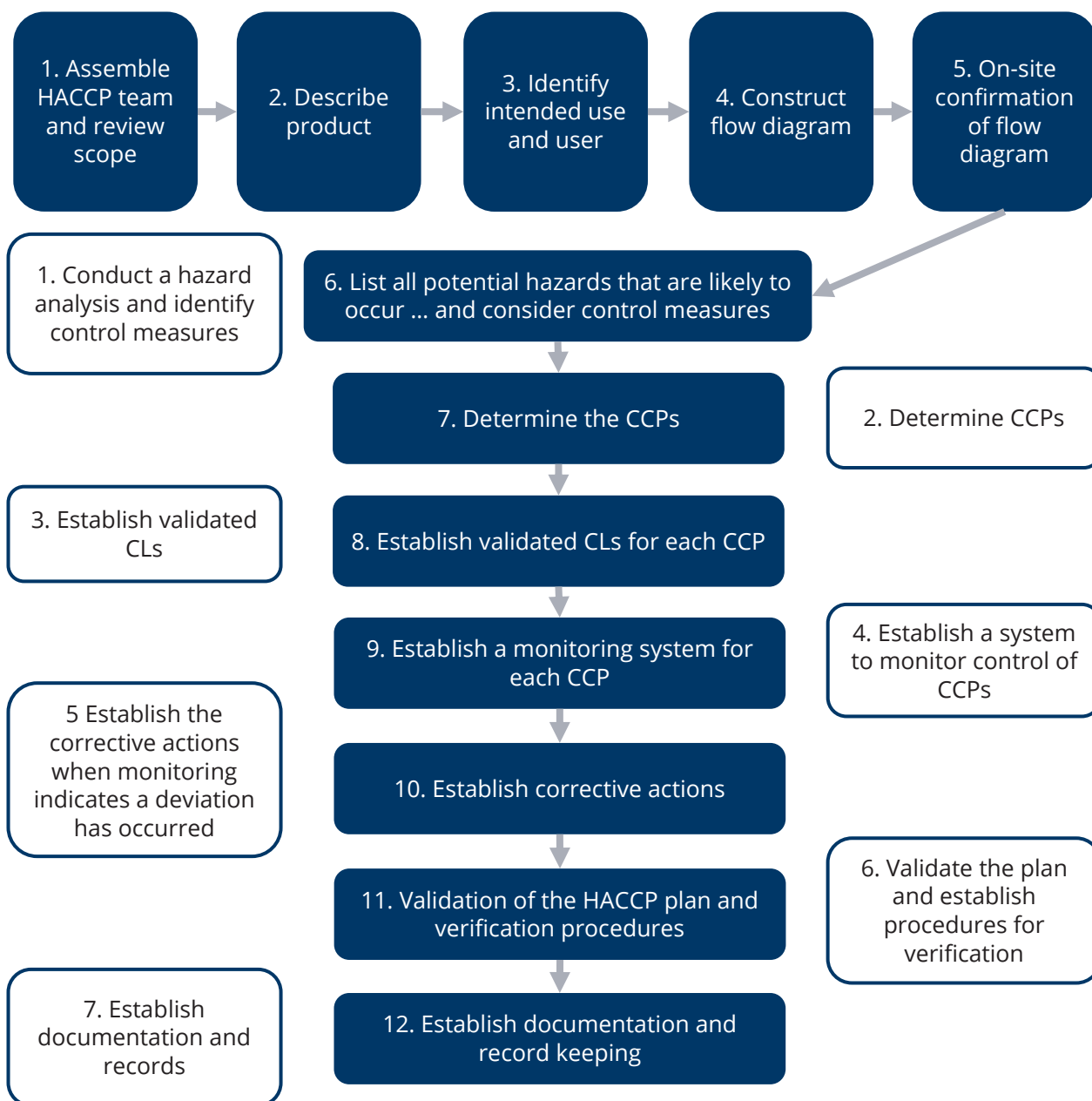


Figure 3 The seven principles and 12 steps of HACCP (abbreviated text)

Table 8: The seven principles and 12 steps of HACCP

Principles	Steps
	1 Assemble HACCP team and identify scope
	2 Describe product
	3 Identify intended use and users
	4 Construct flow diagram
	5 On-site confirmation of flow diagram
1 Conduct a hazard analysis and identify control measures	6 List all potential hazards that are likely to occur and associated with each step, conduct a hazard analysis to identify the significant hazards, and consider any measures to control identified hazards
2 Determine the CCPs	7 Determine the CCPs
3 Establish validated CLs	8 Establish validated CLs for each CCP
4 Establish a system to monitor control of CCPs	9 Establish a monitoring system for each CCP
5 Establish the corrective actions to be taken when monitoring indicates a deviation from a CL at a CCP has occurred	10 Establish corrective actions
6 Validate the HACCP plan and then establish procedures for verification to confirm that the HACCP system is working as intended	11 Validation of the HACCP plan and verification procedures
7 Establish documentation concerning all procedures and records appropriate to these principles and their application	12 Establish documentation and record keeping

There are many guides to implementing HACCP. *Food Standards Code* Standard 3.2.1 Food Safety Programs, does not apply to meat business because the requirements of the *Australian Standard* apply to meat businesses. However, FSANZ has produced a guide to Food Safety Programs, which may give useful advice.³⁹

Some important advice on the development of HACCP plans is to have a multidisciplinary team involved in the development (production, quality assurance staff, senior staff who know what needs to happen and junior staff who know how it is likely to be implemented). Sometimes, external consultants are involved, and when this occurs it is important to make sure that the plan can be implemented by the people in the business.

The development of the plan should be documented (for example, that the steps have been followed and reasons for decisions) and records to show that CCPs have been controlled must be kept.

The HACCP plan is integrated into the overall FSP.

To construct a HACCP plan, hazard control worksheets, which describe how hazards are controlled at each stage of the process, need to be developed. Some approaches to hazard analysis include a form of risk rating based on the likelihood of a hazard occurring and its severity when it does but this *Guideline* does not use this approach.

³⁹ Microsoft Word - Guide 321 FINAL (foodstandards.gov.au)

5.4 Critical steps and useful templates for developing a HACCP plan

While all of the steps of HACCP are important for the development of the HACCP system, the steps of hazard analysis, determining CCPs, and the operation of a CCP are the most critical, and the most likely to get wrong.

The templates presented in this section are not mandatory, but they have been published by the Codex Alimentarius Commission as guides. However, you should have a good reason, and expert advice, before you make changes to them.

5.4.1 Hazard analysis

Hazard analysis consists of identifying potential hazards and evaluating these hazards to determine which of them are significant for the specific food business operation.

The HACCP team should work through all the steps of the process and list all potential hazards (Table 9). The HACCP team should then identify where these hazards are reasonably likely to occur at each step (including all inputs into that step) of the operation. Hazards should be specific, e.g. metal fragments, and the source or reason for presence should be described, e.g. metal from broken blades during chopping.

The HACCP team should next evaluate the hazards to identify which of these hazards are such that their prevention, elimination, or reduction to acceptable levels is essential to the production of safe food.

In conducting the hazard analysis to determine whether there are significant hazards, wherever possible think about these points:

- hazards associated with producing or processing the type of food, including its ingredients and process steps (e.g. from surveys or sampling and testing of hazards in the food chain, from recalls, from information in the scientific literature or from epidemiological data)
- the likelihood of occurrence of hazards, taking into consideration PRPs, in the absence of additional control
- the likelihood and severity of adverse health effects associated with the hazards in the food in the absence of control
- identified acceptable levels of the hazards in the food, e.g. based on regulation, intended use, and scientific information
- the nature of the facility and the equipment used in making the food product
- survival or growth of pathogenic microorganisms
- production or persistence in foods of toxins (e.g. mycotoxins), chemicals (e.g. pesticides, drug residues, allergens) or physical agents (e.g. glass, metal)
- the intended use and/or probability of product mishandling by potential consumers that could make the food unsafe
- conditions leading to the above.

The products chapters of these *Guidelines* will provide advice on the hazards that need to be addressed in the HACCP plan for standard products and processes. The HACCP team must consider the specific product and production process at their site to determine whether the hazard analysis needs to be changed.

Table 9: Hazard analysis worksheet

1 Step	2 Identify potential hazards (Biological, Chemical, Physical)	3 Does this potential hazard need to be addressed in the HACCP plan		4 Justification for decision in column 3	5 What measure(s) can be applied to prevent or eliminate the hazard or reduce it to an acceptable level
		YES	NO		
1	B				
	C				
	P				
2	B				
	C				
	P				

5.4.2 CCP determination

A CCP is a step at which control can be applied so that the hazard is:

- prevented
- eliminated, or
- reduced to an acceptable level.

The system identifies the CCPs and then defines the conditions that have to be met to ensure a safe product.

CCPs are to be determined only for hazards identified as significant as the result of a hazard analysis.

CCPs are established at steps where control is essential and where a deviation could result in the production of a potentially unsafe food. The control measures should result in an acceptable level of the hazard being controlled.

There may be more than one CCP in a process at which control is applied to address the same hazard (e.g. the cook step may be the CCP for killing the vegetative cells of *C. perfringens*, but the cooling step may be a CCP to prevent germination and growth of the spores). Similarly, a CCP may control more than one hazard (e.g. cooking can be a CCP that addresses several microbial pathogens).

Determining whether or not the step at which a control measure is applied is a CCP in the HACCP system can be helped by using a decision tree or a CCP determination worksheet. The CCP may not be at the step where the hazard is first identified.

The table below incorporates four questions that be answered to determine whether a particular step is a CCP (Table 10). These questions can also be presented as a decision tree (or flow chart) (Figure 4). The table format allows the answers to the questions to be recorded, and a decision made after each question is answered, whether later questions need to be answered.

If no control measures exist at any step for an identified significant hazard, then the product or process should be changed.

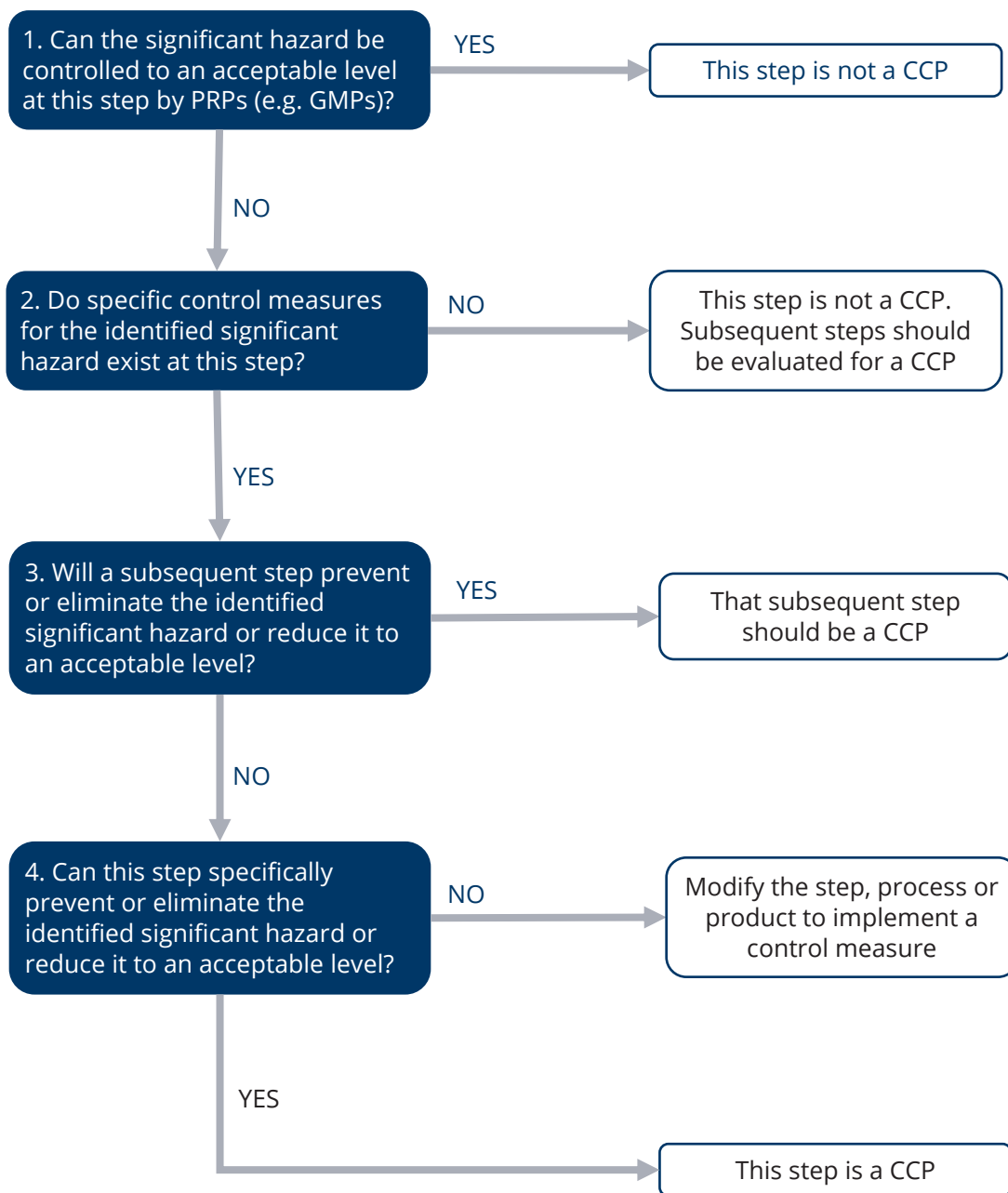


Figure 3: Codex decision tree to determine a CCP (Codex has several footnotes applying to this tree)

Table 10: A CCP determination worksheet

Process step	Significant hazard	Q1 Can the significant hazard be controlled to an acceptable level at this step by PRPs (e.g. GMPs)?	Q2 Do specific control measures for the identified significant hazard exist at this step?	Q3 Will a subsequent step prevent or eliminate the identified hazard or reduce it to an acceptable level?	Q4 Can this step specifically prevent or eliminate the identified significant hazard or reduce it to an acceptable level?	CCP number
		If YES, this step is not a CCP	If YES proceed to Q3	If YES that subsequent step should be a CCP	If YES, this step is a CCP	
		If NO, proceed to Q2	If NO this step is not a CCP. Subsequent steps should be evaluated for a CCP	If NO, proceed to Q4	If NO, modify the step, process or product to implement a control measure	
1						
2						

5.4.3 CLs for CCPs, monitoring, and corrective actions

CLs

CLs define whether a CCP is in control, and in doing so they can be used to separate acceptable products from unacceptable ones. These CLs should be measurable or observable.

Criteria often used include minimum and/or maximum values for critical parameters associated with the control measure, such as measurements of temperature, time, moisture level, pH, a_w . A deviation from the CL shows that it is likely that unsafe food has been produced.

CLs for control measures at each CCP should be specified and scientifically validated to obtain evidence that they are capable of controlling hazards to an acceptable level if properly implemented. CLs could be based on existing literature, regulations or guidance from competent authorities, or studies carried out by a third party.

In the processing chapter (Chapter 7) we have provided some processing parameters that are accepted as validated CLs. We also provide product characteristics (Chapter 1) that are accepted for validation of product as shelf stable.

Monitoring

Monitoring of CCPs is the scheduled measurement or observation of a CCP relative to its CLs. The monitoring method and frequency should be capable of prompt detection of any failure to remain within CLs because product produced outside the CLs needs to be isolated from the rest of the product and evaluated for safety.

The staff doing the monitoring should be trained in the steps to take when monitoring indicates the need to take action. Data derived from monitoring should be evaluated by a designated person with knowledge and

authority to carry out corrective actions when indicated. All records and documents associated with monitoring CCPs should report the results and time of the performed activity.

Automated (online) systems for monitoring can be very useful (e.g. times and temperatures of cool rooms, cooking, cooling, etc). These systems need to establish a record of dates and times of measurements, and if they have an alarm when a CL is breached then there must be a system to alert the right people in the business to take action. An automated system can be very useful, but the actions of the business to an out-of-specification result are just the same as with a manual recording system.

Corrective actions

Specific written corrective actions should be developed for each CCP in the HACCP system so you can effectively respond to deviations when they occur. When CLs at CCPs are checked continuously and a deviation occurs, any product being produced at the time the deviation occurs is potentially unsafe.

The corrective actions taken when a deviation occurs should ensure that the CCP has been brought under control and food that is potentially unsafe is handled appropriately and does not reach consumers. Actions taken should include segregating the affected product and analysing its safety to ensure proper disposition.

Details of the corrective actions, including the cause of the deviation and product disposition procedures, should be documented in the HACCP records. Periodic review of corrective actions should be undertaken to find trends and to ensure corrective actions are effective.

HACCP worksheet (audit table)

The CLs, monitoring requirements and corrective actions for CCPs can be presented in a table (Table 11).

Sometimes it is called a HACCP audit table because it's the table that you will want to be checking frequently to make sure your system is working, and auditors will be checking also.

Table 11: Example of a HACCP worksheet

CCP number	Significant hazard	CLs	Monitoring				Corrective actions	Verification activities	Records
			What	How	When	Who			
1									
2									

6 Ingredients

6.1 Acids

The *Food Standards Code* allows a number of acidity regulators to be added to some smallgoods products:

- Lactates – potassium lactate (326) and sodium lactate (325)
- Acetates – sodium acetate (262) and potassium acetate (261)
- Diacetate – potassium diacetate (261)
- Citric acid (330).

These acidity regulators may be added according to GMP to:

- processed meat, poultry and game products in whole cuts or pieces

- processed comminuted meat, poultry and game products, other than sausage and sausage meat containing raw, unprocessed meat
- Edible casings.

Acidity regulators can contribute to improving the shelf life of products. Lactates and diacetates are used in some products at levels which will prevent the growth of *L. monocytogenes* during the shelf life of the product.

Acids and natural alternatives are sometimes buffered with phosphates to provide the acid without greatly altering the pH of the product. The effect of these products on the pH and therefore the texture of the product must be considered. The inhibitory effect is not only due to the concentration of the acid, but also the pH of the product, so both should be considered when formulating a product.

Some natural products are available that can substitute for these acids:

- vinegar (acetate) - vinegars provide a natural form of acetic acid in high concentration to deliver antimicrobial efficacy, and are buffered to avoid compromising the meat's flavour, texture, and water-holding capacity. Depending on the titratable acidity, they may be considered 'vinegar' or an 'acidity regulator'
- vinegar powder (acetate)
- cultured dextrose/sugar (lactate).

6.2 Alcohol

Wine, rice wine, brandy, port, or similar alcoholic beverages may be used in the production of some sausage products – both fermented and unfermented, to enhance the flavour of the sausage. Alcohol can also have an effect on the structure and texture of the product.

In fermented products, care must be taken not to mix the starter culture into the batter when there is a high concentration of alcohol (i.e. mix the alcohol into the batter first, then the starter culture), to be sure that the concentration of alcohol does not inhibit acid production by the starter culture.

In all products, there are additional labelling requirements in the *Food Standards Code* (Standard 2.7.1 – Labelling of alcoholic beverages and food containing alcohol) to be considered.

6.3 Antioxidants

The *Food Standards Code* allows a number of antioxidants to be added to smallgoods products:

- ascorbate - ascorbic acid (300), Sodium ascorbate (301), Calcium ascorbate (302), potassium ascorbate (303)
- erythorbate - erythorbic acid (315), sodium erythorbate (316).

These antioxidants may be added according to GMP to:

- processed meat, poultry and game products in whole cuts or pieces
- processed comminuted meat, poultry and game products, other than sausage and sausage meat containing raw, unprocessed meat
- edible casings.

Erythorbic acid is very similar in structure to ascorbic acid. It is used in meat products as:

- Antioxidant: it keeps the food fresh (colour, flavour and etc) as sodium erythorbate itself can be oxidized by scavenging oxygen and then inhibiting the oxidation.

- Preservative: it prevents microbial growth and therefore extends the shelf life of food.
- Curing accelerator: it accelerates the curing process of meat products by speeding up the development of the pink colour.

The stable pink colour, unique flavour, aroma as well as microbial control and antioxidant activity are developed by reactions of nitric oxide with meat. The whole process is associated with curing agents and added ingredients and the chemical reactions among them. Nitric oxide is produced from the nitrite that is used in the cure and reacts with myoglobin, the red chemical found in muscle, to form nitrosomyoglobin.

Antioxidants remove oxygen from a UCFM batter. Spoilage bacteria on the raw meat can outgrow the starter cultures and remove their sugar source. These spoilage bacteria are mainly aerobic – they need oxygen to be able to grow but forming the sausage expels most of the oxygen and pulling in a vacuum in the sausage also helps. Ascorbate helps to lower available oxygen and inhibit the spoilers.

These natural products can substitute for these acids:

- cherry powder
- tosemary extract (also listed as a preservative)
- clove
- thyme
- oregano.

6.4 Colours

The *Food Standards Code* allows a number of colours to be added to smallgoods products:

- Annatto extracts (160b) may be added to processed comminuted meat, poultry and game products, other than sausage and sausage meat containing raw, unprocessed meat to a maximum level of 100 mg/kg.
- Paprika oleoresins (160c), caramel colour (150a-150d), and carmine (120) may be added according to GMP to:
 - processed meat, poultry and game products in whole cuts or pieces
 - processed comminuted meat, poultry and game products, other than sausage and sausage meat containing raw, unprocessed meat
 - Edible casings.
- Ponceau 4R (124) is permitted in edible casing to a maximum level of 290 mg/kg.

There are no commonly recognised food safety hazards arising from the use of colours.

6.5 Gelatine

Gelatine is a high protein product produced from the hydrolysis (breakdown) of collagen found in animal products (hides, skins, bones – usually from cattle or pigs). Thus, there are different types of gelatine, according to the species of origin, religious slaughter and degree of hydrolysis.

Gelatin is often used as a gelling agent, stabilizer, emulsifier, thickener, and clarifier in food, and particularly, as an ingredient in pâté. Both food grade and industrial grade gelatine are produced, so it is important to purchase food grade gelatine. As an animal by-product, produced through a drying process, *Salmonella* is a recognised possible contaminant, and the processing and/or specification of the raw material should take this into account.

6.6 Nitrate / nitrite

The *Food Standards Code* allows a number of sources of nitrite:

- Nitrites – potassium nitrite (249) and sodium nitrite (250)
- Nitrates – sodium nitrate (251) and potassium nitrate (252).

Nitrites are allowed in cured meat, dried meat, slow dried cured meat, and processed comminuted meats (except fresh sausage) at a level of 125 mg/kg calculated as sodium nitrite. They are also allowed in sterile canned cured meat at 50 mg/kg. Additionally, nitrates are allowed in slow dried cured meat and UCFM at 500 mg/kg.

The *Australian Standard* assumes that nitrate/nitrite are used and requires that nitrite and nitrate levels are maintained in cured products at concentrations that minimise food safety hazards.

Sodium nitrate is a naturally occurring chemical compound found in soil, water, and plants. In the presence of bacteria (starter cultures, in the case of UCFM) and incubation at a suitable temperature, nitrate is converted to nitrite. Nitrite is the active chemical. Nitrate-based cures may only be used in products such as dry cured hams and dry fermented sausage. The long, slow curing processes rely on a long-term reservoir of nitrate that is slowly converted to nitrite over the course of the process.

The antioxidants (ascorbate or erythorbate) may be used as 'curing accelerators' to further reduce the nitrite to nitric oxide.

Sodium nitrite or potassium nitrite play a key role in the safety of processed meats. Nitrites, or in slow cured meats sodium or potassium nitrates, are the key ingredients in meat cures. They provide excellent protection against botulism (because they inhibit the germination, growth, and toxin production by *C. botulinum*) occurring when processed meats are consumed. The growth of *C. perfringens* is also inhibited. The growth of *L. monocytogenes* can also be inhibited. At the same time their use results in the characteristic colour and flavour of cured meats.

Exceeding the allowed concentrations can result in poisoning of consumers. Nitrites in food has become an issue due to their potential to react with other components of food and produce compounds that are carcinogenic. FSANZ provides consumer information on nitrites.⁴⁰

In the context of nitrite concentration(s), 10–15 ppm is required to induce pigment fixation for commercial stability, 20–50 ppm is required to retard rancidity, 50 ppm is required to ensure proper flavour development, and 40–80 ppm are required to inhibit the outgrowth of *C. botulinum*.⁴¹

Natural sources of nitrite:

- celery juice and cultured celery juice
- beetroot juice
- sea salt.

If using natural sources of nitrite, it is critical that the concentration of nitrite is adequate, and a Certificate of Analysis or guarantee of nitrite concentration should be obtained. The effect of natural sources of nitrite on other product qualities (e.g. pH) should be considered.

⁴⁰ Nitrates and nitrites | Food Standards Australia New Zealand

⁴¹ Nicholas Rivera, Marisa Bunning, and Jennifer Martin (2019) Uncured-Labeled Meat Products Produced Using Plant-Derived Nitrates and Nitrites: Chemistry, Safety, and Regulatory Considerations. *Journal of Agricultural and Food Chemistry* 2019 67 (29), 8074-8084 DOI: 10.1021/acs.jafc.9b01826

6.7 Preservatives

The *Food Standards Code* allows a number of preservatives to be added to some smallgoods products:

- Propionates – propionic acid (280), sodium propionate (281) potassium propionate (283) calcium propionate (282)
- Sorbates – Sorbic acid (200), sodium sorbate (201), potassium sorbate (202) and calcium sorbate (203)
- Natamycin or Pimaricin (235)
- Nisin (234)
- ethyl lauryl arginate (243)
- Rosemary extract (392)
- Nitrate/nitrite, and sulphites / sulphur dioxide are also preservatives - and have their own sections in this chapter.

Acids (6.1) also have a preservative effect.

The quantity of preservative allowed may depend on the type of product being produced (Table 12).

Table 12: Preservatives allowed in processed meat (mg/kg) (Food Standards Code 1.3.1 and Schedule 15)

Preservative	Meat product						
	8.2 processed meat in whole cuts or pieces	8.2.2 cured meat	8.2.3 dried meat	8.2.4 slow dried cured meat	8.3 processed comminuted meat	8.3.1 fermented, uncooked comminuted	8.3.2 sausage and sausage meat containing raw, unprocessed meat
234 nisin	12.5				12.5		
243 ethyl lauroyl arginate	200				315		
280 281 282 283 propionic acid	GMP*			GMP*			
392 rosemary extract	a. 15 for meat with <10% fat; b. 37.5 for meat > 10% fat;	150					a. 40 only sausage b. 100 only dried sausage
249 250 nitrites		125		125	125		
251 252 nitrates				500		500	
200 201 202 203 sorbates			1500			1500	
220 221 222 223 224 225 228 sulphur					500		500

Preservative	Meat product						
	8.2 processed meat in whole cuts or pieces	8.2.2 cured meat	8.2.3 dried meat	8.2.4 slow dried cured meat	8.3 processed comminuted meat	8.3.1 fermented, uncooked comminuted	8.3.2 sausage and sausage meat containing raw, unprocessed meat
dioxide and sulphites							
235 pimaricin (natamycin)							1.2 mg/dm ²

* According to GMP

Sodium propionate (281) is primarily used in baked goods to extend the shelf life and can also be used in meat products to inhibit the growth of mould and other microbes.

Sorbic acid is used usually as potassium sorbate (202). This ingredient can be used in low water content food such as meat products to inhibit the growth of moulds (also mycotoxin-forming moulds), yeast and some bacteria.

Natamycin (235), also known as pimaricin, is used in the surface treatment of sausages to inhibit yeasts and moulds.

Nisin (234) can inhibit the growth of a variety of food spoilage Gram-positive bacteria, such as *Bacillus cereus*, *S. aureus*, *L. monocytogenes* and *C. botulinum*, and it is particularly effective against spores that may be produced by Gram-positive bacteria. Nisin can reduce the addition of sodium nitrite in meat products such as canned ham and sausages.

Rosemary extract is a preservative and antioxidant with application in several food categories, including meat products such as cured meats and cooked meats.

Other plant extracts can also have powerful effect on pathogenic and spoilage bacteria and can extend shelf life, and also inhibit the growth of *L. monocytogenes*. They are 'clean label' products and can be labelled as smoke or natural flavours. You must validate the performance of these ingredients in your products, especially if you want to claim that the growth of *Listeria* is prevented.

6.8 Protective cultures

Protective cultures are selected food cultures, frequently lactic acid bacteria, that through multiple biological interactions with the food matrix and with the flora, including fermentation, have minimal effects on the flavour or appearance of food and can help improve overall quality included but not limited to slow down the growth of unwanted contaminants and helping to reduce food spoilage and enhance food safety. They can be a valuable tool, added to other food safety hurdles, to keep food safe and within specifications

Protective cultures can be added as ingredients to meat products included but not limited to salami, dry cured meats, cooked meats, etc.

The use of protective cultures can make the Standard Plate Count (SPC) of the meat product very high, but that doesn't mean that the product is spoiled. FSANZ has published guidelines for interpreting SPC in foods⁴², and foods with protective cultures are in Category 5 in which the SPC is not applicable. Alternatively, a testing

⁴² Food Standards Australia New Zealand (2022) Compendium of Microbiological Criteria for Food. Compendium of Microbiological Criteria for Food | Food Standards Australia New Zealand

method needs to be applied to the food that can differentiate the protective culture from the other bacteria present.

6.9 Raw meat – microbiological hazards

Raw meat quality is important because of visible contamination and microbiological levels. Traditionally, some high-end products, such as Mettwurst, have been manufactured from meat with a low microbiological level by using internal muscle removed using a high level of hygiene. If you can buy boneless meat with consistently low generic *E. coli* levels it reduces the risk of final product ever containing *Salmonella* or pathogenic *E. coli*.

The following information comes from surveys conducted at one point in time and were generally conducted some time ago, predominantly (or exclusively) from export-registered processing establishments. It is likely that the microbiological quality has improved since the time that these surveys were conducted.

Processing establishments should be expected to have current data on their production, at least for indicator microorganisms, such as SPC (Total Viable Count) and *E. coli*.

6.9.1 Pork

Carcases

A survey of a limited number of export establishments was conducted in 2017-2018.⁴³ The mean log₁₀ APC from carcasses from all three pork establishments was 1.35 log₁₀ cfu/cm², with the average being 1 log₁₀ cfu/cm² higher at one establishment than the other two. *E. coli* prevalence ranged from 5.0-5.4% per establishment with concentration ranging from -0.02 to 0.27 log₁₀/cm².

Primals

A survey of a limited number of export establishments was conducted in 2017-2018.⁴⁴ The mean log₁₀ APC of primals from the three pork establishments was 1.57 log₁₀ cfu/cm². *E. coli* prevalence ranges from 2.1 – 3.8% with the average concentration ranging from -0.92 to 1.00 log₁₀ cfu/cm². While *Y. enterocolitica* is recognised as a hazard that can be found in pork, no survey data is easily available.

Manufacturing (boneless meat)

A survey of a limited number of export establishments was conducted in 2017-2018.⁴⁵ In excised samples of bulk meat, the prevalence of *E. coli* ranged from 1.4 to 3.9%, with the average concentrations approximately 1.2 log₁₀/g.

T. spiralis

T. spiralis, is a roundworm found in both animals and humans. It is the parasite of interest for pork consumption because it is transmitted to humans by the consumption of cysts (larvae) in raw or undercooked pork.

T. spiralis is not present in the animal population in Australia, but may be present in imported pork. The requirement to cook imported pork to meet biosecurity requirements is adequate to destroy *Trichinella*.

⁴³ Jolley, J., Kiermeier, A., Sumner, J., 2023. Microbiological Quality of Australian Beef, Sheep and Pork Carcasses, Cuts and Offals. *Foods* 12, 3832.

⁴⁴ Jolley, J., Kiermeier, A., Sumner, J., 2023. Microbiological Quality of Australian Beef, Sheep and Pork Carcasses, Cuts and Offals. *Foods* 12, 3832.

⁴⁵ Jolley, J., Kiermeier, A., Sumner, J., 2023. Microbiological Quality of Australian Beef, Sheep and Pork Carcasses, Cuts and Offals. *Foods* 12, 3832.

6.9.2 Beef

Carcase

The most recent carcase baseline conducted using standard methods, was conducted in 2004. Carcasses (n=1,155) sampled at 27 slaughter establishments had a mean APC (at 25°C) of 1.3 log CFU/cm². *E. coli* was isolated from 8.0% of the carcasses, with a mean count of -0.8 log CFU/cm² for samples above the detection limit. *Salmonella* was isolated from 0 of 1155 carcasses. No *Campylobacter* spp. were isolated from carcasses. Coagulase-positive staphylococci were isolated from 28.7% of beef carcasses, and samples above the limit of detection had a mean count of 0.3 log CFU/cm².⁴⁶

A survey of a limited number of export establishments was conducted in 2017-2018.⁴⁷ The mean APC from carcasses was 0.84 log₁₀ cfu/cm² with establishment means ranging from 0.39 log₁₀ cfu/cm² to 1.65 log₁₀ cfu/cm². *E. coli* was detected on 2.7% of beef carcasses (ranging from 0.7-5.5% in each establishment) and an average concentration of -0.64 log₁₀/cm² (0.22 cfu/cm²).

Primals

The fourth national baseline microbiological survey of Australian beef was conducted in 2011, including samples from selected beef primal cuts. Cartons of primals were sampled at 29 boning (fabrication) plants. The mean TVC for striploins (*longissimus dorsi*, n=572) and outsides (*biceps femoris*, n=572) were 1.3 and 1.5 log CFU/cm² respectively. *E. coli* isolates were obtained from 10.7 and 25.2% of striploins and outsides, respectively, with mean counts of 20.5 and 20.3 log CFU/cm² on samples above the limit of detection. *E. coli* O157:H7, *Salmonella*, and *Campylobacter* were not isolated from any primal cut samples, and *Salmonella* was not isolated from any of the boneless product (*E. coli* O157:H7 and *Campylobacter* were not tested). *Listeria* spp. was obtained on 1 (0.2%) of 572 striploin samples. Coagulase-positive staphylococci were isolated from 7.7% of beef striploins, and 8.4% of beef outsides, with samples above the limit of detection having mean log counts of 0.2 CFU/cm², and 0.2 CFU/cm², respectively.⁴⁸

A survey of a limited number of export establishments was conducted in 2017.⁴⁹ The mean log₁₀ APC of primals from the beef establishments was 1.65 log₁₀ cfu/cm² with means for specific primals ranging from 1.41 and 1.42 log₁₀ cfu/cm² on internal cuts, such as tenderloins and cube rolls, to 1.80 to 1.99 log₁₀ cfu/cm² on cuts with external surfaces such as outside, brisket and blade. *E. coli* was detected on 3.5-9.5% of beef carcasses and an average concentration ranging from of -1.18 log₁₀/cm² (0.06 cfu/cm²) to -0.03 log₁₀/cm² (0.93 cfu/cm²).

Manufacturing (boneless meat)

The fourth national baseline microbiological survey of Australian beef was conducted in 2011, including frozen boneless beef. Cartons of frozen boneless beef (n=1,165) sampled at 29 boning (fabrication) plants were found to have a mean TVC of 2.2 log CFU/g, and the mean count for the 2.1% of samples with detectable *E. coli* was 1.3 log CFU/g. *Salmonella* was not isolated from any of the boneless product. *Listeria* spp. were not detected in any of the boneless product. Coagulase-positive staphylococci were isolated from 3.4% of boneless beef samples, with positive samples having mean log counts of 1.9 CFU/g.⁵⁰

⁴⁶ Phillips, D., Jordan, D., Morris, S., Jenson, I., Sumner, J., 2006. A national survey of the microbiological quality of beef carcasses and frozen boneless beef in Australia. *J Food Prot* 69, 1113-1117.

⁴⁷ Jolley, J., Kiermeier, A., Sumner, J., 2023. Microbiological Quality of Australian Beef, Sheep and Pork Carcasses, Cuts and Offals. *Foods* 12, 3832

⁴⁸ Phillips, D., Bridger, K., Jenson, I., Sumner, J., 2012. An Australian national survey of the microbiological quality of frozen boneless beef and beef primal cuts. *J Food Prot* 75, 1862-1866.

⁴⁹ Jolley, J., Kiermeier, A., Sumner, J., 2023. Microbiological Quality of Australian Beef, Sheep and Pork Carcasses, Cuts and Offals. *Foods* 12, 3832

⁵⁰ Phillips, D., Bridger, K., Jenson, I., Sumner, J., 2012. An Australian national survey of the microbiological quality of frozen boneless beef and beef primal cuts. *J Food Prot* 75, 1862-1866

A survey of a limited number of export establishments was conducted in 2017-2018.⁵¹ *E. coli* was detected on 1.9 – 11.2% of beef bulk packs and average concentrations ranging from of 1.13 log₁₀/g (13.49 cfu/g) to 1.49 log₁₀/g (31 cfu/g).

6.9.3 Sheep meat

Carcase

The most recent baseline survey of sheep carcasses was conducted in 2004. Carcasses (*n* =1117) sampled at 20 slaughter establishments were found to have a mean log Total Viable Count (TVC, 25 C) of 2.28 cfu/cm² and *E. coli* was isolated from 43.0% carcasses with a mean log 0.03 cfu/cm² on samples above the limit of detection. *Salmonella* was isolated from 0/1117 carcasses. *Campylobacter* sp. were isolated from 4/1117 carcasses. Coagulase-positive staphylococci were isolated from 23.4% of carcasses, with samples above the limit of detection having a mean log count of 0.93 cfu/cm².⁵²

A survey of a limited number of export establishments was conducted in 2017-2018.⁵³ The mean log₁₀ APC from carcasses across three sheep establishments was 1.56 log₁₀ cfu/cm², with one establishment having a mean around 1 log₁₀ units higher than the other establishments. *E. coli* was detected on 22-31% of sheep carcasses, at average concentrations ranging from -0.07 to 0.1 log₁₀/cm² (0.85 – 1.2 cfu/cm²)

Primals

The fourth national baseline microbiological survey of Australian sheep meat was conducted in 2011 including for the first time samples from selected sheep meat primal cuts. Sheep and lamb legs (*n* = 613) and shoulders (*n* = 613) sampled at 12 meat processing establishments were found to have mean TVC (25°C) of 2.02 and 2.29 log₁₀ cfu/cm² respectively; *E. coli* was isolated from 42.9% of legs and 34.6% of shoulders with respective mean counts of -0.44 and -0.63 log₁₀ cfu/cm² on samples above the limit of detection. *E. coli* O157:H7 was isolated from 2/613 leg and 1/613 shoulder samples. *Salmonella* was isolated from 17/613 leg samples, 5/613 shoulders. *Campylobacter* spp. were isolated from 1/613 shoulder samples. *Listeria* spp. was isolated from 1/613 leg samples. Coagulase-positive staphylococci were isolated from 4.2%, and 5.2% of leg, shoulder and frozen boneless sheep meat samples respectively, with samples above the limit of detection having a mean log₁₀ count of -0.21 cfu/cm², and 0.34 cfu/cm² respectively.⁵⁴

A survey of a limited number of export establishments was conducted in 2017-2018.⁵⁵ The mean log₁₀ APC of primals from two sheep establishments was 1.89 log₁₀ cfu/cm². *E. coli* was detected on 28-38% of primals per establishment at an average concentration of -0.15 to -0.06 log₁₀/cm² (0.7 – 0.87 cfu/cm²).

Manufacturing (boneless meat)

The fourth national baseline microbiological survey of Australian sheep meat was conducted in 2011. For samples of frozen boneless sheep meat (*n* = 551) the mean TVC was 2.80 log₁₀ cfu/g and the mean count for the 12.5% of samples with detectable *E. coli* was 1.51 log₁₀ cfu/g. *Salmonella* was isolated from 17/551 samples of frozen boneless product. *Listeria* spp. were not detected in any of the frozen boneless product. Coagulase-positive staphylococci were isolated from 1.8% of samples, with samples above the limit of

⁵¹ Jolley, J., Kiermeier, A., Sumner, J., 2023. Microbiological Quality of Australian Beef, Sheep and Pork Carcasses, Cuts and Offals. *Foods* 12, 3832

⁵² Phillips, D., Jordan, D., Morris, S., Jenson, I., Sumner, J., 2006. Microbiological quality of Australian sheep meat in 2004. *Meat Science* 74, 261-266.

⁵³ Jolley, J., Kiermeier, A., Sumner, J., 2023. Microbiological Quality of Australian Beef, Sheep and Pork Carcasses, Cuts and Offals. *Foods* 12, 3832

⁵⁴ Phillips, D., Jordan, D., Morris, S., Jenson, I., Sumner, J., 2006. Microbiological quality of Australian sheep meat in 2004. *Meat Science* 74, 261-266.

⁵⁵ Jolley, J., Kiermeier, A., Sumner, J., 2023. Microbiological Quality of Australian Beef, Sheep and Pork Carcasses, Cuts and Offals. *Foods* 12, 3832

detection having a mean log₁₀ count of 1.66 cfu/g respectively. Extreme weather patterns may have led to elevated levels of indicator organisms (APC and *E. coli* prevalence) on frozen trim compared with earlier Australian baseline surveys.⁵⁶

A survey of a limited number of export establishments was conducted in 2017-2018.⁵⁷ Mean log₁₀ APCs at were 2.27 and 2.66 log₁₀ cfu/g, respectively. On excised samples of bulk meat, the prevalence of *E. coli* ranged from 15 to 24%, with the average concentrations ≥ 1.3 log₁₀ cfu/g (20 cfu/g).

6.9.4 Chicken meat

Carcase

In 2005-6 a survey was conducted at retail establishments in New South Wales and South Australia.⁵⁸ On whole chicken carcasses the mean total viable count was 4-4.5 log₁₀ CFU/cm², and *E. coli*, which was found in almost every sample averaged about 0.5 log₁₀ CFU/cm². The prevalence of *Salmonella* in whole birds in New South Wales ranged from 77.8% in butcher shops, 40% in specialty shops, and 29.7% in supermarkets. In general, *Salmonella* was present at low concentrations, <1 MPN/cm². *Campylobacter* was detected in >80% of samples usually at mean levels of around 1 log₁₀ CFU/cm².

Chicken pieces

In 2005-6 a survey was conducted at retail establishments in New South Wales and South Australia.⁵⁹ Mean log TVC CFU/cm² on chicken pieces in both states was about 5 log. 43% were positive for *Salmonella*. By far, the most prevalent serovar was *Salmonella* Sofia, which was isolated from 30% of samples. *Campylobacter* was detected in >80% of samples usually at mean levels <1 log₁₀ CFU/cm².

6.9.5 Other species

Data on microbiological hazards in other species should be collected where possible from the scientific literature, and also from processors of these meat species.

6.10 Raw meat – chemical hazards

The National Residue Survey (NRS)⁶⁰ supports Australia's primary producers and agricultural industries by confirming Australia's status as a producer of clean food and facilitating access to domestic and export markets.

6.10.1 Cattle

Around 5000 samples are collected for analysis each year. The results are compared with the Australian standards and where appropriate, relevant international standards (Table 13).

⁵⁶ Phillips, D., Tholath, S., Jenson, I., Sumner, J., 2013. Microbiological quality of Australian sheep meat in 2011. Food Control 31, 291-294.

⁵⁷ Jolley, J., Kiermeier, A., Sumner, J., 2023. Microbiological Quality of Australian Beef, Sheep and Pork Carcasses, Cuts and Offals. Foods 12, 3832

⁵⁸ Pointon, A., Sexton, M., Dowsett, P., Saputra, T., Kiermeier, A., Lorimer, M., Holds, G., Arnold, G., Davos, D., Combs, B., Fabiansson, S., Raven, G., McKenzie, H., Chapman, A., Sumner, J., 2008. A Baseline Survey of the Microbiological Quality of Chicken Portions and Carcasses at Retail in Two Australian States (2005 to 2006). J Food Prot 71, 1123-1134.

⁵⁹ Pointon, A., Sexton, M., Dowsett, P., Saputra, T., Kiermeier, A., Lorimer, M., Holds, G., Arnold, G., Davos, D., Combs, B., Fabiansson, S., Raven, G., McKenzie, H., Chapman, A., Sumner, J., 2008. A Baseline Survey of the Microbiological Quality of Chicken Portions and Carcasses at Retail in Two Australian States (2005 to 2006). J Food Prot 71, 1123-1134.

⁶⁰ National Residue Survey - DAFF (agriculture.gov.au)

The results highlight excellent compliance with Australian standards and demonstrate the strong commitment of the cattle industry to good agricultural practice.

6.10.2 Sheep

Each year 2500-3000 samples are collected for analysis. The results are compared with Australian standards and where relevant, international standards (Table 14).

The results highlight excellent compliance with Australian standards and demonstrate the strong commitment of the industry to good agricultural practice.

Table 13: Compliance rates for beef relative to Australian residue standards

Years	Samples collected	Compliance rates (%)
2015-16	4386	100
2016-17	4576	99.85
2017-18	4576	99.89
2018-19	4877	99.94
2019-20	5352	99.91
2020-21	5649	99.96

Table 14: Compliance rates for sheep meat relative to Australian residue standards

Years	Samples collected	Compliance rates (%)
2015-16	2539	99.68
2016-17	2590	99.96
2017-18	2591	99.69
2018-19	2589	99.73
2019-20	2682	99.78
2020-21	2905	99.86

6.10.3 Goat

Around 300 samples per year are collected for analysis. The results were compared with Australian standards and where relevant, international standards (Table 15).

The results highlight excellent compliance and demonstrate the strong commitment of the industry to good agricultural practice.

Table 15: Compliance rates for goat meat relative to Australian residue standards

Years	Samples collected	Compliance rates (%)
2015-16	155	98.7
2016-17	294	100.0
2017-18	277	98.92
2018-19	277	99.64
2019-20	273	97.80
2020-21	300	99.33

6.10.4 Pig

Around 1000 samples per year are collected for analysis. The results were compared with Australian standards and where relevant, international standards (Table 16).

The results highlight excellent compliance and demonstrate the strong commitment of the industry to good agricultural practice.

Table 16: Compliance rates for pork relative to Australian residue standards

Years	Samples collected	Compliance rates (%)
2017-18	1020	99.41
2018-19	1000	99.40
2019-20	1000	98.80
2020-21	1055	99.24
2021-22	1014	99.51
2022-23	1007	99.40

6.10.5 Chicken

The results of residue testing in chicken were compared with Australian standards and where relevant, international standards (Table 17).

Table 17: Compliance rates for chicken relative to Australian residue standards

Years	Samples collected	Compliance rates (%)
2017-18	300	100
2018-19	301	100
2019-20	300	100
2020-21	301	100
2021-22	301	100
2022-23	300	100

6.11 Salt (Sodium chloride)

Salt combines with water in the meat to lower the water activity of the food. Many bacteria, including *Salmonella* and pathogenic *E. coli*, cannot grow once their environment becomes too salty. Typically, 2.5-3.0% of salt is added to a batter for fermented sausages, and this is taken up only by the water in the meat (water is around 75% of the lean muscle). In a batter with 30% fat, water actually makes up around 50% by weight, which means that, if salt is added to the batter at 3%, its effective concentration in the water phase of the batter is 6%.

6.12 Smoke (liquid)

Liquid smoke is a product that has been produced from various types of wood, which are heated, and the smoke components dissolved in water. This solution can then be added to products in a 'cold smoking' process. (see Chapter 7). Phenols, carbonyl and other organic acids present in the smoke helps to reduce bacterial counts. Testing the concentration is recommended if smoke is used as a control for pathogens.

Liquid smokes used as a spray or a dip can reduce bacterial counts on the surface of products by creating a localised acidic layer.

6.13 Spices and spice extracts

Spices are essential for flavour and colour, and they also contain manganese which is essential for starter growth in UCFM production.

Spices may have extremely high bacterial counts and may contain spore forming bacteria, such as *C. perfringens*, and other pathogens such as *Salmonella*. This potential problem can be avoided by using irradiated or steam treated spices. Irradiation of herbs and spices is permitted and requires the product with an irradiated ingredient to be labelled. Steam treatment will not reduce the bacterial count as much as irradiation, but pathogens such as *Salmonella* are heat sensitive, and the product does not require labelling. Using high quality spices is important, especially for UCFM.

Due to the high cost of spices, they are sometimes found to be subject to various kinds of food fraud, where other ingredients, some of which may be illegal, are used. Purchasing from a reputable supplier is a good way to protect yourself.

Spice extracts can provide the flavour needed for a product and should have lower microbiological risk.

6.14 Starter cultures

Starter cultures are used commercially to ferment a range of foods, across several industries including but not limited to cheese, yogurt and wine manufacturing. In the smallgoods industry the major application is for fermented sausages and whole muscle dry curing. Starter cultures are selected bacteria that are specifically chosen to convert sugars in the meat into lactic acid as well as other functions such as improving flavour, colour and, in some instances, providing an added safety hurdle. The active strains providing pH decline belong to the group of bacteria we call Lactic Acid Bacteria, this may include *Lactobacillus*, *Pediococcus*, and *Lactococcus* species. In addition, selective *Staphylococcus* species, such as *S. carnosus*, *S. xylosus* and *S. vitulinus* as well as *Micrococcus varians* (now called *Kocuria varians*) may also be utilised. These help with nitrate and nitrite reactions. Selected yeasts and moulds may also be used with starter cultures, to provide flavour, aroma and targeted product outcomes.

6.14.1 Acid production

Fermentation must be initiated using a starter culture to produce lactic acid. Starter cultures vary in their ability to convert sugars to lactic acid. Some starters hardly make any lactic acid or make it only slowly, others have been specially selected as fast acid starters. The rate of acid production is important when you consider pH decline must be achieved to below 5.2 within 48 hours (from the commencement of fermentation at 15-16°C). Adjusting temperature (as mentioned below) will affect speed acid production, as this may be closer to optimum conditions for fermentation strains. In some instances, with temperature adjustment, and product diameter taken into consideration, target pH can be achieved between 8 and 48 hours.

The rate of acid production is affected by a number of factors:

- choice of starter and concentration
- temperature of fermentation
- salt content of batter
- type of sugar – complex carbohydrates (sucrose) take longer to be consumed by starter culture than monosaccharides (e.g. dextrose)
- temperature of raw materials.

As a rule, if you supply the starter with 0.5% sugar in the batter it will make enough lactic acid to reduce the pH by one unit (say from pH 6.2 to 5.2). Adjusting sugar content will change final pH achieved. As a rule, more sugar leads to lower final pH.

Temperature of fermentation has a big effect on the rate of acid production, and this will be increased if the starter is growing near its optimum temperature. For most cultures this range may start at 24°C and be as high as 42°C, dependant on the strain. A blend of strains can be used that will be able to work across a spectrum of processing parameters.

Starters are also affected by salt concentration. If salt is added at 3% on a batter with 30% fat, the starter will be growing in an environment of almost 6% salt which is stressful for some starters.

The intent of using starter culture is to provide a massive population of good bacteria to dominate and outcompete the wild microflora bacteria, such as spoilage bacteria and pathogens. A pouch of culture usually has about 1,000,000,000,000 (10^{12}) bacteria so, in a 100 kg batch, there are at least 10,000,000 (10^7)/g of batter. Once they become active, the numbers will further increase over the first 48 hours, providing targeted product outcomes such as pH decline. As well as lactic acid, starter cultures may also produce naturally occurring organic compounds such as bacteriocins, which reduce the growth of pathogens and spoilers.

6.14.2 Nitrate and nitrite reaction

Some starter cultures, such as *Staphylococcus*, are able to change nitrate to nitrite. This is valuable because nitrite gradually gets used up in the maturing period and the starter culture will keep it topped up by converting it from nitrate. Nitrite has two functions:

- Product quality – to enhance the typical red colour of UCFM
- Product safety – preventing *C. botulinum* spores from growing

For this reason, the *Food Standards Code* allows up to 500 mg/kg of a combination of nitrate and nitrite in UCFM of which nitrite must be no more than 125 mg/kg at the time of consumption.

This reaction is specifically important for colour development and colour stability in salami, but also in whole muscle dry curing, where colour is an important factor.

Whole muscle products do not rely on the fast pH decline, but their safety, quality and consistency can be assisted by use of starter cultures to provide a dominant bacteria population producing optimum colour and flavour development as well as potential additional safety hurdles.

6.14.3 Flavour and aroma production

During fermentation and maturation, the starter culture converts proteins and fats into chemicals which improve the flavour and aroma of the product. This happens when the product is maturing and when the water activity is falling. At this time the environment is becoming less favourable for all except the most salt-tolerant bacteria.

6.14.4 Selecting a starter culture

Select a starter culture which suits the type of sausage you are making plus a fermenting temperature that matches the preferences of your starters.

Purchase starter cultures from a reputable supplier, as product integrity, starter culture quality, cell count per pouch, and consistency are critical to the outcome of finished products.

Handling and use of starter culture is a critical element in safe production of fermented foods. Storage conditions are critical - always store cultures according to the label directions, don't use them past their expiry date, and add them at the recommended level.

6.15 Sugars

Simple sugars (lactose, dextrose) may be added in small amounts to the batter for UCFM to help the fermentation process.

Sugar addition will reduce the water activity of the product (but not by as much as adding the equal weight of salt).

In the ingredient declaration the name of the sugar must be used unless referring to raw sugar, white sugar, etc.

6.16 Sulphites / Sulphur dioxide

The *Food Standards Code* allows a number of sulphite additives: sulphur dioxide (220), sodium sulphite (221), sodium bisulphite (222), sodium metabisulphite (223), potassium metabisulphite (224), potassium sulphite (225) and potassium bisulphite (228).

Sulphites are allowed in comminuted meat, poultry and game products (for example, Devon, Chorizo, Salami, Fresh Sausage).

The Maximum Permitted Level (MPL) is 500 mg/kg in product, measured as sulphur dioxide.

Sulphites are effective in inhibiting the growth of yeasts and moulds, and especially bacteria, because they result in sulphurous acid being formed when dissolved in water. Sulphites also help to keep the fresh colour and appearance of red meat.

Some sulphite-sensitive people, many of whom also have asthma, may react to sulphites with allergy-like symptoms. Sulphites in food are an issue with some consumers and FSANZ provide information for consumers.⁶¹

⁶¹ Sulphites | Food Standards Australia New Zealand

7 Processes

There are many different processes involved in the manufacture of a wide range of smallgoods. In this chapter we will discuss the processes that are important to get right to produce a safe product. We will also discuss ways to reduce the variability in your production. Variability can make it more difficult to produce safe products (e.g. because concentrations of salt, or nitrite, may vary between one batch and the next). Reducing variability can also have a significant benefit to your profitability.

7.1 Receiving and temperature control of raw meat

A range of ingredients are used in smallgoods operations, including chilled and frozen pork, beef, sheep and poultry meat, offal, fat, and a variety of other ingredients. When raw materials and ingredients are received, they need to be inspected for wholesomeness, and specifications such as temperature must be checked.

The *Australian Standard* specifies that raw meats must be held at no warmer than 7°C (carcasses) and 5°C (pieces of meat). These temperatures were set when the *Australian Standard* was first developed in the mid-1990s and are based on the fact that target pathogens (*Salmonella*, *E. coli* and *S. aureus*) cannot grow at these temperatures (see Chapter 9.1 for more information on these target bacteria). For pieces of meat the *Australian Standard* was set to align with the *Food Standards Code* which required retail storage no warmer than 5°C. These temperatures are regulatory requirements and there is no tolerance for temperatures warmer than those stipulated, except under an approved program.

Some pathogens will not grow at 5°C (e.g. *E. coli*) and even if above the limit for some time, may still be considered safe, especially if the meat is being used for a cooked product, or a process that will rapidly stop the growth or inactivate pathogens. The University of Wisconsin has developed guidance for raw product that is held outside of temperature control (refrigeration). Depending on the process, meat may warm up and then cool to a safe temperature more than once, or temperature may fluctuate across a series of steps before meat returns to temperature control (refrigeration) or the cooking step begins. In all cases, product is intended to be fully cooked by the consumer or processor.⁶²

All incoming meat must be labelled, and records must be kept identifying the source of meat, the date it was processed/packed etc., so that any lot which causes a problem can be identified and action taken.

Returned goods should be clearly identified and stored in a designated area.

Once accepted, raw materials should be:

- moved to storage or directed to processing as soon as possible
- maintained at right temperatures for safety and quality
- protected against contamination or damage
- stored in their own, or in clean, containers on racks or shelves to ensure no contact with the floor
- used on a FIFO basis.

Here's the problem. It's a 40°C day, you're the final delivery, and meat arrives warmer than allowed in the *Australian Standard*. You have the choice to reject it, and you'll probably consider how much warmer the meat is than the CL and how long it's been there. Carcasses

⁶² University of Wisconsin-Madison. Raw Products Critical Limits table. Raw Product Critical Limit Tables (wisc.edu) Center for Meat Process Validation - THERM Calculator (wisc.edu)

Tompkin, R.B. 1996. The Significance of time-temperature to growth of foodborne pathogens during refrigeration at 40-50°F timetemp.doc (wisc.edu)

may be easy to cool because it's the surface temperature that's important, but carton meat may be very difficult to cool – and you may decide to reject it. If the carton meat was not recently boned or the temperature is well over 7°C, there is a strong possibility that temperature abuse has occurred during transit and the meat should be isolated and returned.

But if you plan to use it today there are sensible things you can do:

- Record the meat temperature and place it in front of the blowers in the chill room until it conforms with the Standard
- Tag it for use only for cooked products on the same day
- Check the University of Wisconsin CLs table to see if the product is good for cooked product 62.

Remember that there are requirements for temperature reduction of meat after slaughter via the Refrigeration Index (RI) which is mentioned in the *Australian Standard*, and the boning room should be tracking the RI until it reaches 5°C or lower– so you might want to know what the RI was before dispatch to compare it with the limits in the *Australian Standard*. If you accept warm meat, you are taking over the responsibility for ensuring that the meat reaches the correct temperature in the allowed time.

7.2 Receiving and storing raw materials

A range of ingredients and packaging materials are used in smallgoods operations.

When raw materials and ingredients are received, they need to be inspected by a trained person for wholesomeness, and that it complies with specifications.

Packaging materials must be safe for use. You should buy them from a reputable source. They should arrive at your premises in sealed cartons or shrink wrap covering for protection and then store them in a dust and vermin proof room, on racks above the floor so that it is easy to clean underneath.

Records must be kept so that any lot which causes a problem can be found. It is part of your systems for traceability.

Returned goods should be clearly identified and stored in a designated area.

Once accepted, raw materials should be:

- moved to storage or directed to processing as soon as possible
- maintained at right temperatures for safety and quality
- protected against contamination or damage
- stored in their own, or in clean, containers on racks or shelves to ensure no contact with the floor
- used on a FIFO basis.

7.3 Formulation and assembly of raw materials

There is a good reason for regulating the use of ingredients and additives within the smallgoods industry. Many chemicals such as nitrite and sulphite are toxic or poisonous when too much is ingested. The quantity of ingredients added is crucial to the health of consumers. For example, if sodium nitrite and sodium chloride are mixed up and nitrite is added at the amount meant for sodium chloride, the dose could be lethal.

A fail-safe system of batching up ingredients and additives is needed. Consider buying a premix with the amount you need pre-weighed so that the entire bag is added to a batch. Or set up a specific area where one or two trained people follow carefully designed procedures to make sure that everything is weighed out and labelled correctly.

Consistency is an important part of process control. Some elements that need to be considered when making batches of ingredients are listed in Table 18.

Table 18: Reducing variability in formulation

Stage	Check	Because
Meat	Variability in size of legs or pieces	If cook cycles are based on the core temperature of the largest piece, smaller pieces will have a lower moisture content
	Fat content	Variable fat content means difference in moisture content of product, and this affects concentration of salt and nitrite
Dry goods	Premix – or do you weigh individual ingredients? Scales or scoop? Are your scales accurate enough? How many people do this on a regular basis? Do you all do it the same way? Is there a documented procedure?	Scoop or 'up to here' on a bucket can give variability based on the person doing the measuring. Some larger scales are ± 200 g or more. Floor scales are even less accurate.
	How is nitrite or sulphite incorporated? Use in strict FIFO and within use-by	If nitrite or sulphite is in the blend with the spices, it can degrade rapidly - shelf life can be as short as three months. Nitrite blended with salt/sugars alone is much more stable. Only use ingredients within their use-by date.

7.4 Tempering and thawing

The *Australian Standard* defines tempering as warming frozen meat to no warmer than -2°C, while thawing is warming to a temperature warmer than -2°C.

Tempering of frozen meat in the chiller is a GMP which prevents growth of pathogenic bacteria and is important for getting the correct particle size in the bowl chopper.

Thawing may be carried out in air or water. Thawing in air is normally carried out by removing the cartons and putting the plastic-wrapped meat on trays. When thawing in a water bath, the water must be flowing, potable, no warmer than 10°C and not recycled unless approved by the controlling authority. All product should be fully immersed.

Some alternate methods for tempering and thawing have been validated.⁶³

Tempering and thawing are also important in preventing plastic ripping from the liner and contaminating the batch. Polyentrapment happens when plastic film becomes 'trapped' between pieces of meat as it is packed into the plastic liner. After freezing, the film becomes tightly wedged in the block of meat. If the liner breaks, small pieces of plastic may spread through the batch and become hazardous.

⁶³ University of Wisconsin – Madison. Microsoft Word - SOP for Tempering.docx (wisc.edu)

The hazard is reduced by using thicker gauge liners which are less likely to tear. If the liners are blue, it makes the hazard easier to see. During batching of raw meat, if the bag tears it should be set aside in the chiller for 24 hours and, after carefully removing all plastic, used as thawed meat.

7.5 Massaging, tumbling, injecting, and curing

These processes are best done in a refrigerated room so the product temperature can be maintained below 5°C and as close to 1-2°C as possible. You can achieve this by:

- chilling the curing brine
- chilling the final mixture
- working in a cool room
- jacket-cooling the equipment
- very carefully adding liquid nitrogen or carbon dioxide.

Salt, sugar, and other ingredients combine with water in the meat to form brine and this lowers the water activity of the food. There are usually two stages to brining: injection and massaging. Injecting salt at a concentration of 3-4% will prevent the growth of *Salmonella* and *E. coli* and acts in tandem with the chill temperature of the muscle meats and the brine. Additives which may be included in the cure mixture are listed in the *Food Standards Code* (Standard 1.3.1 and Schedule 15) (see Chapter 6. Ingredients).

Fresh brine solutions should be used for every batch. Curing solutions used for injection should be checked for salinity or dissolved solids (Brix) and nitrite concentration and should not be recycled after the first day of use or between batches.

Consistency is an important part of process control. Some elements that need to be considered when making batches of brine and injecting are listed in Table 19.

Brine injector machines should be cleaned and sanitised after each day's operation and needles cleaned regularly between batches. Immersion-curing equipment should be cleaned and sanitised between batches. The weight of meat into, and out of, the brining process should be checked to make sure that the right amount of brine has been added.

Massaging helps the brine components (e.g. sodium chloride and nitrite) to spread uniformly through the muscles. Salt also helps to bind the pieces of meat into the ham shape within the netting.

Weights of meat pieces before and after brining should be checked to make sure that the correct volume of brine has been injected (and therefore the correct concentration of salt and nitrite has been achieved).

Table 19: reducing variability in brines

Stage	Check	Because
Brine make up	Brine temperature	Brine must be cold before injection to maintain product temperature and to minimise loss of nitrite and some other ingredients.
	How is water measured - weight or volumetric? How many people do this on a regular basis? Do you all do it the same way? Is there a documented procedure?	Make up using volume can be inaccurate unless well controlled. Variability in the brine concentration leads to variation in antimicrobial concentration.
	Are dry goods used in accordance with suppliers' instructions?	Are the nitrite and salt levels as specified?

Stage	Check	Because
	Are the dry goods fully dissolved in the brine before use?	Undissolved dry goods means that salt and nitrite levels will be variable
Filling / hanging	Brine temperature	Brine must be cold before injection to maintain product temperature and to minimise loss of nitrite

Nitrite is added to control the growth of *C. botulinum* in the cooked product by preventing spores from growing (legal upper limit is 125 mg/kg). *Clostridium* species are anaerobic and can only grow in reduced oxygen environments. These conditions exist in the deep tissues of meat muscle. If the bacterium is carried into the deep muscle on the injectors or in the curing solution it has the potential to grow.

7.6 Cutting, mincing and grinding

In large operations this equipment is used more or less constantly during the working day. Heat is generated and because some material may be left in 'dead spots', the microbial count may increase. For this reason, ensure cutting equipment is sharp to minimise heating and, at the end of each working day, all material in the screw and plates of the grinder must be discarded (or treated in a way that makes it safe) as it can 'seed' tomorrow's batch with potentially dangerous bacteria. Equipment should also be cleaned and sanitised between batches and at the end of each day's production.

7.7 Stuffing / filling

Products which are either sold uncooked (e.g. fresh sausage) or cooked (e.g. luncheon meat) should be hygienically filled into food grade casings. If casings are pre-soaked before filling, they must be soaked in potable water and the water changed regularly. Filling the casing by using a vacuum filler helps to remove air (oxygen) which would otherwise support the growth of undesirable bacteria.

7.8 Smoking

Smoking is important for flavour and may be applied hot or cold. Smoke has chemicals which inhibit the growth of bacteria and moulds and is important in preventing mould growth.

Hot smoking is usually applied to meat products prior to cooking or blanching. Mould-ripened salamis are not usually smoked. Product in the smokehouse should be evenly spaced to help air circulation and enhance even smoking. Temperatures can be from about 50°C to 75–80°C, and the relative humidity must be high to avoid dehydration. With this procedure, the smoking time is reduced to hours.

Cold smoking involves generating the smoke separately to applying it to product which is usually done at temperatures between 20 and 30°C. The duration of this process can be days or weeks because the smoke used is poor in aromatic and preserving components.

Smoke can also be 'added' as a liquid flavour product.

7.9 Blanching

For several reasons, the blanching of fresh sausages is becoming increasingly important for the food service trade.

- Blanching pasteurises the product so that a high proportion of spoilage and pathogenic bacteria are killed. Food safety and shelf life are improved.
- Blanched sausages can be vacuum packed, which protects them and further extends the shelf life.

Blanching is done either by hanging the sausage links in a steam cabinet or by immersing or covering them in water at 75-80°C for a short time. Both these processes give a surface heat treatment and set the core of the sausage.

Blanching does not cook the sausage. Blanched sausage cannot be labelled or marketed as cooked sausage. The blanching process is not a CCP, and the final product still requires thorough cooking to ensure safety.

Cooling of blanched sausage is a CCP to prevent outgrowth of *C. perfringens* spores. The cooling regime in the *Australian Standard* sets temperature-time targets for cooling of uncured products such as fresh sausage. The most important range is between 50° and 30°C when *C. perfringens* grows extremely rapidly.

7.10 Heat treatment

The term 'heat treatment' is usually used for a time and temperature of processing that is less than cooking (see definition in following section). The *Food Standards Code* requires UCFM that are heated for 55°C for 20 minutes or equivalent at a higher temperature, to be labelled as 'heat treated' (Standard 1.6.2—3 and Standard 2.2.1—9). It is likely that the heat treatment option was added to the *Food Standards Code* in the late 1990s or early 2000s when *E. coli* was a major concern, and the *Code* was trying to provide options for manufacture of a safe product.

Instantaneously heating a fermented sausage to 55°C for 20 minutes would be expected to achieve a 2 log reduction in *E. coli*, though there are significant differences in the temperature sensitivity of *E. coli* strains.

The available scientific data shows that if the temperature is increased by 6°C, the inactivation of *E. coli* (and most other bacteria) is 10 times faster. In other words, for a 6°C increase in heating temperature, the required treatment time (at the centre of the sausage) would be one-tenth as long. So, at 61°C, the equivalent time as at 55°C would be 2 minutes; at 67°C, it would be 12 seconds, and so on.

The death of *E. coli* at temperatures of 55°C and above are incorporated into the MLA *E. coli* Predictive tool (see Chapter 9.3) for evaluating inactivation of *E. coli* in UCFM.

Some guidance on "low temperature" heating steps are available but these documents should be used only for their insights into the science because they have been written to suit a different regulatory environment.⁶⁴

7.11 Cooking

For each cooked product, a suitable heat-processing step must be applied to kill target pathogenic vegetative cells (a food safety requirement, and additionally there is a biosecurity requirement when cooking imported pork). Heat processing is a time/temperature relationship dependent on the product composition and size, with the slowest heating point (usually at the centre of the product) in the largest piece measured and recorded.

- Smokehouses, steam cookers and water cookers should be tuned and adjusted so the cold spots are known and taken into account when loading.
- Thermometers, humidity gauges and other measuring and controlling devices need to be regularly calibrated to make sure the equipment is working effectively.
- If a smokehouse or steam cooker is overloaded or partially loaded, then its performance may change. Adjustments to cooking cycles may need to be made for partially loaded batches. Products should be evenly spaced, and products should not touch each other; product may only take up 50% of the available space.

⁶⁴ FSIS-GD-2023-0002: FSIS Ready-to-Eat Fermented, Salt-Cured, and Dried Products Guideline (usda.gov). Appendix 8: Critical Operational Parameters for a Low-Temperature Heat Step

- If product is cooked in an open hot water bath, then the product should be held at least 10cm below the water surface with equipment such as a metal screen. Also, don't overload the water bath; not more than half the volume should be meat.

Cooking is a CCP which eliminates pathogens such as *Salmonella*, pathogenic *E. coli* and *L. monocytogenes*. Bringing the thermal centre of the meat to at least 65°C for a minimum of 10 minutes (or an equivalent temperature:time cook as set out in Table 20 is sufficient to give a 6 log reduction (that is, 1 in a million will survive) of *L. monocytogenes*. *Salmonella* and *E. coli* are more temperature sensitive. Some regulations are prescriptive about time and temperature, and some controlling authorities want to approve any alternative process before implementation. When cooking imported pork, you also need to consider the biosecurity requirements for cooking. The longer of the food safety and biosecurity cooking times should be used at the selected temperature. Finding the thermal centre (the point that heats most slowly) is critical. It is usually in the middle of the largest muscle.

To monitor the process, ensure the temperature probe is calibrated and located at the slowest heating point of the product. Probes must be placed into the largest sized product to ensure thorough cooking of the entire oven load, and the product needs to be checked with two probes at two different locations at the end of the cooking time. If the correct temperature has not been reached, cooking must be continued until the desired temperature is achieved.

Table 20: Holding times at product core temperature required to deliver 6 log reductions in *L. monocytogenes* counts (domestic and imported product) and cooking requirements to meet biosecurity requirements

Temperature (°C)	6 log <i>L. monocytogenes</i> reduction - Domestic and imported meat Time (minutes:seconds) ⁶⁵	Imported Pork Time (minutes) ⁶⁶
55	200	
56	146	60
57	108	55
58	79	50
59	58	45
60	43:34	40
61	32:03	35
62	23:34	30
63	17:21	25
64	12:45	22
65	9:23	20
66	6:54	17
67	5:05	15
68	3:44	13
69	2:45	12

⁶⁵ Gaze, J.E., Brown, G.D., Gaskell, D.E., Banks, J.G., 1989. Heat resistance of *Listeria monocytogenes* in homogenates of chicken, beef steak and carrot. *Food Microbiology* 6, 251-259.

Warne, D (2011) Low temperature cooking of meats. Report A.MFS.0248. North Sydney: Meat & Livestock Australia.

⁶⁶ [Biosecurity] Approved Arrangements: 3.2 – imported pig meat processing version 6.0 8 March 2024

Temperature (°C)	6 log <i>L. monocytogenes</i> reduction - Domestic and imported meat Time (minutes:seconds) ⁶⁵	Imported Pork Time (minutes) ⁶⁶
70	2:01	11
71	1:29	
72	1:06	
73	0:48	
74	0:36	
75	0:26	
76	0:19	
77	0:14	
78	0:10	
79	0:08	
80	0:05	
81	0:04	
82	0:03	
83	0:02	
84	0:02	
85	0:01	

6 D or 6 log reduction means reducing the count of the target microorganism from 1,000,000 to 1

If products are cooked in a non-moisture-proof casing, there will be weight loss. Consistency is an important part of process control. Some elements that need to be considered to give consistent weight loss, and therefore consistent concentrations of moisture, protein, salt and nitrite in product are listed in Table 21.

Table 21: Reducing variability in cooking

Stage	Check	Because
Cooking (non-moisture proof casing)	Is the cooker humidity controlled?	Controlled humidity will help reduce variability in weight loss during cook.
	Do you make smoked products?	Smoking is often the driest part of the cook cycle.
	How is time controlled?	Product surface has to be dry before smoking – or smoke won't adhere.
	Manual or part of a program?	If this is manually done, could introduce more variability.
	Is there much variability in length of cook for this product?	Longer in the cooker means more weight lost during cook. Variability in weight loss means variability in salt, nitrite.
	Do you know the cook loss or yield?	Moisture loss during cooking results in concentration of ingredients.

7.12 Cooling

The *Australian Standard* provides criteria for judging the safety of the cooling process (5.10.1). If the Standard can't be met, you'll need to supply your controlling authority with an alternative process which provides an equivalent outcome to the standard (7.10.2)

7.12.1 Cooling according to the *Australian Standard*

Smallgoods must be cooled correctly to minimise the growth of spores of pathogens, especially *C. perfringens*, which are capable of surviving the cooking process. Smallgoods can be cooled by:

- water showers in the oven or outside the oven
- water or ice water baths
- refrigerated air flow
- refrigerated salt brines.

Some cooling methods, for example, using water, may introduce hazards, such as *L. monocytogenes*, to the product, so this possibility needs to be recognised in the HACCP plan.

Cooling under the *Australian Standard* is a two-stage process (Table 22). The slowest cooling point is important because, if *C. perfringens* is at that point, it has the best chance to grow to a dangerous level.

To monitor the process, ensure the temperature probe is calibrated and located at the slowest cooling point of the product. Probes must be placed into the largest sized product to ensure effective cooling of the entire batch, and the product needs to be checked with two probes at two different locations. If the correct temperature has not been reached in the allowed time, cooling (and monitoring) must be continued until the desired temperature is achieved, and a decision made about how to deal with this non-conforming product.

Table 22: Two stage cooling of cooked meats

Temperature	Maximum time (hours)	
	Uncured products	Cured products*
52 °C to 12 °C	6	7.5
To below 5 °C	Within 24 hours of the completion of cooking	

* Cured products have a minimum 2.5% salt on water phase and 100ppm nitrite in-going.

When cooked products are chilled in non-moisture proof casing, chilling time affects moisture loss. Consistency is an important part of process control. Some elements that need to be considered to give consistent weight loss, and therefore consistent concentrations of moisture, protein, salt and nitrite in finished product are listed in Table 23.

Table 23: Reducing variability during cooling

	Check	Because
Chilling (non-moisture proof casing)	How much time does the product spend in the chiller before packing?	Extended time in chiller (if not vacuum packed) leads to loss of moisture and potentially higher bacterial load and shorter shelf life.

7.12.2 An alternative arrangement for cooling

If it is difficult to cool large, cured meat cuts within the first stage in the *Australian Standard* (from 52°C to 12°C within 7.5 hours) then an alternative arrangement is required for the control of *C. perfringens*.

The alternative arrangement is based on temperature and time which allows an increase in *C. perfringens*, but within safe levels. This bacterium can produce a toxin that causes diarrhea and is considered the main public health risk to consumers of cooked, processed meats.

An alternative arrangement for submission to your controlling authority should present information on:

1. Ingredients which control growth of the bacterium during cooling
2. The elements of your alternative arrangement
3. Prediction of the growth of *C. perfringens* while product cools
4. Risk of illness from consuming cured, cooked meats which have undergone your alternative arrangement.

Chapter 9.4 discusses using predictive modelling to develop (validate) an alternative cooling arrangement to control the growth of *C. perfringens*

7.13 Fermenting

Starter culture plays a crucial role in salami production by producing lactic acid, to lower the pH of the sausage to 5.2 or below within 48 hours of fermentation.

Starter culture begins converting sugar (e.g. dextrose) to lactic acid once the sausage warms up to 15-16°C. In wide-diameter sausages, it may take up to 12 hours for the starter cultures to become active after filling. Some culture blends may also include strains that contribute to colour, flavour and additional safety hurdles.

Salt in meat batter inhibits the growth of *Salmonella* and pathogenic *E. coli*, especially when the sausage temperature exceeds 7°C.

S. aureus, which doesn't thrive under anaerobic and low-temperature conditions, is also controlled through acidification within 48 hours.

Manufacturers also rely on water loss and targeted water activity during maturation as part of salami preservation. This weight loss can be dependent on the salami style being produced.

According to the *Food Standards Code* (Standard 4.2.3 – Production and Processing), using a starter culture for meat fermentation is mandatory. Manufacturers must adhere to specific instructions related to the starter culture:

- Suitability for the product (especially the optimal temperature).
- Storage and shelf life.
- Rate of addition.
- Reconstitution methods.
- Quantity and type of fermentable sugar for aiding fermentation.
- Temperature and relative humidity during fermentation.
- Expected final pH and the time it should be achieved.

Detailed records of the fermentation process must be kept, including pH measurements (at least the final pH and pH at 48 hours) and temperature monitoring.

Achieving a pH of 5.2 or lower within 48 hours is considered effective protection against pathogen (*S. aureus*) growth. This time and temperature combination is critical for successful fermentation.

Case hardening can begin during the fermentation (see discussion in 7.14 Maturing).

7.14 Maturing

In UCFM production, fermented sausages are matured by holding in rooms with low relative humidity and low air movement. Maturation reduces the water activity and, together with the pH fall in fermentation, prevents the growth of the target bacteria, *Salmonella* and pathogenic *E. coli*. Once these bacteria stop growing (probably in the fermentation phase), they die – faster at higher temperatures, and slower at low temperatures (*E. coli* predictor) – so the time and temperature of maturation are important factors to determine the safety of the product and compliance with the *Food Standards Code*.

Moisture loss further reduces the water activity and, because drying is fastest at the surface, a_w will vary across the diameter of the sausage. The longer the maturing stage, the greater the weight loss.

It is important to keep the relative humidity within a specified range, especially in the early stages of fermentation and maturing. If the relative humidity in the chamber is decreased too fast, rapid drying will occur, which can result in “case hardening”. Case hardening is when the surfaces become too dry while there is still a high moisture content inside the sausage. Dry surfaces inhibit the further evaporation of moisture, which may result in products not uniformly dried and in microbiological spoilage or unpredictable behaviour of pathogens in the areas where the moisture content stays too high.

Similarly, sausages of different diameters will dry at different rates and require different lengths of time to achieve the required water activity (weight loss).

7.15 Drying

Dried products include semi-dry and dry salamis, slow cured hams and dried meats such as jerky. The key is to achieve drying wherever there are bacteria which could spoil or make the product unsafe. These bacteria may be on the surface (jerky) or in the centre (salami) and GMPs must be effective in both locations. Dried meat (without curing) must achieve a water activity of no more than 0.85 (*Australian Standard*).

The rate and amount of drying depends on factors such as:

- air velocity (rate of air flow over the product)
- difference between the air moisture (relative humidity of the air) and product moisture (relative humidity of the food). The relative humidity of the food is usually described as water activity
- moisture diffusion within the product. As pH more water diffuses from the core to the marginal layer and increases the evaporation on the surface. If drying occurs too quickly the pores at the surface may become clogged with sugars and salts before the centre is really dry and case hardening (dry edge) can occur
- thickness and diameter
- time
- temperature.

7.16 Slicing

These operations rely on GMPs and SSOPs to prevent or minimise recontamination of the cooked product with spoilage and pathogenic microorganisms. See Chapter 3 for advice about cleaning and control of *Listeria* in the plant. RTE meats like hams, luncheon meats, salamis, pâtés and roasts are susceptible to recontamination after processing. Slicing and packing requires a high standard of hygiene to prevent recontamination with *L. monocytogenes*. *L. monocytogenes* grows under refrigeration conditions and can tolerate the salt content of smallgoods. So, in a long shelf life product such as sliced ham, it builds up to levels which can cause serious illness in consumers who are pregnant (the unborn baby could die), the very young,

the very old and those who are immunocompromised or whose immune systems are low. *L. monocytogenes* is able to colonise food plants and is very hard to remove from conveyor belts and rollers, drains, floors and equipment. There are a number of ways in which contamination with *L. monocytogenes* can be minimised.

In large plants this *Listeria* contamination can be minimised by:

- Separating cooked and raw products. This includes during chilled storage, and slicing and packing.
- Having dedicated equipment for handling cooked products.
- Conducting an end-of-day clean down which includes sanitising cooked product areas.
- Cleaning-as-you-go through the working day.
- Using handling procedures that prevent hands coming into contact with cooked products.
- Maintaining good personal hygiene.
- Keeping staff in their own sections and providing staff from each area (raw and cooked) with different amenities and different colour uniforms.
- Having staff enter through an airlock to put on their uniforms, boots, hats and to wash hands.
- Cooked products may be handled in clean rooms with filtered air and positive air pressure in slicing and packing rooms.
- Linking slicing/packing rooms with the dispatch area through a tiny hatch.
- Applying treatments to the surfaces of products just before slicing and packing to reduce levels of contamination or prevent the growth of *L. monocytogenes* if it contaminates product at this stage (see 7.17.1).
- Pasteurising products in-pack (see 7.17.2).

Steps must be taken to break the *Listeria* cycle in the plant environment (see Chapter 3.4).

For smaller operations and butcher shops, which don't have dedicated processing areas, recontamination can be minimised by:

- slicing and packing first thing, when there is no raw product around
- cleaning the room and equipment before packing starts
- changing into clean clothing
- giving the cleaned slicer and benches a spray with a 'no rinse' sanitiser and dry it before starting
- spraying all working surfaces with an antimicrobial
- spraying the outside of each product with an antimicrobial
- during the working day, keep slicing and packing area clean of packaging and food build up
- avoiding hand contact with sliced meats
- training staff in how and when they must wash their hands and change gloves.

Further information on the control of *L. monocytogenes* can be found in Chapter 3.4.

7.17 Packing

Packing materials, gases, machines and formats are a huge area of interests in product and process development, which also has an impact on product shelf life and safety.

Packaging fulfils several functions:

- holding the product
- protection of the product from hazards and preserving its characteristics for as long as possible
- promoting sales of the product.

The latter function is seen very well in the wide range of attractive forms of packaging that have become available for smallgoods products in recent years. The second function is of greatest concern to product safety. Packaging protects meat and meat products during processing, storage and distribution from physical, chemical and biological hazards. Packaging is a barrier against contamination of meat, although the inhibition of the initial contaminant bacteria cannot rely only on packaging. To reduce growth of pathogens or spoilage bacteria, packaging has to be associated with other treatments, which limit the growth of microorganisms.

In addition to surface treatments (see below) the atmosphere (gas) that is in the pack is important to the way that the pack affects the growth of pathogens.

Aerobic Packaging – packaging in air will protect product from further contamination but will have little impact on the potential growth of pathogens or spoilage bacteria. The shelf life of product is likely to only be a few days unless the product is shelf stable.

MAP – results in a reducing of the oxygen concentration in the package by replacement of air with a gas or a mixture of gases. Carbon dioxide and nitrogen are often chosen. Nitrogen is added to replace oxygen and inhibit the growth of aerobic bacteria (those that like to grow in the presence of oxygen). Carbon dioxide has a major effect by making aerobic bacteria adjust to the new environment (we call this the lag phase) and slowing their growth. MAP can have an effect on the growth of pathogens such as *L. monocytogenes*, however, gaseous atmosphere created may select for other bacteria which can spoil the product. Oxygen, nitrogen and carbon dioxide are used in different combinations and proportions depending on the product, on the bacteria and moulds to be inhibited and on the colour stability requirements.

VP - consists in the elimination of air from the pack. The product in a specific bag, is placed in a vacuum chamber equipped with a vacuum pump for the air extraction 75–85%, or a maximum of 90%, is eliminated from the pack. The main advantage of this technique is an increase in product shelf-life.

7.17.1 Surface treatment

The weak point in processing RTE meats is the stage between when products come out of the cookers and when they are placed in the final pack. During this period, products may be contaminated by *Listeria* from:

- aerosols from air cooling units, drains or floors
- contact with working surfaces
- contamination on equipment such as slicers, dicers, shredders
- the hands or gloves of operators.

Contamination by *Listeria* at this stage is confined to the surface and treatments can be applied in two ways:

- as surface applications
- incorporated into packaging material.

The most commonly used treatments are antimicrobial sprays with lactic acid and acetic acid at a concentration of 2.5%. One product on the market has a mixture of organic acids plus phenols, with smoke flavouring an option as a surface spray. Protective cultures are becoming more widely used. All surfaces are sprayed just before placing product in the vacuum bag and sealing. Under vacuum the antimicrobial is spread in a thin layer over the entire meat surface and becomes incorporated into the product. These treatments should be listed as ingredients in the product.

Packaging film impregnated with nisin has proved effective in controlling *Listeria* in RTE meats.

In summary, surface application to whole muscle pieces are an effective way of controlling *Listeria* growth over the shelf life. As with using antimicrobials in the formulation, care must be taken if these treatments are used to extend the shelf life since suppression of the pathogen needs to be proved over whole of the (new) shelf life.

7.17.2 Pasteurising product in-pack

Some smallgoods are retailed in the package in which they were cooked e.g. liverwursts and some pâtés. This process reduces the likelihood of *Listeria* contamination to tiny proportions though a leaking pack offers opportunity for contamination. To obtain a similar level of confidence, hot pasteurisation in the final pack can be used.

In hot pasteurising, sufficient heat must be applied to the slowest heating point in a pack to produce a 2-log reduction in *Listeria*. A 2-log reduction is suggested because the level of contamination during the slicing and/or packaging of an already cooked product is expected to be small and this level of reduction will reduce the risk significantly. In a risk assessment, a postprocessing inactivation treatment that achieved a 1–2-log kill, resulted in a 150-fold decrease in predicted annual cases of listeriosis attributable to RTE smallgoods.⁶⁷ In addition to reducing the risk of contamination and illness, your controlling authority may reduce the requirements for testing for the presence of *L. monocytogenes* in product or the environment.

A 2-log reduction in *Listeria* for in-pack pasteurisation will require the surface to be at temperature for one-third of the time that the centre of the product is required to be at the same temperature for a 6-log reduction in a cooking process (See Table 20).

The inactivation of *Listeria* may be achieved by various means:

- immersion in hot water, maintained by steam
- microwave heating
- integrated steam pasteurising and packing.

A common method is for final packs of product to be immersed in a hot water bath with steam injected to quickly increase the water temperature to 90-95°C. Depending on the product and packaging format, immersion for around three minutes at >90°C is required to assure a 2-log reduction in *Listeria*.

There are several practical issues:

- Restoring pasteurising temperatures after immersing a batch of chilled product leads to extended periods in the water bath, even if steam is injected.
- Purge results in weight loss plus an unsightly appearance.
- Heavier duty packaging film needed to withstand heat treatment adds to cost.
- The process cannot be used for MAP because the upper surface of product will receive no direct heat from the medium.

The process is only effective when product can receive heat evenly at all surfaces. So, frankfurters packed in scalloped packs will receive even heating all over the surface while a pack of interleaved slices will have a slower heating point at the centre. There are suggestions that only whole primal pieces may be suitable for in-pack pasteurisation.

⁶⁷ Ross, T., Rasmussen, S., Sumner, J., 2009. Using a quantitative risk assessment to mitigate risk of *Listeria monocytogenes* in ready-to-eat meats in Australia. *Food Control* 20, 1058-1062.

Careful work must be done to show that all surfaces of the product are heated to the desired temperature for sufficient time to achieve a 2-log reduction of *L. monocytogenes*. You will likely need some help to measure temperatures and times and perform calculations to demonstrate a 2-log reduction.

Microwave heating has been tested at the experimental level only and, while a 5-log reduction in *Listeria* is achievable, the technology requires more R&D before it can be used.

Some packaging equipment integrates a steaming and packaging process that may achieve the desired result of having product surfaces free of *Listeria*.

7.17.3 High pressure processing (HPP)

Some smallgoods are retailed in the package in which they were cooked e.g. liverwursts and some pâtés. The process of heating in the pack reduces the likelihood of *Listeria* contamination to tiny proportions, though a leaking pack offers opportunity for contamination. To obtain a similar level of confidence, HPP pasteurisation in the final pack can also be used.

In one research study on commercial products, cold pasteurisation is achieved by HPP which has been demonstrated to achieve a 4-log reduction in *Listeria* in RTE meats and also extend product shelf life of several smallgoods products.⁶⁸

HPP affects all the hazardous bacteria that may be found in a product, so it is possible to make significant changes to the formulation of the product if HPP is used. Drawbacks are that MAP will not withstand the high pressures (350 MPa).

7.18 Temperature control of finished product

Controlling the temperature of finished products is important for products that are not shelf stable, because keeping the temperature below 5°C, as required by the *Food Standards Code*, prevents many pathogens from growing. However, *L. monocytogenes* is able to grow at chill temperatures and it can grow to dangerously high levels if the composition of the product permits growth. Reformulating products so that they will not support the growth of *L. monocytogenes* is a possibility (see Chapter 9.2).

You need to have records that show what you have done right, if something goes wrong these records will limit your product losses and help to reduce how much product you may need to recall. You will need some way of proving to your auditor or controlling authority that you have been doing the right things.

7.19 Measurements during production

7.19.1 pH

The *Food Standards Code* requires the following method of pH measurement to be applied to UCFM production:

Mince a representative portion of the sample of the UCFM and place that portion in a stoppered bottle with twice its weight of water. Shake at five-minute intervals for 30 minutes and measure the pH value of the liquid electrometrically at 20°C.

Alternatively, the pH can be measured using calibrated, direct-contact pH probes or meters.

⁶⁸ Hayman, M.M., Baxter, I., O'Riordan, P.J., Stewart, C.M., 2004. Effects of High-Pressure Processing on the Safety, Quality, and Shelf Life of Ready-to-Eat Meats. *J Food Prot* 67, 1709-1718.

7.19.2 Water activity

Water activity (a_w) is a measure of the water in the food which is available to microorganisms to allow them to grow. Pure water has $a_w = 1.00$ and raw meat has $a_w = 0.99$. Many dangerous bacteria cannot grow once the water activity drops below 0.95. Most smallgoods are processed to reduce water activity. One pathogen, *S. aureus*, can tolerate low water activity (down to 0.85) and its growth is usually controlled by lowering the temperature (Table 24).

Table 24: Control of microorganisms by reducing water activity

Water activity (a_w)	Lower limit for
0.90	Growth of most bacteria
0.87	Toxin production by <i>S. aureus</i>
0.86	Growth of <i>S. aureus</i>
0.85	Growth of many yeasts
0.80	Growth of most moulds
0.70	Growth of most xerophilic* moulds

* moulds that like really dry conditions

In smallgoods manufacture there are two ways of reducing water activity:

- Drying by holding meat in a hot oven or air stream (jerky, biltong). These products have low moisture (about 20%) and feel dry.
- Binding the water so it is not available to the bacteria. This is done by adding curing agents such as salt to form brine. Other ingredients will also reduce the water activity, but usually salt has the biggest effect. These products, such as ham and corned beef, are quite moist but almost all bacteria are inhibited because they cannot tolerate the low water activity of the brine.

Sometimes both means of controlling water activity are used. In salami manufacture, pathogens are controlled in the early stages by adding 2.5-3% salt and also in maturing, by lowering the moisture content and, at the same time, the water activity.

Water activity can be checked by using a water activity meter. Other methods include measuring weight loss and moisture content which can then be related to a_w . When measuring water activity, you will want to have a representative sample of product (e.g. cutting through the width of a sausage). If you want to know whether the centre of the product is at the right water activity, then you should take a sample at the centre.

7.19.3 Weight loss

Weight loss is an important measurement in UCFM production and may be used as an alternative to measurement of water activity.

Checking weight loss is important in deciding that maturing has proceeded correctly. You'll need to verify that reaching a certain weight corresponds to the required a_w , so your controlling authority and auditor are both confident that you are releasing product with the correct water activity. To check weight loss, you should use the following principles:

- Make sure your scales are accurate. It is no use putting a 150g stick on a scale which weighs up to 50kg – the accuracy will not be enough to support your validation.
- Weigh a representative sample - ten sticks should be sufficient.
- Tie a label on each stick and write the starting weight and the date on it.

- Each time you check-weigh the stick, write the new weight and the date on the label.
- Do not just average the ten weights because that only allows you to say, “on average my product is shelf stable”.
- Keep each individual weighing - this will tell you how variable your process is. If it is so variable that some sticks are too moist to be released, you will need to find out why there is uneven drying.
- Record and keep the results as part of your verification.

7.19.4 Nitrite

Test strips, such as might be used in water or urine testing, may be useful for checking the nitrite concentration of brines. These are not designed for the purpose of testing brines, so you need to do your own validation to show that they can be used to check nitrite concentration in brine.

7.19.5 Salt in brine

The salinometer or salometer (brinometer) consists of a float with a stem attached, marked in degrees. The instrument will float at its highest level in a saturated brine and will read 100 degrees (26.4 % salt solution). This is known as a fully saturated brine at 15-16°C. In weaker brines the stem will float at lower levels and the reading will be lower. With no salt present the reading will be 0. Keep in mind that a salinometer’s scale measures the density of a solution containing salt and water. Once you add other ingredients the salinometer will measure the density of a solution and not the salinity of the brine.

7.19.6 Solids in brine

Brix is a unit of measurement that indicates the amount of sugar dissolved in water. Brix is measured using a device called a refractometer, which calculates the concentration of soluble solids by measuring the refractive index of a solution. Degrees Brix (symbol °Bx) is the sugar content of an aqueous solution. One degree Brix is 1 gram of sucrose in 100 grams of solution. If the solution contains dissolved solids other than pure sucrose, then the °Bx only approximates the dissolved solid content.

A Brix Refractometer is a device used across a wide range of industries. When light enters a liquid at an angle, it changes direction. This phenomenon is called refraction. Light will refract more when travelling through a liquid with dissolved or suspended solids. Therefore, refraction can be used to measure the concentration of dissolved or suspended solids within a solution. There is a direct relationship between the refractive index and the final Brix percentage.

When using a refractometer for testing a brine, you need to determine the required degrees Brix for each brine formulation that you use. Once you have determined the specification, then the Brix Refractometer is a quick way of making sure that the total concentration of solids in the brine is correct/

7.19.7 Measurements for the *L. monocytogenes* predictive model

To use all of the parameters available in the FSSP *L. monocytogenes* model (Chapter 9.2), a number of analyses of product are required.

Dry Matter/Moisture

Laboratory analysis of the dry matter percentage is determined by heating at 105 °C for 24 hours⁶⁹

⁶⁹ Anonymous. (1995) Moisture in Meat. Air Drying. In AOAC, Official Methods of Analysis (p. 950.46). Arlington: AOAC.

NaCl in water phase (%)

- Laboratory analysis of the percentage sodium chloride in the sample by modified Volhard titration method or equivalent⁷⁰.
- Calculate Dry Matter or lab analysis of Dry Matter (%).
- Laboratory analysis of the percentage Dry Matter by heating at 105 °C for 24 hours⁷¹.

pH ⁷²

- Measure using a calibrated pH meter.
- Homogenise the samples 1:1 with distilled water – or use a ‘stab’ type probe that has been made for these kinds of products.
- Measure the pH on the slurry.

There is also a method for measuring pH of UCFM in the Schedule to Standard 4.2.3 of the *Food Standards Code*

Phenol (ppm)

Laboratory analysis of the amount of wood smoke in products can be measured as phenol in the sample by either the modified Gibbs method which measures phenols as 2,6-dimethoxyphenol⁷³ or the French standard for smoked salmon method^{74*}.

* For total phenols quantification, 4g were homogenised with 50ml ethanol (95%) for one min using a blender (Ultraturax, GmbH, Dottingen, Germany). After centrifugation (2500g, 10 minutes), 5ml supernatant was put in a decantation flask and energetically mixed with 30ml distilled water and 0.6ml of a 2% phenyl-2,3-dimethyl-4-amino-5-pyrazolone solution (Merck, Darmstadt, Germany). 2N ammonia solution (2ml) was added and the mixture homogenised manually. This procedure was then repeated with 2ml of 2% potassium hexacyanoferrate solution (Prolabo, Fontenay sous bois, France). The mixture was then left to stand for five minutes before adding 10ml chloroform and mixing energetically for 15 minutes with a stirring machine. After decantation, the chloroform phase was filtered through a Durieux filter (no. 126) containing 3g of anhydrous sodium sulphate. Optical density was read at 455nm on a spectrophotometer and compared with a standard curve established with a serially diluted 1mg/l standard phenol solution (Prolabo, Fontenay sous bois, France).

%CO₂ in headspace gas at equilibrium

- You can calculate this value using the calculator in the *L. monocytogenes* Growth Model.
- Analyse the %CO₂ in headspace at least two days after production to allow for equilibration.

⁷⁰ Anonymous. (1995) Salt (chlorine as Sodium Chloride) in seafood. Volumetric method. In AOAC, Official Methods of Analysis (p. 937.09). Arlington: AOAC.

⁷¹ Anonymous. (1995) Moisture in Meat. Air Drying. In AOAC, Official Methods of Analysis (p. 950.46). Arlington: AOAC.

⁷² Dalgaard, P. & Jorgensen, L. (1998) Predicted and observed growth of *Listeria monocytogenes* in seafood challenge tests and in naturally contaminated cold-smoked salmon. International Journal of Food Microbiology, 40:105-115

⁷³ Tucker, I. (1942) Estimation of phenols in meat and fat. Journal of the AOAC, 25:779-782.

⁷⁴ AFNOR (Association française de Normalisation) (1995) Poisson transformé. Saumon fume. Norme. NF V 45-065. AFNOR.

Nitrite (mg/kg)

- Laboratory analysis of the amount of sodium nitrite in the composite sample by colorimetric method or equivalent^{75 76}.

Organic acids in water phase of product

By analysis:

Organic acids including acetic acid, benzoic acid, citric acid, lactic acid and sorbic acid can be analysed by HPLC (Pecina et al. 1984). In previous work neutralised perchloric acid (PCA) extracts were separated on a BIORAD HPX87H column at 50 °C with a 0.008M H₂SO₄ eluent. Flow rate was 0.6mL min⁻¹, run time 120 minutes and injecting volume 0.30µL. Organic compound were detected by UV absorbance at 210nm. Identification relied on retention time as compared with external standards also used for quantification⁷⁷.

By calculation:

Lactic and acetic acid can be calculated provided you:

- are aware of the type and purity of the antimicrobials you are using
- use a defined quantity of antimicrobials (in the brine or added at the massager)
- know the lowest percentage of product weight lost during cooking and chilling (which results in highest moisture content).

The calculation involves the following:

- discount the water fraction of the additive (many liquid blends are 40% water)
- discount the sodium or potassium proportion of the component (only the lactate or diacetate contributes to the organic acids)
- convert the lactic or diacetate to lactic and acetic acid content (molarity)
- work out how much is added and how much is residual in the product given the evaporative loss of moisture during cooking and chilling (if in porous casing)
- convert the lactic and/or acetic content to ppm in the water phase as required for input into the Food Safety and Spoilage Predictor (FSSP) Model.

⁷⁵ Dalgaard, P. & Jorgensen, L. (1998) Predicted and observed growth of *Listeria monocytogenes* in seafood challenge tests and in naturally contaminated cold-smoked salmon. *International Journal of Food Microbiology*, 40:105-115

⁷⁶ Anonymous. (1995) Moisture in Meat. Air Drying. In AOAC, *Official Methods of Analysis* (950.46). Arlington: AOAC.

⁷⁷ Dalgaard, P. & Jorgensen, L. (1998) Predicted and observed growth of *Listeria monocytogenes* in seafood challenge tests and in naturally contaminated cold-smoked salmon. *International Journal of Food Microbiology*, 40:105-115

8 Products

8.1 Fresh sausage

8.1.1 Description of product

Fresh sausages are made from frozen and chilled fat and meat, salt, possibly spices and other ingredients, and usually sulphur dioxide. The ingredients are minced or comminuted and usually extruded into a casing. They are intended to be consumed after cooking. The meat of numerous species may be used to produce fresh sausages. A wide range of flavoured sausages are produced that may contain allergens, e.g. nuts, eggs, gluten, and allergens that can be present in ingredients such as Worcestershire sauce.

Sausage manufacture is highly regulated in terms of meat, fat, and preservative contents. In this section we follow the process of manufacturing fresh sausage to supply safe products which have a good shelf life.

The following sample description should be reviewed and completed (step 2 in the HACCP system development process)

Ingredients	Meat (frozen, chilled) of the required species Fat and trimmings (frozen, chilled) of the required species Salt Sulphites (measured as sulphur dioxide) Spices Other ingredients
Primary Packaging	
Storage Conditions	Refrigerated: Store under refrigeration not more than 5°C.
Shelf Life	'Best-before' date: x days from production. Shelf life once opened: x days once opened.
Labelling related to product safety	contains sulphites contains other ingredients that are allergens Allergens that may be present without being listed as ingredients Keep refrigerated – store at no more than 5°C Must be cooked

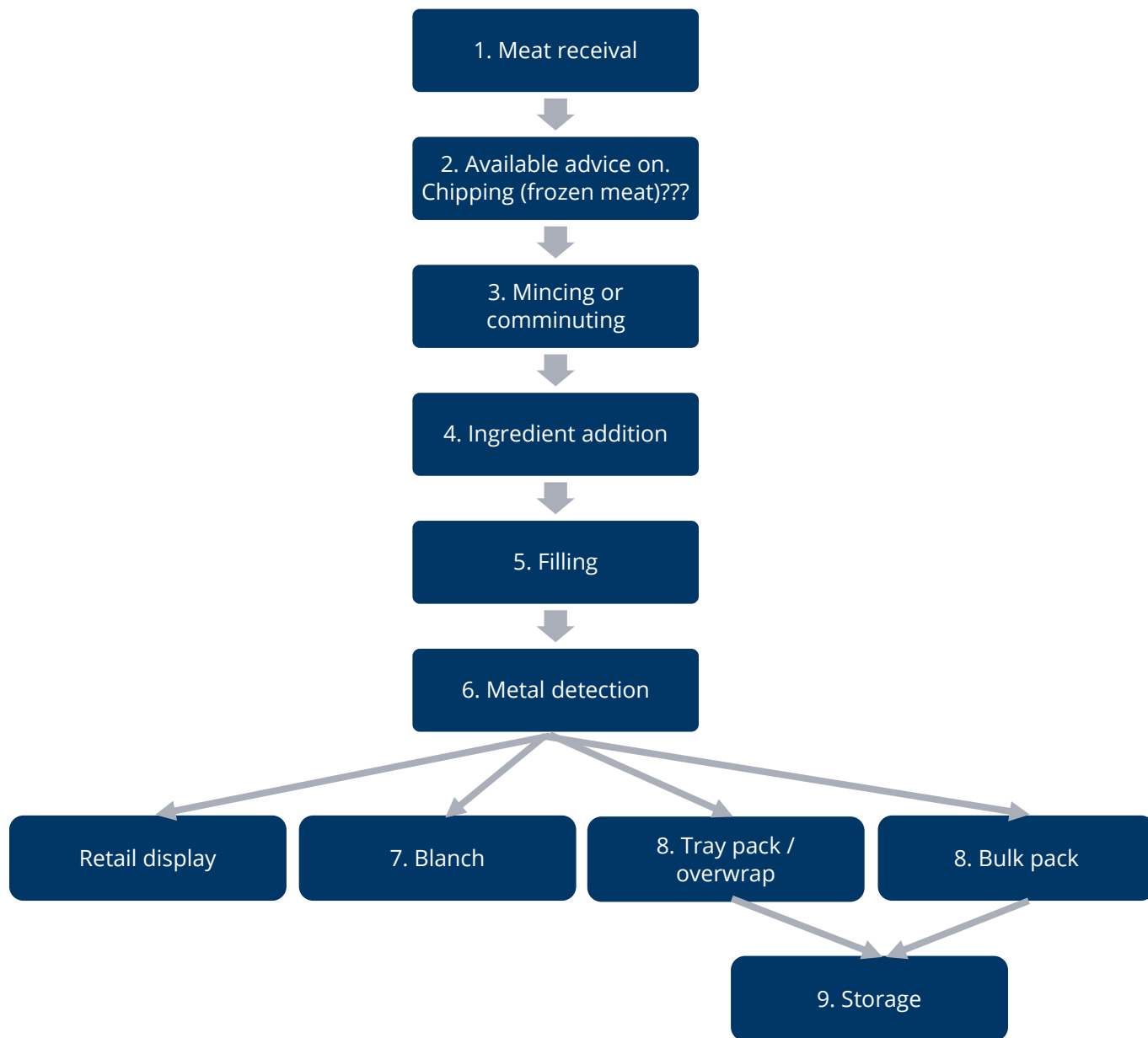
8.1.2 Intended use and users

The following sample description of intended use should be reviewed and completed (step 3 in the HACCP system development process)

Sensitive Customer	
Customer Preparation	Must be cooked

8.1.3 Flow diagram

The process flow may vary between products and with available equipment. This is a sample flow diagram, used to prepare the sample HACCP analysis. Constructing your own flow diagram and on-site confirmation of the process are two steps (steps 4 and 5) in the HACCP system development.



8.1.4 Potential hazards and control measures

This is a sample hazard analysis based on the sample flow diagram. You need to conduct your own hazard analysis based on your product, production process, and circumstances (Step 6 of HACCP system development)

1	2	3	4	5	
Step					
1 Meat receptal and storage	B Pathogens All meat: <i>Salmonella</i> , <i>S. aureus</i> , <i>L. monocytogenes</i> , <i>C. botulinum</i> , <i>C. perfringens</i> Beef: pathogenic <i>E. coli</i> Pork: <i>Y. enterocolitica</i> Lamb: pathogenic <i>E. coli</i> Chicken – <i>Campylobacter</i> sp.		N	The prevalence and/or concentration of these pathogens in Australian meat is low. Imported pork cannot be used in these products.	Customer will cook the product.
	B <i>S. aureus</i>	Y		<i>S. aureus</i> may grow and produce toxins above 10°C and these toxins may remain active until consumption.	Follow the temperature requirements of the <i>Australian Standard</i>
	C Residues of agricultural and veterinary chemicals		N	The prevalence of these chemicals in Australian meat is low.	
	P Bone splinters, foreign objects, plastic wrap	Y		May cause injury to consumers	Physical contamination checks
	B				
C					

1	2	3	4	5	
2 Chipping (frozen meat)	P	Fragments of metal	Y	Fragment of metal from machinery may cause injuries to consumers	Physical contamination checks
	B				
3 Mincing or chopping	C				
	P	Fragments of metal	Y	Fragment of metal from machinery may cause injuries to consumers	Physical contamination checks
	B				
4 Ingredient addition	C	Sulphite	Y	Sulphites may be hazardous for some consumers and may not exceed 500 mg/kg	Care with sulphite addition Labelling
	C	Ingredients	Y	Some ingredients may be allergens	Labelling
	P				
	B				
5 Filling	C				
	P	Fragments of metal	Y	Fragment of metal from machinery may cause injuries to consumers	Physical contamination checks
	B				
6 Metal detection	C				
	P				
	B				
7 Blanching and cooling of	B	<i>C. perfringens</i>	Y	<i>C. perfringens</i> may survive blanching, germinate, grow, and produce toxins during cooling	Follow the cooling requirements in the <i>Australian Standard</i>
	C				

1	2	3	4	5	
blanched product	P				
8 Packing	B				
	C				
	P				
9 Storage	B	Pathogens such as <i>L. monocytogenes</i> , <i>Y. enterocolitica</i> , (<i>Salmonella</i> , <i>E. coli</i>)	Y	Pathogens of concern may be able to grow at greater than 5 °C	Follow the temperature requirements of the <i>Australian Standard</i>
	B	<i>S. aureus</i>	Y	<i>S. aureus</i> may grow and produce toxins above 10°C and these toxins may remain active until consumption.	Follow the temperature requirements of the <i>Australian Standard</i>
	C				
	P				

8.1.5 CCPs and CLs

CCPs

This is a sample analysis of CCPs based on the sample hazard analysis. You need to determine the CCPs based on your own analysis of hazards (step 7).

Process step	Significant hazard	Q1 Can the significant hazard be controlled to an acceptable level at this step by PRP (e.g. GMPs)?	Q2 Do specific control measures for the identified significant hazard exist at this step?	Q3 Will a subsequent step prevent or eliminate the identified hazard or reduce it to an acceptable level?	Q4 Can this step specifically prevent or eliminate the identified significant hazard or reduce it to an acceptable level?	CCP number
		If YES, this step is not a CCP	If YES proceed to Q3	If YES that subsequent step should be a CCP	If YES, this step is a CCP	

Process step	Significant hazard	Q1 Can the significant hazard be controlled to an acceptable level at this step by PRP (e.g. GMPs)?	Q2 Do specific control measures for the identified significant hazard exist at this step?	Q3 Will a subsequent step prevent or eliminate the identified hazard or reduce it to an acceptable level?	Q4 Can this step specifically prevent or eliminate the identified significant hazard or reduce it to an acceptable level?	CCP number
		If NO, proceed to Q2	If NO this step is not a CCP. Subsequent steps should be evaluated for a CCP	If NO, proceed to Q4	If NO, modify the step, process or product to implement a control measure	
1. meat receival and storage	Growth and toxin production by <i>S. aureus</i>	N	Y	N	Y	CCP1
	Bone splinters, foreign objects, plastic wrap	Y				
2. Chipping (frozen meat)	Fragments of metal	Y				
3. mincing or chopping	Fragments of metal	Y				
4. Ingredient addition	Sulphite levels	Y				
	Allergens in ingredients	Y				
5. filling	Fragments of metal	Y				
7. Blanching and cooling of	Growth of <i>C. perfringens</i>	N	Y	N	Y	CCP2

Process step	Significant hazard	Q1 Can the significant hazard be controlled to an acceptable level at this step by PRP (e.g. GMPs)?	Q2 Do specific control measures for the identified significant hazard exist at this step?	Q3 Will a subsequent step prevent or eliminate the identified hazard or reduce it to an acceptable level?	Q4 Can this step specifically prevent or eliminate the identified significant hazard or reduce it to an acceptable level?	CCP number
blanched product						
9. Storage	Growth and toxin production by <i>S. aureus</i>	N	Y	N	Y	CCP3

CLs

This is a sample of the CLs, monitoring and corrective actions based on the sample hazard analysis and identification of CCPs. You need to state CLs (step 8) for your CCP, establish a monitoring system (step 9), determine corrective actions (step 10), and procedures for verification (step 11 of HACCP system development) and record keeping (step 12).

CCP number	Significant hazard	CLs	Monitoring				Corrective actions	Verification activities	Records
			What	How	When	Who			
CCP1	<i>S. aureus</i> toxin production	Not greater than 5°C (<i>Australian Standard</i> clause 11.6)* **	Raw meat	Chiller temperature	Twice daily	Stores supervisor	1. Immediately chill product to correct temperature. 2. Assess safety of product for use.)	1. Calibration of temperature measuring devices 2. Weekly check of records.	Chiller log
CCP2	<i>C. perfringens</i> growth and toxin production during cooling	Cooling according to <i>Australian Standard</i> clause 13.20(a)***.	Largest piece of product at the slowest cooling point	Automated recording of temperature against time at slowest cooling point	Throughout cooling. Every batch.	Chiller operator	1. Hold all product until appropriate disposition taken based on microbiological tests 2. Determine and eliminate the cause of the deviation;	1. Ensure temperature probes are inserted correctly 2. Ensure thermometers are calibrated	Time – temperature records

CCP number	Significant hazard	CLs	Monitoring				Corrective actions	Verification activities	Records
			What	How	When	Who			
				in the largest piece				3. Check every batch.	
CCP3	<i>S. aureus</i> toxin production	Not greater than 5°C (Australian Standard clause 11.6) **	sausage	Chiller temperature	Twice daily	Stores supervisor	1. Immediately chill product to correct temperature. 2. Assess safety of product for use. <i>S. aureus</i> does not produce toxin below 10°C and a high level of <i>S. aureus</i> is required (Chapter 9.1)	1. Calibration of temperature measuring devices 2. Weekly check of records.	Chiller log

* some pathogens will not grow at 5° C. A guideline for CLs for raw meat that will be used in a product intended to be fully cooked by the consumer or processor can be found at [Raw Product Critical Limit Tables \(wisc.edu\)](http://www.wisc.edu/~meathaccp/therm/)

** *S. aureus* does not produce toxin below 10°C and a high level of *S. aureus* is required (Chapter 9.1). A predictive tool can be used to assess the amount of growth that may occur: <https://meathaccp.wisc.edu/therm/> Ingham, S.C., Fanslau, M.A., Burnham, G.M., Ingham, B.H., Norback, J.P., Schaffner, D.W., 2007. Predicting Pathogen Growth during Short-Term Temperature Abuse of Raw Pork, Beef, and Poultry Products: Use of an Isothermal-Based Predictive Tool. J Food Prot 70, 1445-1455.

*** or alternative time and temperature controls based on predictive models (Chapter 9.4)

Guidelines on procedures for CCPs and important GMPs can be found in the following places:

Information on CCPs

CCP1 7.1 Receiving and temperature control of raw meat

CCP2 7.12 Cooling

CCP3 5.18 Temperature control of finished product

Important GMPs

Step 1 7.1 Receiving and temperature control of raw meat

Steps 1,2,3,5 4.7 Physical contamination and foreign body detection

Step 4 7.3 Formulation and assembly of raw materials

Step 4 4.4 Weighing and adding ingredients (sulphites and other ingredients)

Step 4 4.5 Allergen management

8.1.6 Validation

A safe product is one that

- Is made from raw meat stored at no more than 5°C
- Contains sulphur dioxide at no more than 500 mg/kg
- Is labelled as containing sulphites and any other allergens
- If blanched, is cooled according to the *Australian Standard*
- Is stored at no more than 5°C
- Instructs the consumer to cook the product

8.1.7 Verification

There are no microbiological criteria in the *Food Standards Code*.

Microbiological quality will have an impact on whether product reliably achieves the expected shelf life, so keeping control of the quality of raw materials, hygiene and temperature control of product are important.

8.2 Bacon

8.2.1 Description of product

Meat intended for bacon production is cured by injecting with curing brine, soaking in pickle, then drying and smoking before chilling and slicing. English bacon was traditionally made from pork middles – but can also be made from other parts of a pork carcass or from the meat of other species. Generally, bacon is cooked before it is eaten, which is a kill step for target pathogens though some consumers state their preference for consuming bacon without cooking. Nevertheless, bacon is considered to be a low risk product.

Bacon manufacture involves injecting brine into or dry salting pork 'middles', other pork pieces or meat pieces from other species. Beef and turkey are the most common non-pork meats used in bacon. It's important that the correct injection rate is achieved through the entire meat piece and across the entire batch.

After brining, meat pieces may be sprayed to remove salts such as phosphate or nitrite and drained to reduce the amount of moisture prior to drying. Traditionally, the drying phase was not intended to cook the product but to dry and darken the surface layers.

Smoke is generated from sawdust, woodchips or wood blocks in a smoke generator and smoke flavour is taken up. Steam is added to the atmosphere to raise the internal temperature in the muscle to enhance the pink colour of the lean portions of the bacon, but again, the heat treatment does not meet the regulatory definition of cooking.

Meat pieces are cooled at ambient temperature to remove some of the heat, then active chilling is carried out, followed by tempering to bring the temperature of the meat to 0° to -1°C. Tempered bacon slices satisfactorily because the meat holds together well.

There is a regulatory requirement to store bacon under refrigeration no warmer than 5°C. This prevents growth of most pathogenic bacteria except for *L. monocytogenes*. Even though the product is intended to be cooked, the use of a 'Use-by' date can be justified based on potential growth of *L. monocytogenes*, and the possibility of a consumer choosing to not cook the product adequately.

The following sample description should be reviewed and completed (step 2 in the HACCP system development process)

Ingredients	Pork (or other species) Salt Nitrite Sugar Wood smoke
Primary Packaging	
Storage Conditions	Refrigerated: Store under refrigeration not more than 5°C.
Shelf Life	'Use- by' date: x days from production. Shelf life once opened: x days once opened.
Labelling related to product safety	Keep refrigerated – store at no more than 5°C Cook prior to consumption Allergens that may be present without being listed as ingredients

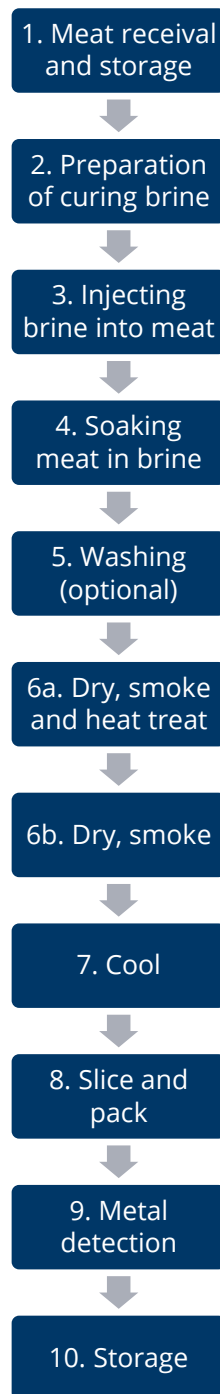
8.2.2 Intended use and users

The following sample description of intended use should be reviewed and completed (step 3 in the HACCP system development process)

Sensitive Consumer	
Customer Preparation	Not RTE – cook prior to consumption

8.2.3 Flow diagram

The process flow may vary between products and with available equipment. This is a sample flow diagram, used to prepare the sample HACCP analysis. Constructing your own flow diagram and on-site confirmation of the process are two steps (steps 4 and 5) in the HACCP system development.



8.2.4 Potential hazards and control measures

This is a sample hazard analysis based on the sample flow diagram. You need to conduct your own hazard analysis based on your product, production process, and circumstances (step 6 of HACCP system development)

1	2	3	4	5
Step	Identify potential hazards	Does this potential hazard need to be addressed in the HACCP plan	Justification for decision in column 3	What measure(s) can be applied to prevent or eliminate the hazard or reduce it to an acceptable level
		YES NO		
1. meat receival and storage	B Pathogens All meat: <i>Salmonella</i> , <i>S. aureus</i> , <i>L. monocytogenes</i> , <i>C. botulinum</i> , <i>C. perfringens</i> Beef: pathogenic <i>E. coli</i> Pork: <i>Y. enterocolitica</i> , <i>T. spiralis</i> (if imported) Lamb: pathogenic <i>E. coli</i> Chicken: <i>Campylobacter</i> sp.	Y	Pathogens may be present on the raw meat and could grow if temperature abuse occurred. Controlled by brining, drying, smoking and cooking. Imported pork (without bones) can be used but must be subject to DAFF biosecurity requirements (Chapter 7.11).	Purchase to specification from approved supplier. Maintain and monitor storage (and thawing) temperature below 5°C (<i>Australian Standard</i>). Careful attention to control of the manufacturing process, particularly, salt concentration. Nitrate/nitrite to control <i>C. botulinum</i> Customer will cook product
	B <i>S. aureus</i>	Y	Could grow and produce toxin above 10°C and these toxins may remain active until consumption.	Maintain and monitor storage (and thawing) temperature below 5°C (<i>Australian Standard</i>).
	C Chemical residues	N	Controlled by slaughter establishment.	
	P Bone splinters Plastic Foreign objects	N		Purchase to specification from approved supplier. Visual inspection of meat pieces during trimming

1	2	3	4	5	
2. preparation of curing brine	B	growth of pathogens	Y	Correct salt level and low brine temperature to prevent the growth of pathogens such as <i>S. aureus</i> during soaking. Correct nitrite level to prevent the growth of pathogens such as <i>C. perfringens</i> and <i>C. botulinum</i> during soaking.	
	C	nitrite	Y	Correct nitrite level to prevent nitrite concentration being above the limit.	Maximum level of nitrite 125 mg/kg calculated as sodium nitrite (<i>Food Standards Code</i>)
	P				
3. injecting brine into pork middles	B	Pathogens	N	Pathogens may be moved to the centre of the meat piece, but product will be cooked. Growth will be prevented by low temperature and nitrite. Product will be cooked by consumer.	Curing liquid is stored at 5°C or colder (<i>Australian Standard</i>). Nitrite concentration
	C				
	P	Metal fragments in product	Y	Injection needles can break.	Examination of needles
4. soaking meat in brine	B	<i>S. aureus</i> <i>C. perfringens</i> <i>C. botulinum</i>	Y	Pathogens could grow and produce toxins. <i>S. aureus</i> may produce toxins above 10°C and these toxins may remain active until consumption.	Cold brine with correct salt and nitrite concentration. Cure at not more than 5°C (<i>Australian Standard</i>)
	C				
	P				

1	2	3	4	5	
5. washing	B				
	C				
	P				
6. dry, smoke and cook	B	<i>S. aureus</i> <i>C. perfringens</i> <i>C. botulinum</i>	Y	Slow warming of product to the heat treatment temperature may allow growth and toxin production.	Drying occurs. Salt, nitrite and other ingredients may prevent the growth of these pathogens. Heat treatment may be less than 65°C for 10 minutes, or equivalent. Imported pork must be heated to meet DAFF Biosecurity requirements (Chapter 7.11).
	C				
	P				
7. cool	B	<i>C. perfringens</i>	Y	<i>C. perfringens</i> may grow and produce toxin. Cooking prior to consumption cannot be relied upon to destroy toxin.	Cooling must meet <i>Australian Standard</i> or approved alternative process
	C				
	P				
8. slicing and packing	B	Pathogens, particularly <i>L. monocytogenes</i> , <i>S. aureus</i>	Y	<i>L. monocytogenes</i> , <i>S. aureus</i> may recontaminate product from the production environment.	Environmental controls, hygiene standards for equipment, environment and workers.
	C				
	P				
9. metal detection	B				
	C				

1	2	3	4	5	
	P				
10. storage	B	<i>L. monocytogenes</i>	Y	Growth may occur depending on the specifications (pH, water activity) and presence of additives such as nitrite, smoke, smoke, or organic acids.	During this step the only action is to keep the product refrigerated, which will minimise, but not prevent growth, in those products where growth is possible. Set use-by date based on <i>L. monocytogenes</i> growth.
	B	<i>S. aureus</i>	Y	Growth and toxin production may occur above 10°C and these toxins may remain active until consumption.	Not greater than 5°C (<i>Australian Standard</i> clause 11.6). Toxin not produced under 10°C.
	C				
	P				

8.2.5 CCPs and CLs

CCPs

This is a sample analysis of CCPs based on the sample hazard analysis. You need to determine the CCPs based on your own analysis of hazards (step 7) and state the validated CLs (step 8 of HACCP system development).

Process step	Significant hazard	Q1 Can the significant hazard be controlled to an acceptable level at this step by PRP (e.g. GMPs)?	Q2 Do specific control measures for the identified significant hazard exist at this step?	Q3 Will a subsequent step prevent or eliminate the identified hazard or reduce it to an acceptable level?	Q4 Can this step specifically prevent or eliminate the identified significant hazard or reduce it to an acceptable level?	CCP number
		If YES, this step is not a CCP	If YES proceed to Q3	If YES that subsequent step should be a CCP	If YES, this step is a CCP	
		If NO, proceed to Q2	If NO this step is not a CCP. Subsequent steps should be evaluated for a CCP	If NO, proceed to Q4	If NO, modify the step, process or product to implement a control measure	
1. Meat receival and storage	Pathogen growth in raw meat.	Y				
	<i>S. aureus</i> growth and toxin production.	N	Y	N	Y	CCP1
2. Preparation of curing brines	Salt concentration in curing brine.	Y				
	Nitrite in curing brine.	Y				

Process step	Significant hazard	Q1 Can the significant hazard be controlled to an acceptable level at this step by PRP (e.g. GMPs)?	Q2 Do specific control measures for the identified significant hazard exist at this step?	Q3 Will a subsequent step prevent or eliminate the identified hazard or reduce it to an acceptable level?	Q4 Can this step specifically prevent or eliminate the identified significant hazard or reduce it to an acceptable level?	CCP number
3. injecting brine into pork middles	Metal fragments in product.	Y				
4. soaking meat in brine	Some pathogens may produce toxins.	Y				
5. washing						
6a. dry smoke and heat treatment	<i>S. aureus</i> and <i>C. perfringens</i> may produce toxins during heat treatment.	N*	Y	N	Y	CCP2a
6b. dry, smoke and cook	<i>S. aureus</i> and <i>C. perfringens</i> may produce toxins during heat treatment.	N*	Y	N	Y	CCP2b
7. cool	<i>C. perfringens</i> grows and produces toxin during cooling.	N	Y	N	Y	CCP3
8. slicing and packing	Recontamination with pathogens, particularly <i>L. monocytogenes</i> or <i>S. aureus</i> .	Y				
	Recontamination with <i>S. aureus</i> .	Y				

Process step	Significant hazard	Q1 Can the significant hazard be controlled to an acceptable level at this step by PRP (e.g. GMPs)?	Q2 Do specific control measures for the identified significant hazard exist at this step?	Q3 Will a subsequent step prevent or eliminate the identified hazard or reduce it to an acceptable level?	Q4 Can this step specifically prevent or eliminate the identified significant hazard or reduce it to an acceptable level?	CCP number
9. metal detection						
10. storage	<i>L. monocytogenes</i> growth.	Y				
	<i>S. aureus</i> growth and toxin production.	Y				

* depends on the formulation and the time/temperature conditions.

CLs

This is a sample of the CLs, monitoring and corrective actions based on the sample hazard analysis and identification of CCPs. You need to state CLs (step 8) for your CCP, establish a monitoring system (step 9), determine corrective actions (step 10), and procedures for verification (step 11 of HACCP system development).

CCP number	Significant hazard	CLs	Monitoring				Corrective actions	Verification activities	Records
			What	How	When	Who			
CCP1	<i>S. aureus</i> toxin production.	Not greater than 5°C (Australian Standard clause 11.6) * **.	Raw meat	Chiller temperature	Twice daily	Stores supervisor	1. Immediately chill product to correct temperature. 2. Assess safety of product for use.	1. Calibration of temperature measuring devices. 2. Weekly check of records.	Chiller log.

CCP number	Significant hazard	CLs	Monitoring				Corrective actions	Verification activities	Records
			What	How	When	Who			
CCP2a	Growth and toxin production by <i>S. aureus</i> or <i>C. perfringens</i> .	Smoking at >50°C. Reaching this temperature in <6h prevents toxin formation by <i>S. aureus</i> and <i>C. perfringens</i> ⁷⁸ .	Time and temperature (>50°C in <6 hours).	(Automated) recording of temperature against time at slowest cooling point in the largest piece.	Throughout heat treatment. Every batch.	Oven operator.	1.Hold all product produced from last acceptable check until appropriate disposition taken based on microbiological tests. 2.Determine and eliminate the cause of the deviation.	Ensure temperature probes are inserted correctly. Ensure thermometers are calibrated. Supervisor reviews records weekly.	Time – temperature records.
CCP2b	Pathogens may survive the cooking process.	Cooking to internal temperature of 65°C for 10 minutes or equivalent (<i>Australian Standard</i> clause 13.5) ^{****} .	Largest piece of product at the slowest warming point.	Automated recording of temperature against time at slowest warming point in the largest piece.	Continuously during cooking.	Oven operator.	Cook again.	1. Ensure temperature probes are inserted correctly. 2. Ensure thermometers are calibrated 3. Check every batch.	Cooker log.

⁷⁸ Peter J. Taormina, Gene W. Bartholomew (2005) Validation of Bacon Processing Conditions To Verify Control of Clostridium perfringens and Staphylococcus aureus, Journal of Food Protection,68(9) 1831-1839

CCP number	Significant hazard	CLs	Monitoring				Corrective actions	Verification activities	Records
			What	How	When	Who			
CCP3	<i>C. perfringens</i> growth and toxin production during cooling.	Cooling according to <i>Australian Standard</i> clause 13.17***.	Largest piece of product at the slowest cooling point.	(Automated) recording of temperature against time at slowest cooling point in the largest piece.	Throughout cooling. Every batch.	Chiller operator.	1.Hold all product produced from last acceptable check until appropriate disposition taken based on microbiological tests. 2.Determine and eliminate the cause of the deviation.	Ensure temperature probes are inserted correctly. Ensure thermometers are calibrated. Supervisor reviews records weekly.	Time – temperature records.

* some pathogens will not grow at 5°C. A guideline for CLs for raw meat that will be used in a product intended to be fully cooked by the consumer or processor can be found at [Raw Product Critical Limit Tables \(wisc.edu\)](http://www.wisc.edu/~meathaccp/therm/)

** *S. aureus* does not produce toxin below 10°C and a high level of *S. aureus* is required (Chapter 9.1). A predictive tool can be used to assess the amount of growth that may occur: <https://meathaccp.wisc.edu/therm/> Ingham, S.C., Fanslau, M.A., Burnham, G.M., Ingham, B.H., Norback, J.P., Schaffner, D.W., 2007. Predicting Pathogen Growth during Short-Term Temperature Abuse of Raw Pork, Beef, and Poultry Products: Use of an Isothermal-Based Predictive Tool. J Food Prot 70, 1445-1455.

*** or alternative time and temperature controls based on predictive models (Chapter 9.4)

**** imported pork must be cooked to also meet DAFF biosecurity requirements

Information on CCPs

CCP1	7.1 Receiving and temperature control of raw meat
CCP2a	7.10 Heat treatment
CCP2b	7.12 Cooking
CCP2	7.12 Cooling

Important GMPs

Step 1	7.1 Receiving and temperature control of raw meat
Step 2	7.3 Formulation and assembly of raw materials 4.4 Weighing and adding ingredients 1.8.2 Shelf life and growth of <i>L. monocytogenes</i>
Step 3,9	4.7 Physical contamination – and foreign body detection
Step 4	7.5 Massaging, tumbling, injecting and curing
Step 6	7.8 Smoking
Step 8	3.4 Keeping control of <i>Listeria</i> 6.8 Protective cultures 7.17 Packing
Step 10	7.18 Temperature control of finished product

8.2.6 Validation

A safe product is one that:

- contains nitrite at the correct concentration
- is cooled according to the requirement of the *Australian Standard*
- is kept refrigerated, no warmer than 5°C
- advises to cook product prior to consumption.

8.2.7 Verification

There are no microbiological limits in the *Food Standards Code* for bacon.

8.3 Roast Meats

8.3.1 Description of product

Cuts and joints of meat are cooked in an oven or in a water bath, after which they are chilled. A wide range of meat species may be 'roasted' in this way. Some are injected with seasonings. Note that injecting changes the site of microbiological concern from the surface of the meat piece to the centre of the muscle.

The cooking step makes these products safe to eat with no further preparation required by the consumer. However, these products are not shelf stable. Therefore, these products must be frozen or refrigerated throughout their shelf-life to maintain product safety. These products meet the definition of RTE product.

Roast meats do not contain nitrite so there is no control for *C. botulinum* if it happened to be introduced into the deep tissues during injecting. However, if roasts are cooled in accordance with the *Australian Standard* there is little likelihood that any surviving spores of *C. botulinum* can germinate, grow and produce toxin.

The product will have a short shelf life unless it has been formulated to prevent the growth of *L. monocytogenes*. You can validate whether your product supports the growth of *L. monocytogenes* following the advice in Chapter 1.8.2. It is possible to reformulate your product so that it does not support the growth of *L. monocytogenes* following the advice in Chapter 9.2.

The following sample description should be reviewed and completed (step 2 in the HACCP system development process).

Ingredients	Meat (cuts, joints) of the required species Salt Seasoning Plant protein Other ingredients
Primary Packaging	Vacuum pack MAP Loose
Storage Conditions	Refrigerated: Store at not more than 5°C.
Shelf Life	'Use-by' date: x days from production. Shelf life once opened: x days once opened.
Labelling related to product safety	Keep refrigerated – store below 5°C Allergens, if added Allergens that may be present without being listed as ingredients

8.3.2 Intended use and users

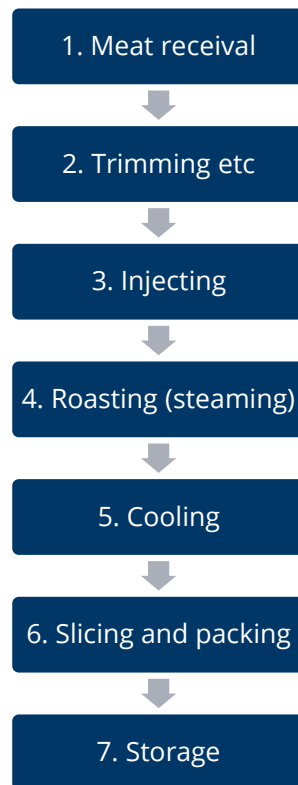
The following sample description of intended use should be reviewed and completed (step 3 in the HACCP system development process)

Sensitive Customer	
Customer Preparation	RTE

8.3.3 Flow diagram

The process flow may vary between products and with available equipment. This is a sample flow diagram, used to prepare the sample HACCP analysis.

Constructing your own flow diagram and on-site confirmation of the process are two steps (steps 4 and 5) in the HACCP system development.



8.3.4 Potential hazards and control measures

This is a sample hazard analysis based on the sample flow diagram. You need to conduct your own hazard analysis based on your product, production process, and circumstances (Step 6 of HACCP system development)

1	2	3	4	5	
Step	Identify potential hazards	Does this potential hazard need to be addressed in the HACCP plan	Justification for decision in column 3	What measure(s) can be applied to prevent or eliminate the hazard or reduce it to an acceptable level	
		YES	NO		
1. Meat receival	B Pathogens All meat: <i>Salmonella</i> , <i>S. aureus</i> , <i>L. monocytogenes</i> , <i>C. botulinum</i> , <i>C. perfringens</i> Beef: pathogenic <i>E. coli</i> Pork: <i>Y. enterocolitica</i> Lamb: pathogenic <i>E. coli</i> Chicken – <i>Campylobacter</i> sp.		N	The prevalence and/or concentration of these pathogens in Australian meat is low. Imported pork (without bones) can be used but must be subject to DAFF biosecurity requirements (Chapter 7.11).	
	B <i>S. aureus</i>	Y		<i>S. aureus</i> may grow and produce toxins above 10°C and these toxins may remain active until consumption.	Follow the temperature requirements of the <i>Australian Standard</i> .
	C Residues of agricultural and veterinary chemicals		N	The prevalence of these chemicals in Australian meat is low.	
	P Bone splinters, foreign objects, plastic wrap	Y		May cause injury to consumers.	Physical contamination checks.
2 Trimming etc.	B				
	C				
	P				

1	2	3	4	5	
3 Injecting	B	Pathogens	Y	Pathogens may be moved to the centre of the meat piece if brine is injected. Pathogen survival would make a RTE food unsafe.	Follow the cooking requirements of the <i>Australian Standard</i> .
	C				
	P	Metal fragments	Y	Injection needles can break.	Examination of needles. Weight increase when injecting.
4 Roasting (steaming)	B	Pathogens	Y	Pathogens may be in the centre of the product if brine has been injected. Most pathogens can be reduced to an acceptable level by cooking.	Follow the cooking requirements of the <i>Australian Standard</i> . Imported pork (without bones) must be subject to DAFF biosecurity requirements (Chapter 7.11)
	C				
	P				
5 Cooling	B	<i>C. perfringens</i> or <i>C. botulinum</i> may grow	Y	<i>C. perfringens</i> may survive cooking, germinate, grow and produce toxin during cooling.	Follow the cooling requirements in the <i>Australian Standard</i> .
	C				
	P				
6 Slicing and packing	B	Pathogens other than <i>L. monocytogenes</i>	N	Pathogens may be able to grow if the product is packed in a modified atmosphere and the gas mixture is incorrect.	Pathogens are unlikely to contaminate the product

1	2	3	4	5	
	B	<i>S. aureus</i>	Y	Transfer of <i>S. aureus</i> from workers.	Wearing of gloves, facemasks
	B	<i>L. monocytogenes</i>	Y	Contamination of the slicing and/or packing machine, or the environment transfers to product.	Control of the production environment. Formulation of product.
	C				
	P				
7. Storage	B	Pathogens such as <i>Y. enterocolitica</i> , (<i>Salmonella</i> , <i>E. coli</i>)	Y	Pathogens of concern will be able to grow at greater than 5 (7) °C.	Follow the temperature requirements of the <i>Australian Standard</i> .
	B	<i>S. aureus</i>	Y	<i>S. aureus</i> may grow and produce toxins above 10°C and these toxins may remain active until consumption.	Follow the temperature requirements of the <i>Australian Standard</i> .
	B	<i>L. monocytogenes</i>	Y	<i>L. monocytogenes</i> may grow in product.	Formulation of product.
	C				
	P				

8.3.5 CCPs and CLs

CCPs

This is a sample analysis of CCPs based on the sample hazard analysis. You need to determine the CCPs based on your own analysis of hazards (step 7) and state the validated CLs (step 8 of HACCP system development).

Process step	Significant hazard	Q1 Can the significant hazard be controlled to an acceptable level at this step by PRP (e.g. GMPs)?	Q2 Do specific control measures for the identified significant hazard exist at this step?	Q3 Will a subsequent step prevent or eliminate the identified hazard or reduce it to an acceptable level?	Q4 Can this step specifically prevent or eliminate the identified significant hazard or reduce it to an acceptable level?	CCP number
		If YES, this step is not a CCP	If YES proceed to Q3	If YES that subsequent step should be a CCP	If YES, this step is a CCP	
		If NO, proceed to Q2	If NO this step is not a CCP. Subsequent steps should be evaluated for a CCP	If NO, proceed to Q4	If NO, modify the step, process or product to implement a control measure	
1. Meat receival	Growth and toxin production by <i>S. aureus</i>	N	Y	N	Y	CCP1
	Bone or foreign objects	Y				
3. Injecting	Pathogens may be moved to the centre of the meat piece	N	Y	Y-step 4		
4. Roasting (steaming)	Pathogens may survive the cooking process	N	Y	N	Y	CCP2
5. cooling	<i>C. perfringens</i> may grow	N	Y	N	Y	CCP3

Process step	Significant hazard	Q1 Can the significant hazard be controlled to an acceptable level at this step by PRP (e.g. GMPs)?	Q2 Do specific control measures for the identified significant hazard exist at this step?	Q3 Will a subsequent step prevent or eliminate the identified hazard or reduce it to an acceptable level?	Q4 Can this step specifically prevent or eliminate the identified significant hazard or reduce it to an acceptable level?	CCP number
6. Slicing and packaging	<i>S. aureus</i> contaminates product	Y				
	<i>L. monocytogenes</i> contaminates product	Y				
7. Storage	Growth and toxin production by <i>S. aureus</i>	N	Y	N	Y	CCP4
	Growth of <i>L. monocytogenes</i>	Y				
	Growth of other pathogens	Y				

CLs

This is a sample of the CLs, monitoring and corrective actions based on the sample hazard analysis and identification of CCPs. You need to state CLs (step 8) for your CCP, establish a monitoring system (step 9), determine corrective actions (step 10), and procedures for verification (step 11 of HACCP system development) and record keeping (step 12).

CCP number	Significant hazard	CLs	Monitoring				Corrective actions	Verification activities	Records
			What	How	When	Who			
CCP1	<i>S. aureus</i> toxin production	Not greater than 5°C (<i>Australian Standard</i> clause 11.6) * **	Raw meat	Chiller temperature	Twice daily	Stores supervisor	1. Immediately chill product to correct temperature. 2. Assess safety of product for use.	1. Calibration of temperature measuring devices. 2. Weekly check of records.	Chiller log

CCP number	Significant hazard	CLs	Monitoring				Corrective actions	Verification activities	Records
			What	How	When	Who			
CCP2	Pathogens may survive the cooking process	Cooking to internal temperature of 65°C for 10 minutes or equivalent (Australian Standard clause 13.5)	Largest piece of product at the slowest warming point	Automated recording of temperature against time at slowest warming point in the largest piece	Continuously during cooking	Oven operator	Cook again	1. Ensure temperature probes are inserted correctly. 2. Ensure thermometers are calibrated. 3. Check every batch.	Cooker log
CCP3	<i>C. perfringens</i> growth and toxin production during cooling	Cooling according to Australian Standard clause 13.17 *** ****	Largest piece of product at the slowest cooling point	Automated recording of temperature against time at slowest cooling point in the largest piece	Throughout cooling. Every batch.	Chiller operator	1. Hold all product produced from last acceptable check until appropriate disposition taken based on microbiological tests. 2. Determine and eliminate the cause of the deviation;	1. Ensure temperature probes are inserted correctly. 2. Ensure thermometers are calibrated. 3. Check every batch.	Time – temperature records
CCP4	<i>S. aureus</i> toxin production	Not greater than 5°C (Australian Standard clause 11.6) **	Product	Chiller temperature	Twice daily	Stores supervisor	1. Immediately chill product to correct temperature. 2. Assess safety of product for use.	1. Calibration of temperature measuring devices. 2. Weekly check of records.	Chiller log

* some pathogens will not grow at 5° C. A guideline for CLs for raw meat that will be used in a product intended to be fully cooked by the consumer or processor can be found at [Raw Product Critical Limit Tables \(wisc.edu\)](http://www.wisc.edu/~meathaccp/therm/)

** *S. aureus* does not produce toxin below 10°C and a high level of *S. aureus* is required (Chapter 9.1). A predictive tool can be used to assess the amount of growth that may occur: <https://meathaccp.wisc.edu/therm/> Ingham, S.C., Fanslau, M.A., Burnham, G.M., Ingham, B.H., Norback, J.P., Schaffner, D.W., 2007. Predicting Pathogen Growth during Short-Term Temperature Abuse of Raw Pork, Beef, and Poultry Products: Use of an Isothermal-Based Predictive Tool. J Food Prot 70, 1445-1455.

*** or alternative time and temperature controls based on predictive models (Chapter 9.4)

**** imported pork must be cooked to also meet DAFF biosecurity requirements

Guidelines on procedures for CCPs and important GMPs can be found in the following places:

Information on CCPs

CCP1	7.1 Receiving and temperature control of raw meat
CCP2	7.11 Cooking
CCP3	7.12 Cooling
CCP4	7.18 Temperature control of finished product

Important GMPs

Step 3	1.8.2 Shelf life and growth of <i>L. monocytogenes</i> 64.4 Weighing and adding ingredients
Step 6	3.4 Keeping control of <i>Listeria</i>
Step 6	4.8 Protective cultures
Step 6	7.17 Packing

8.3.6 Validation

A safe product is one that is:

- cooked to at least 65°C for 10 minutes, or equivalent
- cooled at the site of microbiological concern, according to the requirements of the *Australian Standard*
- stored and distributed at temperature no warmer than 5°C
- formulated to prevent the growth of *L. monocytogenes* during shelf life and/or handled after heat treatment with high standards of hygiene.

8.3.7 Verification

The following microbiological criteria will be applied if there is testing undertaken by the controlling authority. Testing for these microorganisms may not necessarily be part of a regular testing program, but the production process must be designed to meet them.

You can validate whether your product supports the growth of *L. monocytogenes* following the advice in Chapter 1.8.2. It is possible to reformulate your product so that it does not support the growth of *L. monocytogenes* following the advice in Chapter 9.2.

Verification of compliance with the criterion for *L. monocytogenes* (on a single sample) is required by controlling authorities for RTE products.⁷⁹

	Number of samples (n)	Number of samples allowed to be >m but ≤M	Limit (m)	Limit (M)
Coagulase-positive staphylococci	5	1	10 ² /g	10 ³ /g
<i>Salmonella</i>	5	0	Not detected in 25g	
Product in which growth of <i>L. monocytogenes</i> can occur	5	0	Not detected in 25g	

⁷⁹ Australian Meat Regulators Group (2019) Standard 4.2.3 - Guidelines for the Management of *Listeria*.

	Number of samples (n)	Number of samples allowed to be >m but ≤M	Limit (m)	Limit (M)
Product in which growth of <i>L. monocytogenes</i> will not occur	5	0	10 ² /g	

8.4 Cured and cooked

8.4.1 Description of product

Products which are cured and then cooked include muscle meats and emulsified meat packed in an edible casing or inedible casings that are removed prior to sale. The definition of 'cured' is not found in food regulations, and refers to the addition, often of salt, nitrates and/or nitrites to preserve meat. The *Australian Standard* implies that curing requires both salt (sodium chloride) and nitrate and/or nitrite. The cooking process must be adequate to kill pathogens present at the slowest heating point (the site of microbiological concern). Cooling, particularly at the slowest cooling point (the site of microbiological concern) is important to prevent any surviving bacteria from growing, as is temperature control during storage and distribution.

The formulation of the product will determine whether *L. monocytogenes* will be able to grow in the product and this will affect the shelf life and whether a 'best before' or 'use-by'. You can validate whether your product supports the growth of *L. monocytogenes* following the advice in Chapter 1.8.2. Shelf stability of the product may also be predicted using the Shelf Stability Predictor.⁸⁰ It is possible to reformulate your product so that it does not support the growth of *L. monocytogenes* following the advice in Chapter 9.2.

This category contains muscle meats such as ham, pastrami and corned silverside, and emulsified meat packed in an edible casing, or inedible casings removed prior to sale, such as frankfurters and Strasburg. Many products are traditionally made with pork but may also be made with meat of other species, such as lamb to make a ham product.

The following sample description should be reviewed and completed (step 2 in the HACCP system development process)

Ingredients	Meat (frozen, chilled) of the required species Fat and trimmings (frozen, chilled) of the required species Salt Nitrite Spices Other ingredients
Primary Packaging	
Storage Conditions	Refrigerated: Store under refrigeration at not more than 5°C.
Shelf Life	'Best-before' date (when <i>L. monocytogenes</i> is not able to grow): x days from production. 'Use-by' date (when <i>L. monocytogenes</i> is able to grow): x days from production. Shelf life once opened: x days once opened.
Labelling related to product safety	Presence of any allergens Allergens that may be present without being listed as ingredients Keep refrigerated – store at not more than 5°C

⁸⁰ University of Wisconsin – Madison (Shelf Stability Predictor | Center for Meat Process Validation (wisc.edu))

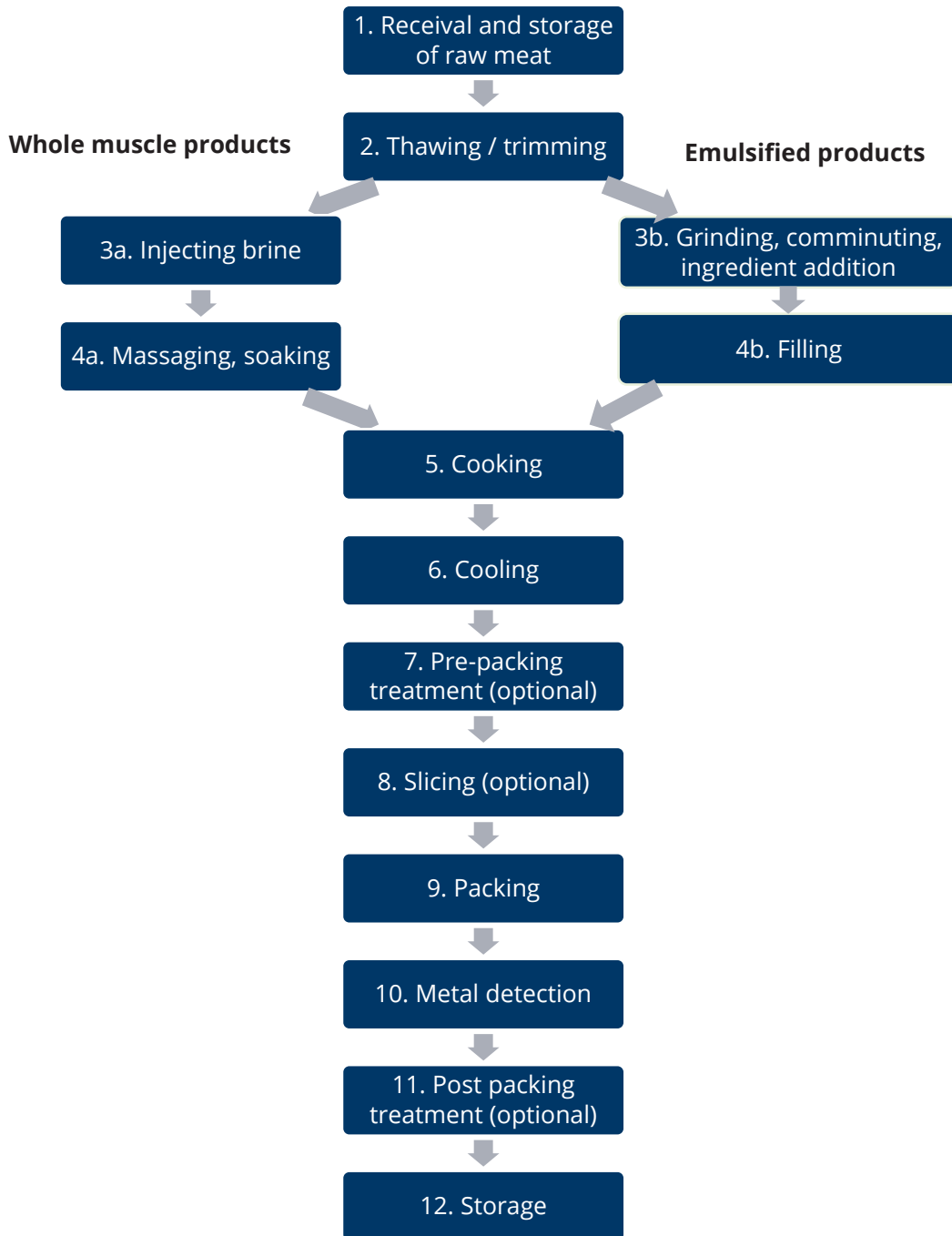
8.4.2 Intended use and users

The following sample description of intended use should be reviewed and completed (step 3 in the HACCP system development process).

Sensitive Consumer	
Customer Preparation	RTE, but some products are warmed before consumption

8.4.3 Flow diagram

The process flow may vary between products and with available equipment. This is a sample flow diagram, used to prepare the sample HACCP analysis. Constructing your own flow diagram and on-site confirmation of the process are two steps (steps 4 and 5) in the HACCP system development.



8.4.4 Potential hazards and control measures

This is a sample hazard analysis based on the sample flow diagram. You need to conduct your own hazard analysis based on your product, production process, and circumstances (Step 6 of HACCP system development)

1	2	3	4	5
Step	Identify potential hazards	Does this potential hazard need to be addressed in the HACCP plan	Justification for decision in column 3	What measure(s) can be applied to prevent or eliminate the hazard or reduce it to an acceptable level
		YES NO		
1. Meat receival and storage	B Pathogens All meat: <i>Salmonella</i> , <i>S. aureus</i> , <i>L. monocytogenes</i> , <i>C. botulinum</i> , <i>C. perfringens</i> Beef: pathogenic <i>E. coli</i> Pork: <i>Y. enterocolitica</i> , <i>T. spiralis</i> (imported product only) Lamb: pathogenic <i>E. coli</i> Chicken – <i>Campylobacter</i> sp.	N	The prevalence and/or concentration of these pathogens in Australian meat is low. Imported pork (without bones) can be used but must be subject to DAFF biosecurity requirements (Chapter 7.11).	Customer will cook the product.
	B <i>S. aureus</i>	Y	<i>S. aureus</i> may grow and produce toxins above 10°C and these toxins may remain active until consumption.	Follow the temperature requirements of the <i>Australian Standard</i> .
	C Chemical residues	N	Controlled by slaughter establishment. Imported product will meet Australian requirements.	

1	2	3	4	5
	P Bone splinters, plastic, foreign objects		N	Purchase to specification from approved supplier. Visual inspection of meat pieces during trimming.
2. Thawing / trimming	B Bacterial pathogens	Y		Growth of pathogens could occur if temperature is not controlled.
	C			
	P Soft plastic		N	May be trapped or torn when product is unevenly thawed (polyentrapment). Soft plastic is not a hazard.
3a. Injecting brine	B <i>C. botulinum</i>	Y		Growth and toxin production can cause serious intoxication and death
	C			
	P Metal fragments in product	Y		Injection needles can break. Examination of needles.
3b. Grinding, comminuting, ingredient addition	B <i>C. botulinum</i>	Y		Growth and toxin production can cause serious intoxication and death.
	C			
	P Metal fragments in product	Y		Chopper, grinder may lose metal Inspection of equipment
4a. Massaging, soaking	B <i>C. botulinum</i> <i>S. aureus</i>	Y		Growth and toxin production. Addition of correct quantity of nitrite and/or low temperature maintained during the process.

1	2	3	4	5	
	C				
	P				
4b. Filling	B				
	C				
	P				
5. Cooking	B	Pathogens (<i>Salmonella</i> , pathogenic <i>E. coli</i> , <i>Y. enterocolitica</i> , <i>L. monocytogenes</i> , <i>S. aureus</i>)	Y	Survival of pathogens.	Cooking to 65°C for 10 minutes (<i>Australian Standard</i>) or equivalent. Imported pork (without bones) must be subject to DAFF biosecurity requirements (Chapter 7.11).
	C				
	P				
6. Cooling	B	Spore forming bacteria (<i>C. perfringens</i> , <i>C. botulinum</i>)	Y	Germination of spores, growth and production of toxins.	Cooling according to requirements of the <i>Australian Standard</i> .
	C				
	P				
7. Pre-packing treatment (optional)	B				
	C				
	P				
8. Slicing (optional)	B	<i>S. aureus</i>	Y	Transfer of <i>S. aureus</i> from workers.	Wearing of gloves, face masks.

1	2	3	4	5
	B <i>L. monocytogenes</i>	Y	Contamination of the slicing machine, or the environment transfers to product.	Control of the production environment. Formulation of product.
	C			
	P			
9. Packing	B Pathogens other than <i>L. monocytogenes</i>	N	Pathogens may be able to grow if the product is packed in a modified atmosphere and the gas mixture is incorrect.	Pathogens are unlikely to contaminate the product.
	B <i>S. aureus</i>	Y	Transfer of <i>S. aureus</i> from workers.	Wearing of gloves.
	B <i>L. monocytogenes</i>	Y	Contamination of the packing machine, or the environment transfers to product.	Control of the production environment.
	C			
	P			
10. Metal detection	B			
	C			
	P			
11. Post-packing treatment (optional)	B			
	C			
	P			
12. Storage	B Pathogens, <i>Y. enterocolitica</i> , (<i>Salmonella</i> , <i>E. coli</i>)	Y	Pathogens of concern will be able to grow at greater than 5 (7) °C.	Follow the temperature requirements of the <i>Australian Standard</i> plus other controls if allowed.

1	2	3	4	5
	B <i>S. aureus</i>	Y	<i>S. aureus</i> may grow and produce toxins above 10°C.	Follow the temperature requirements of the <i>Australian Standard</i> .
	B <i>L. monocytogenes</i>	Y	<i>L. monocytogenes</i> may grow in product.	
	C			
	P			

8.4.5 CCPs and CLs

This is a sample analysis of CCPs based on the sample hazard analysis. You need to determine the CCPs based on your own analysis of hazards (step 7) and state the validated CLs (step 8 of HACCP system development).

CCPs

Process step	Significant hazard	Q1 Can the significant hazard be controlled to an acceptable level at this step by PRP (e.g. GMPs)?	Q2 Do specific control measures for the identified significant hazard exist at this step?	Q3 Will a subsequent step prevent or eliminate the identified hazard or reduce it to an acceptable level?	Q4 Can this step specifically prevent or eliminate the identified significant hazard or reduce it to an acceptable level?	CCP number
		If YES, this step is not a CCP	If YES proceed to Q3	If YES that subsequent step should be a CCP	If YES, this step is a CCP	

Process step	Significant hazard	Q1 Can the significant hazard be controlled to an acceptable level at this step by PRP (e.g. GMPs)?	Q2 Do specific control measures for the identified significant hazard exist at this step?	Q3 Will a subsequent step prevent or eliminate the identified hazard or reduce it to an acceptable level?	Q4 Can this step specifically prevent or eliminate the identified significant hazard or reduce it to an acceptable level?	CCP number
		If NO, proceed to Q2	If NO this step is not a CCP. Subsequent steps should be evaluated for a CCP	If NO, proceed to Q4	If NO, modify the step, process or product to implement a control measure	
1. Meat receival and storage	<i>S. aureus</i> grows and produces toxin in raw meat	N	Y	N	Y	CCP1
2. Thawing / trimming	Bacterial pathogens grow during thawing/trimming	N	Y	Y (step 5)		
3a /3b	Nitrites can cause adverse reactions in consumers if the level is too high. Too low nitrites could allow pathogens such as <i>C. botulinum</i> to grow. Salt must be added at the correct level to inhibit growth of pathogens such as <i>E. coli</i> and <i>Salmonella</i> .	Y				
3a Injecting brine /3b grinding, comminuting, ingredient addition	<i>S. aureus</i> growth and toxin production	N	Y	N	Y	CCP2
	Metal fragments in product	Y				

Process step	Significant hazard	Q1 Can the significant hazard be controlled to an acceptable level at this step by PRP (e.g. GMPs)?	Q2 Do specific control measures for the identified significant hazard exist at this step?	Q3 Will a subsequent step prevent or eliminate the identified hazard or reduce it to an acceptable level?	Q4 Can this step specifically prevent or eliminate the identified significant hazard or reduce it to an acceptable level?	CCP number
4a	Growth and toxin production by <i>S. aureus</i>	N	Y	N	Y	CCP2
5. Cooking	Pathogens survive cooking	N	Y	N	Y	CCP3
6. Cooling	Spores germinate, grow, and produce toxin during cooling	N	Y	N	Y	CCP4
8. Slicing	<i>S. aureus</i> contaminates product and is able to grow and produce toxin	Y				
	<i>L. monocytogenes</i> contaminates and grows in product	Y				
9. Packing	<i>S. aureus</i> contaminates product, grows and produces toxin	Y				
	<i>L. monocytogenes</i> contaminates and grows in product	Y				
12. Storage	Growth of pathogens during storage	Y				
	Growth of <i>L. monocytogenes</i> during storage	Y				
	Growth and toxin production by <i>S. aureus</i> during storage	N	Y	N	Y	CCP5

CLs

This is a sample of the CLs, monitoring and corrective actions based on the sample hazard analysis and identification of CCPs. You need to state CLs (step 8) for your CCP, establish a monitoring system (step 9), determine corrective actions (step 10), and procedures for verification (step 11 of HACCP system development).

CCP number	Significant hazard	CLs	Monitoring				Corrective actions	Verification activities	Records
			What	How	When	Who			
CCP1	<i>S. aureus</i> toxin production	Not greater than 5°C (<i>Australian Standard</i> clause 11.6) * **	Raw meat	Chiller temperature	Twice daily	Stores supervisor	1. Immediately chill product to correct temperature. 2. Assess safety of product for use.	1. Calibration of temperature measuring devices. 2. Weekly check of records.	Chiller log
CCP2	<i>S. aureus</i> toxin production	Not greater than 5°C (<i>Australian Standard</i> clause 13.3) **	Brine	Brine temperature	Twice daily	Production supervisor	1. Immediately chill product to correct temperature. 2. Assess safety of product for use.	1. Calibration of temperature measuring devices. 2. Weekly check of records.	Brine log
CCP3	Pathogens survive the cooking process	65°C for 10 minutes or equivalent (<i>Australian Standard</i> clause 13.5)****	Largest piece of product at the slowest warming point	Automated recording of temperature against time at slowest warming point in the largest piece	Continuously during cooking	Oven operator	Cook again	1. Ensure temperature probes are inserted correctly. 2. Ensure thermometers are calibrated 3. Check every batch.	Cooker log

CCP number	Significant hazard	CLs	Monitoring				Corrective actions	Verification activities	Records
			What	How	When	Who			
CCP4	<i>C. perfringens</i> growth and toxin production during cooling	Cooling according to <i>Australian Standard</i> clause 13.17 ***	Largest piece of product at the slowest cooling point	Automated recording of temperature against time at slowest cooling point in the largest piece	Throughout cooling. Every batch.	Chiller operator	1. Hold all product produced from last acceptable check until appropriate disposition taken based on microbiological tests. 2. Determine and eliminate the cause of the deviation.	1. Ensure temperature probes are inserted correctly. 2. Ensure thermometers are calibrated. 3. Check every batch.	Time – temperature records
CCP5	<i>S. aureus</i> toxin production	Not greater than 5°C (<i>Australian Standard</i> clause 11.6 **)	Product	Chiller temperature	Twice daily	Stores supervisor	1. Immediately chill product to correct temperature. 2. Assess safety of product for use.	1. Calibration of temperature measuring devices. 2. Weekly check of records.	Chiller log

* some pathogens will not grow at 5° C. A guideline for CLs for raw meat that will be used in a product intended to be fully cooked by the consumer or processor can be found at [Raw Product Critical Limit Tables \(wisc.edu\)](http://www.wisc.edu/~meathaccp/therm/)

** *S. aureus* does not produce toxin below 10°C and a high level of *S. aureus* is required (Chapter 9.1). A predictive tool can be used to assess the amount of growth that may occur: <https://meathaccp.wisc.edu/therm/> Ingham, S.C., Fanslau, M.A., Burnham, G.M., Ingham, B.H., Norback, J.P., Schaffner, D.W., 2007. Predicting Pathogen Growth during Short-Term Temperature Abuse of Raw Pork, Beef, and Poultry Products: Use of an Isothermal-Based Predictive Tool. J Food Prot 70, 1445-1455.

*** or alternative time and temperature controls based on predictive models (Chapter 9.4)

**** imported pork must be cooked to also meet DAFF biosecurity requirements

Guidelines on procedures for CCPs and important GMPs can be found in the following places:

Information on CCPs

CCP1	7.1 Receiving and temperature control of raw meat
CCP2	7.5 Massaging, tumbling, injecting and curing
CCP2	7.11 Cooking
CCP3	7.12 Cooling
CCP4	7.18 Temperature control of finished product

Important GMPs

Step 1	7.1 Receiving and temperature control of raw meat
Step 3a/3b	4.4 Weighing and adding ingredients 1.8.2 Shelf life and growth of <i>L. monocytogenes</i>
Steps 8,9,11,12	3.4 Keeping control of <i>Listeria</i> 4.8 Protective cultures 7.16 Slicing 7.17 Packing
Step 12	7.18 Temperature control of finished product

8.4.6 Validation

A safe product is one that:

- Curing agents are present at a level which preserves the product (the *Australian Standard* requires a “minimum of 2.5% salt on water phase and 100 ppm nitrite in-going” in products using the cooling standard for cured products). However, low-salt meats may contain a lower level of salt.
- Products receive a heat treatment of at least 65°C for 10 minutes or an equivalent process.
- Cooling conforms with the requirements of the *Australian Standard* or with an alternative arrangement approved by the controlling authority.
- Storage, distribution, and retail temperatures no warmer than 5°C.
- Is formulated to prevent the growth of *L. monocytogenes* during shelf life and/or handled after cooking with high standards of hygiene.

8.4.7 Verification

The following microbiological criteria will be applied if there is testing undertaken by the controlling authority. Testing for these microorganisms may not necessarily be part of a regular testing program, but the production process must be designed to meet them.

You can validate whether your product supports the growth of *L. monocytogenes* following the advice in Chapter 1.8.2. It is possible to reformulate your product so that it does not support the growth of *L. monocytogenes* following the advice in Chapter 9.2.

Verification of compliance with the criterion for *L. monocytogenes* (on a single sample) is required by controlling authorities for RTE products.⁸¹

	Number of samples (n)	Number of samples allowed to be >m but ≤M	Limit (m)	Limit (M)
Coagulase-positive staphylococci	5	1	10 ² /g	10 ³ /g
<i>Salmonella</i>	5	0	Not detected in 25g	
Product in which growth of <i>L. monocytogenes</i> can occur	5	0	Not detected in 25g	
Product in which growth of <i>L. monocytogenes</i> will not occur	5	0	10 ² /g	

8.5 Pâtés and similar products

8.5.1 Description of product

Pâtés, liverwursts and terrines (including brawn) are an emulsion of cooked, cooled and packaged meat or offal (which may contain meat pieces). Gelatine or a garnish, such as cracked pepper, may be added to the surface. Nitrite is added to some pâtés to give a red colour.

Technology for pâté manufacture varies mainly in how the product is cooked. A jacketed bowl chopper introduces steam for cooking and water for cooling. This allows several operations to be performed in the same piece of equipment.

An alternative method is to cook the meat/offal on a stove and blend it in a non-jacketed chopper.

Pâtés may be packed in various forms from a loaf of about 1kg, which is sliced to order in delicatessens, to small retail vacuum-packs.

You can validate whether your product supports the growth of *L. monocytogenes* following the advice in Chapter 1.8.2. It is possible to reformulate your product so that it does not support the growth of *L. monocytogenes* following the advice in Chapter 9.2.

The following sample description should be reviewed and completed (step 2 in the HACCP system development process)

Ingredients	Meat (frozen, chilled) of the required species Offals of the required species Gelatine Nitrite Salt Spices Other ingredients
Primary Packaging	
Storage Conditions	Refrigerated: Store under refrigeration not more than 5°C.

⁸¹ Australian Meat Regulators Group (2019) Standard 4.2.3 - Guidelines for the Management of Listeria.

Shelf Life	'Best-before' (if pathogens are not able to grow) or 'use-by' (if pathogens are able to grow) date: x days from production. Shelf life once opened: x days once opened.
Labelling related to product safety	Keep refrigerated: store at no more than 5°C Presence of any allergens Allergens that may be present without being listed as ingredients

8.5.2 Intended use and users

The following sample description of intended use should be reviewed and completed (step 3 in the HACCP system development process)

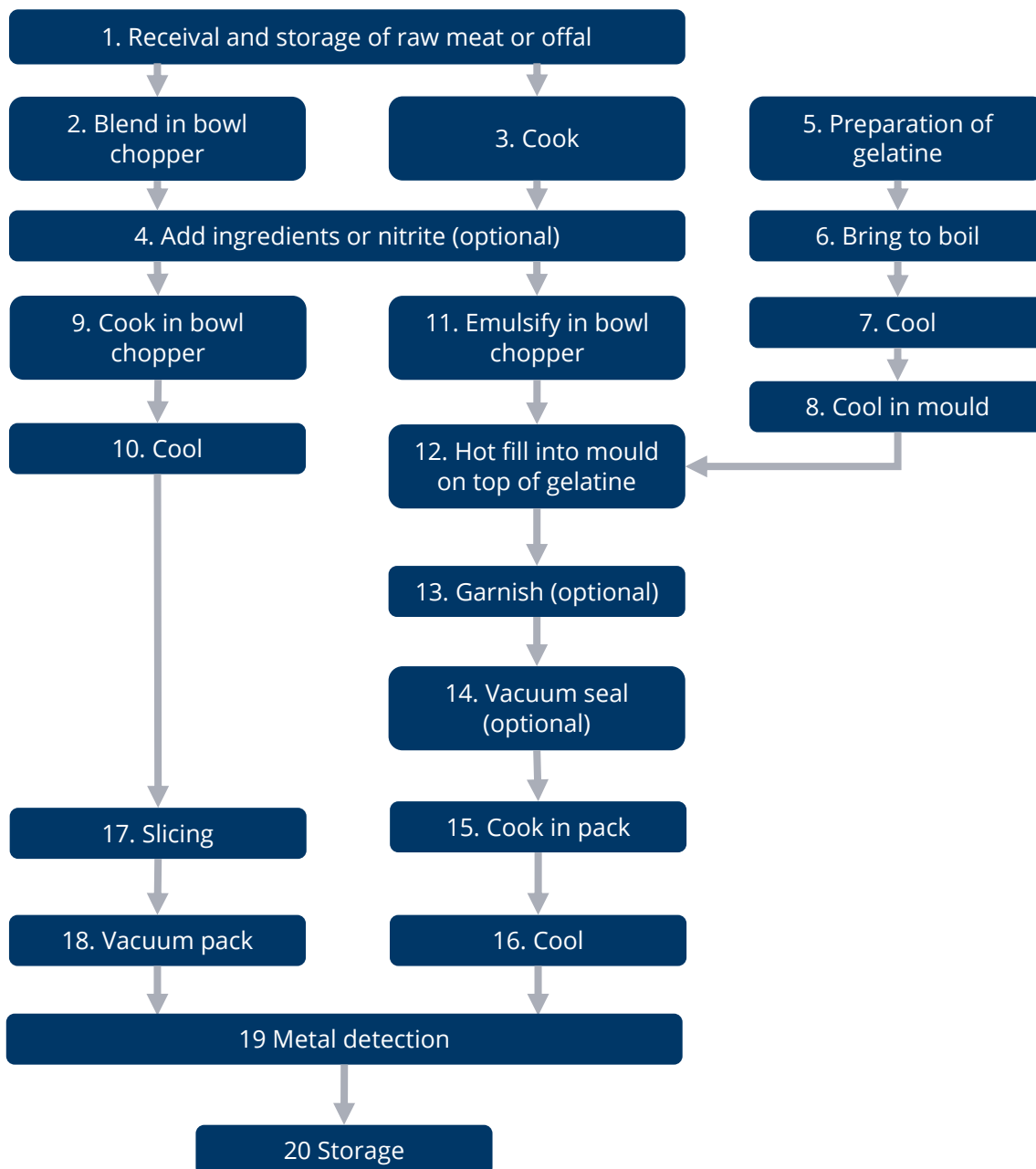
Sensitive Consumer	
Customer Preparation	RTE

8.5.3 Flow diagram

The process flow may vary between products and with available equipment. This sample flow diagram, presents two different methods that may be used to prepare pâté:

1. cook/cool in bowl chopper
2. cook in pack

which are then analysed in the sample HACCP analysis. Constructing your own flow diagram and on-site confirmation of the process are two steps (steps 4 and 5) in the HACCP system development.



8.5.4 Potential hazards and control measures

This is a sample hazard analysis based on the sample flow diagram. You need to conduct your own hazard analysis based on your product, production process, and circumstances (Step 6 of HACCP system development)

1	2	3	4	5
Step	Identify potential hazards	Does this potential hazard need to be addressed in the HACCP plan	Justification for decision in column 3	What measure(s) can be applied to prevent or eliminate the hazard or reduce it to an acceptable level
		YES NO		
1. Reveal and storage of raw meat and offals	B Pathogens All meat: <i>Salmonella</i> , <i>S. aureus</i> , <i>L. monocytogenes</i> , <i>C. botulinum</i> , <i>C. perfringens</i> Beef: pathogenic <i>E. coli</i> Pork: <i>Y. enterocolitica</i> Lamb: pathogenic <i>E. coli</i> Chicken – <i>Campylobacter</i> sp.	N	The prevalence and/or concentration of these pathogens in Australian meat is low. Imported pork (without bones) can be used but must be subject to DAFF biosecurity requirements (Chapter 7.11).	Customer will cook the product.
	B <i>S. aureus</i>	Y	<i>S. aureus</i> may grow and produce toxins above 10°C and these toxins may remain active until consumption.	Follow the temperature requirements of the <i>Australian Standard</i> .
	C Chemical residues	N	Controlled by slaughter establishment.	
	P Bone splinters Plastic Foreign objects	N		Purchase to specification from approved supplier. Visual inspection of meat pieces.
	B			
C				

1	2	3	4	5	
2. Blending in bowl chopper	P	Metal fragments	Y	Metal fragments may be lost from bowl chopper.	Inspect for metal loss, and use metal detector on product.
	B	Pathogens	Y	Pathogens may survive cooking.	Cook according to the <i>Australian Standard</i> . Imported pork (without bones) but must be subject to DAFF biosecurity requirements (Chapter 7.11).
	C				
3. Cooking	P				
	B	Pathogens	Y	Ingredients may contain pathogens.	Cook according to the <i>Australian Standard</i> .
	C	Nitrite	Y	Correct amount to control <i>C. botulinum</i> without being toxic.	Careful control of ingredient weight out and addition.
4. Add ingredients and nitrite (optional)	P				
	B	Pathogens	Y	Salmonella or other pathogens may be present.	Purchase from approved suppliers. Boiling is sufficient to destroy non-spore forming pathogens.
	C				
5. Preparation of gelatine	P				
	B				
	C				
6. Bring to boil	B				
	C				
	P				

1	2	3	4	5
7. Cool	B <i>C. perfringens</i>	Y	May grow and produce toxin if cooling is too slow – combined with step 8.	Cool according to the <i>Australian Standard</i> requirements.
	C			
	P			
8. Cool in mould	B <i>C. perfringens</i>	Y	May grow and produce toxin if cooling is too slow – combined with step 8.	Cool according to the <i>Australian Standard</i> requirements.
	C			
	P			
9. Cook in bowl chopper	B Pathogens	Y	Pathogens may survive cooking.	Cook according to the <i>Australian Standard</i> .
	C			
	P			
10. Cooling	B <i>C. perfringens</i>	Y	May grow and produce toxin if cooling is too slow.	Cool according to the <i>Australian Standard</i> requirements.
	C			
	P			
11. Emulsify in bowl chopper	B Pathogens	Y	Pathogens may contaminate the product after cooking.	
	C			
	P Metal fragments	Y	Metal fragments may be lost from bowl chopper.	Inspect for metal loss, and use metal detector on product.

1	2	3	4	5
12. Hot fill into mould on top of gelatine	B Pathogens	Y	Pathogens may contaminate the product after cooking.	
	C			
	P			
13. Garnish (optional)	B Pathogens	Y	Pathogens in garnish ingredients will not receive heat treatment.	Source of garnish ingredients must be carefully controlled, and treatment to control pathogens applied, if possible.
	C			
	P			
14. Vacuum pack (optional)	B			
	C			
	P			
15. Cook in pack	B Pathogens	Y	Pathogens may survive cooking.	Cook according to the <i>Australian Standard</i> .
	C			
	P			
16. Cool	B <i>C. perfringens</i>	Y	May grow and produce toxin if cooling is too slow – combine with step 15.	Cool according to the <i>Australian Standard</i> requirements.
	C			
	P			
17. Slicing	B Pathogens other than <i>S. aureus</i> and <i>L. monocytogenes</i>	N	Pathogens, may contaminate product from environment or equipment.	Careful attention to environmental and equipment hygiene.

1	2	3	4	5
	B <i>S. aureus</i>	Y	Transfer of <i>S. aureus</i> from workers.	Wearing of gloves, face masks.
	B <i>L. monocytogenes</i>	Y	Contamination of the slicing machine, or the environment transfers to product.	Control of the production environment. Formulation of product.
	C			
	P			
18. Vacuum pack	B Pathogens	Y	Pathogens, particularly <i>L. monocytogenes</i> , may contaminate product from environment or equipment.	Careful attention to environmental and equipment hygiene.
	B <i>S. aureus</i>	Y	Transfer of <i>S. aureus</i> from workers.	Wearing of gloves.
	B <i>L. monocytogenes</i>	Y	Contamination of the packing machine, or the environment transfers to product.	Control of the production environment. Formulation of product.
	C			
	P			
19. Metal detection	B			
	C			
	P			
20. Storage	B Pathogens such as <i>Y. enterocolitica</i> , (<i>Salmonella</i> , <i>E. coli</i>)	Y	Pathogens of concern will be able to grow at greater than 5 (7) °C.	Follow the temperature requirements of <i>Australian Standard</i> . Formulation of product.
	B <i>S. aureus</i>	Y	<i>S. aureus</i> may grow and produce toxins above 10°C and these toxins may remain active until consumption.	Follow the temperature requirements of the <i>Australian Standard</i> .

1	2	3	4	5
	B <i>L. monocytogenes</i>	Y	<i>L. monocytogenes</i> may grow in product.	Formulation of product.
	C			
	P			

8.5.5 CCPs and CLs

CCPs

This is a sample analysis of CCPs based on the sample hazard analysis and on the flow chart presented. You need to determine the CCPs based on your own flowchart (steps 4 and 5) analysis of hazards (step 7) and state the validated CLs (step 8 of HACCP system development).

In the sample flow diagrams there are multiple cooking steps, and only the last cooking step is considered a CCP. There are also several cooling steps, and every cooling step is considered to be a CCP, because if *C. perfringens* germinates, grows and produces toxin, that toxin will remain after a subsequent cooking step.

Process step	Significant hazard	Q1 Can the significant hazard be controlled to an acceptable level at this step by PRP (e.g. GMPs)?	Q2 Do specific control measures for the identified significant hazard exist at this step?	Q3 Will a subsequent step prevent or eliminate the identified hazard or reduce it to an acceptable level?	Q4 Can this step specifically prevent or eliminate the identified significant hazard or reduce it to an acceptable level?	CCP number
		If YES, this step is not a CCP	If YES proceed to Q3	If YES that subsequent step should be a CCP	If YES, this step is a CCP	
		If NO, proceed to Q2	If NO this step is not a CCP. Subsequent steps should be evaluated for a CCP	If NO, proceed to Q4	If NO, modify the step, process or product to implement a control measure	

Process step	Significant hazard	Q1 Can the significant hazard be controlled to an acceptable level at this step by PRP (e.g. GMPs)?	Q2 Do specific control measures for the identified significant hazard exist at this step?	Q3 Will a subsequent step prevent or eliminate the identified hazard or reduce it to an acceptable level?	Q4 Can this step specifically prevent or eliminate the identified significant hazard or reduce it to an acceptable level?	CCP number
1. Reveal and storage of raw meat and offals	<i>S. aureus</i> may grow and produce toxin in raw meat if not stored at correct temperature	N	Y	N	Y	CCP1
2. Blending in bowl chopper	Metal fragments from bowl chopper	Y				
3. Cooking	Pathogens may survive cooking	N	Y	Y (step 15)		
4. Add ingredients and nitrite (optional)	Ingredients may contain pathogens	N	Y	Y (steps 9 or 15)		
	Incorrect quantity of nitrite	Y				
5. Preparation of gelatine	Pathogens in gelatine	N	N	Y (step 15)		
7. Cool 8. Cool in mould	<i>C. perfringens</i> may grow and produce toxin if cooling is too slow	N	Y	N	Y	CCP2
9. Cook in bowl chopper	Pathogens may survive cooking	N	Y	N	Y	CCP3

Process step	Significant hazard	Q1 Can the significant hazard be controlled to an acceptable level at this step by PRP (e.g. GMPs)?	Q2 Do specific control measures for the identified significant hazard exist at this step?	Q3 Will a subsequent step prevent or eliminate the identified hazard or reduce it to an acceptable level?	Q4 Can this step specifically prevent or eliminate the identified significant hazard or reduce it to an acceptable level?	CCP number
10. Cooling	<i>C. perfringens</i> may grow and produce toxin if cooling is too slow	N	Y	N	Y	CCP2
11. Emulsify in bowl chopper	Pathogens may survive if they contaminate the product after cooking	N	Y	Y (step 15)		
	Metal fragments may be lost from bowl chopper	Y				
12. Hot fill into mould on top of gelatine	Pathogens may survive if they contaminate the product after cooking	N	Y	Y (step 15)		
13. Garnish (optional)	Pathogens in garnish ingredients will not receive heat treatment	N	Y	Y (step 15)		
15. Cook in pack	Pathogens may survive cooking	N	Y	N	Y	CCP3
16. Cool in blast chiller	<i>C. perfringens</i> may grow and produce toxin if cooling is too slow	N	Y	N	Y	CCP2
17. Slicing	<i>L. monocytogenes</i> may contaminate product from environment or equipment	Y				
	<i>S. aureus</i> may grow and produce toxin					
18. Vacuum pack	<i>L. monocytogenes</i> may contaminate product from environment or equipment	Y				

Process step	Significant hazard	Q1 Can the significant hazard be controlled to an acceptable level at this step by PRP (e.g. GMPs)?	Q2 Do specific control measures for the identified significant hazard exist at this step?	Q3 Will a subsequent step prevent or eliminate the identified hazard or reduce it to an acceptable level?	Q4 Can this step specifically prevent or eliminate the identified significant hazard or reduce it to an acceptable level?	CCP number
	<i>S. aureus</i> may grow and produce toxin					
20. Chill storage	Pathogens grow in product if it is not stored correctly	Y				
	<i>L. monocytogenes</i> able to grow in product	Y				
	<i>S. aureus</i> may grow and produce toxin in product	N	Y	N	Y	CCP4

CLs

This is a sample of the CLs, monitoring and corrective actions based on the sample hazard analysis and identification of CCPs. You need to state CLs (step 8) for your CCP, establish a monitoring system (step 9), determine corrective actions (step 10), and procedures for verification (step 11 of HACCP system development).

These CCPs may relate to multiple steps in the flow diagram (in part, because there are two alternate methods of producing the product) but they operate in the same way.

CCP number	Significant hazard	CLs	Monitoring				Corrective actions	Verification activities	Records
			What	How	When	Who			
CCP1	<i>S. aureus</i> toxin production	Not greater than 5°C (<i>Australian Standard</i> clause 11.6) * **	Raw meat	Chiller temperature	Twice daily	Stores supervisor	1. Immediately chill product to correct temperature. 2. Assess safety of product for use.	1. Calibration of temperature measuring devices. 2. Weekly check of records.	Chiller log

CCP number	Significant hazard	CLs	Monitoring				Corrective actions	Verification activities	Records
			What	How	When	Who			
CCP2	<i>C. perfringens</i> growth and toxin production during cooling	Cooling according to the <i>Australian Standard</i> clause 13.17(a), and 13.20(a) ***	Largest piece of product at the slowest cooling point	Automated recording of temperature against time at slowest cooling point in the largest piece	Throughout cooling. Every batch.	Chiller operator	1. Hold all product produced from last acceptable check until appropriate disposition taken based on microbiological tests. 2. Determine and eliminate the cause of the deviation.	1. Ensure temperature probes are inserted correctly. 2. Ensure thermometers are calibrated. 3. Check every batch.	Time – temperature records
CCP3	Pathogens may survive the cooking process	Cooking to internal temperature of 65°C for 10 minutes or equivalent (<i>Australian Standard</i> clause 13.5) ****	At the slowest warming point	Automated recording of temperature against time at slowest warming point	Continuously during cooking	Oven operator	Cook again	1. Ensure temperature probes are inserted correctly. 2. Ensure thermometers are calibrated 3. Check every batch.	Cooker log
CCP4	<i>S. aureus</i> toxin production	Not greater than 5°C (<i>Australian Standard</i> clause 11.6) **	Product	Chiller temperature	Twice daily	Stores supervisor	1. Immediately chill product to correct temperature. 2. Assess safety of product for use.	1. Calibration of temperature measuring devices. 2. Weekly check of records.	Chiller log

* some pathogens will not grow at 5° C. A guideline for CLs for raw meat that will be used in a product intended to be fully cooked by the consumer or processor can be found at [Raw Product Critical Limit Tables \(wisc.edu\)](http://www.wisc.edu/~meathaccp/therm/)

** *S. aureus* does not produce toxin below 10°C and a high level of *S. aureus* is required (Chapter 9.1). A predictive tool can be used to assess the amount of growth that may occur: <https://meathaccp.wisc.edu/therm/> Ingham, S.C., Fanslau, M.A., Burnham, G.M., Ingham, B.H., Norback, J.P., Schaffner, D.W., 2007. Predicting Pathogen Growth during Short-Term Temperature Abuse of Raw Pork, Beef, and Poultry Products: Use of an Isothermal-Based Predictive Tool. J Food Prot 70, 1445-1455.

*** or alternative time and temperature controls based on predictive models (Chapter 9.4)

**** imported pork must be cooked to also meet DAFF biosecurity requirements

Information on CCPs

CCP1	7.1 Receiving and temperature control of raw meat
CCP2	7.12 Cooling
CCP3	7.11 Cooking
CCP4	7.18 Temperature control of finished product

Important GMPs

Step 2, 11	4.7 Physical contamination – and foreign body detection
Step 4	4.4 Weighing and adding ingredients 1.8.2 Shelf life and growth of <i>L. monocytogenes</i>
Step 17, 18	3.3 Environmental monitoring and microbiological verification
3.4 Keeping control of <i>Listeria</i>	4.8 Protective cultures 7.17 Packing
Step 19	4.7 Physical contamination – and foreign body detection
Step 20	7.18 Temperature control of finished product

8.5.6 Validation

A safe product is one that:

- cooks all ingredients to at least 65°C for 10 minutes or equivalent
- cools according to the *Australian Standard*
- has hygiene controls and GMPs for post-process handling and packing
- storage, distribution and retail temperatures no warmer than 5°C.

8.5.7 Verification

The following microbiological criteria will be applied if there is testing undertaken by the regulator. Testing for these microorganisms may not necessarily be part of a regular testing program, but the production process must be designed to meet them.

You can validate whether your product supports the growth of *L. monocytogenes* following the advice in Chapter 1.8.2. It is possible to reformulate your product so that it does not support the growth of *L. monocytogenes* following the advice in Chapter 9.2.

Verification of compliance with the criterion for *L. monocytogenes* (on a single sample) is required by controlling authorities for RTE products.⁸²

	Number of samples (n)	Number of samples allowed to be >m but ≤M	Limit (m)	Limit (M)
<i>Salmonella</i>	5	0	Not detected in 25g	
Product in which growth of <i>L. monocytogenes</i> can occur	5	0	Not detected in 25g	
Product in which growth of <i>L. monocytogenes</i> will not occur	5	0	10 ² /g	

8.6 Dried meats

8.6.1 Description of product

Dried meats are low moisture, air- or oven-dried products. Both the *Food Standards Code* and the *Australian Standard* define dried meats in terms of the final water activity (a_w) of the product being below 0.85.

Jerky and Biltong are typical of low moisture (about 20%) meat products which are salted and then dried. Their processes differ – meat for jerky is salted under refrigeration and usually dried at a moderate temperature (55–65°C) while meat for Biltong is cured with salt and vinegar before drying at ambient temperature (around 30°C) with high air movement. Jerky relies on salting and heat treatment to make it safe, whereas Biltong relies on a series of controls each of which only partially address food safety concerns.

Since the safety of Biltong relies on a series of controls each of which only partially address food safety concerns, and production processes vary considerably, the specific process must be carefully validated.

Some of the processes relevant to food safety are:

- Slicing, which reduces the thickness of raw meat to allow uniform take-up of salt and also allows uniform drying of the product which helps prevent bacterial growth.
- Salting, which lowers the water activity (a_w) in meat, which also inhibits the growth of many pathogens. Lean strips of meat are put in a salt solution of around 6%. The final result is a salt solution in the meat of around 3% (assuming meat moisture content of around 70%). Salt lowers the water activity of the meat and slows the growth of some pathogenic and spoilage bacteria. Brining may occur over several days in a chill room. Some processors use raw salt packed around meat strips. Salting controls pathogens such as *Salmonella* and pathogenic *E. coli* because it prevents their growth. *S. aureus* is salt tolerant and its growth is controlled by refrigeration during brining or by the low pH due to use of vinegar.
- Nitrite addition to improve the colour of jerky. Using nitrite in both products will also help to control pathogens. A concentration of no more than 125 mg/kg (ppm) nitrite does not cause a toxic reaction in consumers.
- Drying for Jerky occurs in a hot air oven which is preheated to around 45°C before the meat is loaded on the racks. It takes around three hours to bring the oven temperature back to 45°C. From then on, the oven cycles between 55-65°C. Moisture is progressively removed over five hours. For Biltong, drying occurs at a lower temperature (about 25-30°C) for several days or even weeks. Large scale processes with specialised equipment can often reduce the time of drying to just a few days, which improves the

⁸² Australian Meat Regulators Group (2019) Standard 4.2.3 - Guidelines for the Management of Listeria.

product safety. After drying, the moisture content of Jerky is 30-35% and the salt content is 11-12%. Drying controls the growth pathogens such as *Salmonella*, pathogenic *E. coli* and *S. aureus*, and may lead to a reduction in numbers.

- Packaging to prevent mould growth for product with an a_w of >0.7. Packaging should:
 - have low oxygen and moisture transmission rates
 - contain an oxygen scavenger.

The use of sugar and other sweeteners, and soy sauce (which contains salt and is acidic) can also contribute to lowering the water activity of the product. Jerky may be smoked.

Dried meats are shelf stable products. Therefore, they are excluded from microbiological criteria for *L. monocytogenes*, which applies only to RTE foods (as defined in Standard 1.6.1 of the *Food Standards Code*).

The following sample description should be reviewed and completed (step 2 in the HACCP system development process)

Ingredients	Beef (frozen, chilled), or other species Salt Sugar Vinegar Nitrite Spices (e.g. black pepper, coriander) Smoke Other ingredients
Primary Packaging	
Storage Conditions	Ambient storage
Shelf Life	'Best before' date: x days from production. Shelf life once opened: x days once opened.
Labelling related to product safety	Presence of allergens Allergens that may be present without being listed as ingredients

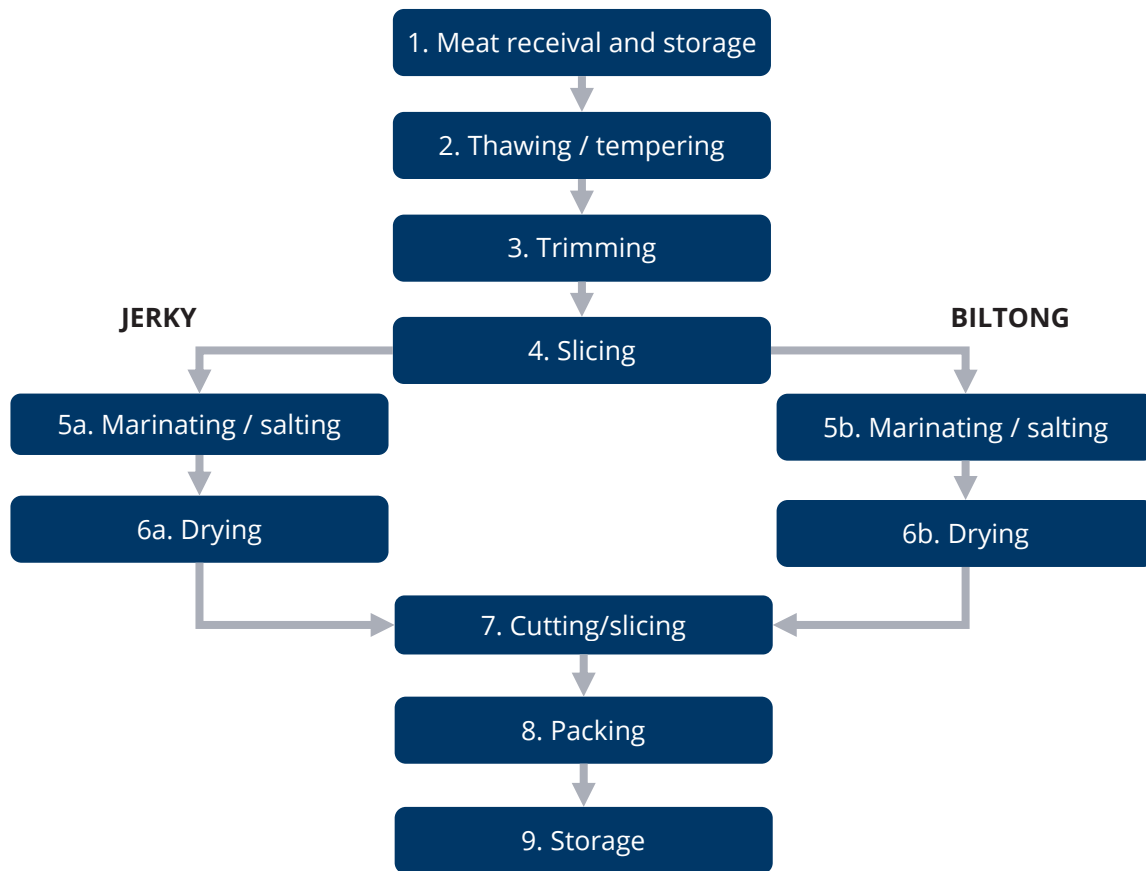
8.6.2 Intended use and users

The following sample description of intended use should be reviewed and completed (step 3 in the HACCP system development process)

Sensitive Consumer	
Customer Preparation	RTE

8.6.3 Flow diagram

The process flow may vary between products and with available equipment. This is a sample flow diagram, used to prepare the sample HACCP analysis. Constructing your own flow diagram and on-site confirmation of the process are two steps (steps 4 and 5) in the HACCP system development.



8.6.4 Potential hazards and control measures

This is a sample hazard analysis based on the sample flow diagram. You need to conduct your own hazard analysis based on your product, production process, and circumstances (Step 6 of HACCP system development).

1	2	3	4	5
Step	Identify potential hazards	Does this potential hazard need to be addressed in the HACCP plan <hr/> YES NO	Justification for decision in column 3	What measure(s) can be applied to prevent or eliminate the hazard or reduce it to an acceptable level
1. Meat receival and storage	B Pathogens All meat: <i>Salmonella</i> , <i>S. aureus</i> , <i>L. monocytogenes</i> , <i>C. botulinum</i> , <i>C. perfringens</i> Beef: pathogenic <i>E. coli</i> Pork: <i>Y. enterocolitica</i> Lamb: pathogenic <i>E. coli</i> Chicken – <i>Campylobacter</i> sp.	N	The prevalence and/or concentration of these pathogens in Australian meat is low. Imported pork cannot be used as the process does not meet DAFF Biosecurity requirements (Chapter 7.11).	
	B <i>S. aureus</i>	Y	<i>S. aureus</i> may grow and produce toxins above 10°C and these toxins may remain active until consumption.	Follow the temperature requirements of the <i>Australian Standard</i> .
	C Residues of agricultural and veterinary chemicals	N	The prevalence of these chemicals in Australian meat is low.	
	P			
2. Thawing / tempering	B <i>S. aureus</i>	Y	<i>S. aureus</i> may grow and produce toxins.	Follow the temperature requirements of the <i>Australian Standard</i> .
	C			

1	2	3	4	5
	P Plastic may be trapped in between pieces of frozen meat		N Soft plastic is not a food safety hazard.	Temper for sufficient time for the meat to thaw and allow easy removal of plastic.
3. Trimming	B			
	C			
	P			
4. Slicing	B			
	C			
	P			
5a. Jerky Marinating / Salting	B <i>S. aureus</i>	Y	Poor temperature control or salting could allow growth of <i>S. aureus</i> .	Add correct amount of ingredients. Follow the temperature requirements of the <i>Australian Standard</i> .
	C Nitrite	Y	If added in excess could be toxic to consumers.	Careful control of ingredient weighing and addition.
	P			
5b. Biltong Marinating / Salting	B <i>S. aureus</i>	Y	Low levels of salt or vinegar could allow growth of <i>S. aureus</i> .	Add correct amount of ingredients, particularly salt and vinegar.
	C Nitrite	Y	If added in excess could be toxic to consumers.	Careful control of ingredient weighing and addition.
	P			

1	2	3	4	5
6a. Jerky Drying	B <i>S. aureus</i>	Y	Poor moisture control could allow growth and toxin production by <i>S. aureus</i> .	Drying to rapidly reduce water activity, and ensuring centre of meat reaches 55-65°C.
	C			
	P			
6b. Biltong Drying	B <i>S. aureus</i>	Y	Poor pH control could allow growth and toxin production by <i>S. aureus</i> .	Prevent growth by vinegar addition. pH <4.5
	C			
	P			
7. Cutting / slicing	B <i>S. aureus</i>	Y	Transfer of <i>S. aureus</i> from workers.	Wearing of gloves, face masks. Formulation of product
	B <i>L. monocytogenes</i>	Y	Contamination of the slicing machine, or the environment transfers to product.	Control of the production environment. Formulation of product
	C			
	P			
8. Packing	B Moulds	Y	Moulds could produce toxins.	Vacuum pack with low oxygen permeability film and oxygen scavengers. Water activity <0.7.
	B Pathogens other than <i>L. monocytogenes</i> and <i>S. aureus</i>	N	Pathogens are unlikely to contaminate the product.	
	B <i>S. aureus</i>	Y	Transfer of <i>S. aureus</i> from workers.	Wearing of gloves. Formulation of product.

1	2	3	4	5
	B <i>L. monocytogenes</i>	Y	Contamination of the packing machine, or the environment transfers to product.	Control of the production environment. Formulation of product.
	C			
	P			
9. Storage	B			
	C			
	P			

8.6.5 CCPs and CLs

CCPs

This is a sample analysis of CCPs based on the sample hazard analysis. You need to determine the CCPs based on your own analysis of hazards (step 7) and state the validated CLs (step 8 of HACCP system development).

Process step	Significant hazard	Q1 Can the significant hazard be controlled to an acceptable level at this step by PRP (e.g. GMPs)?	Q2 Do specific control measures for the identified significant hazard exist at this step?	Q3 Will a subsequent step prevent or eliminate the identified hazard or reduce it to an acceptable level?	Q4 Can this step specifically prevent or eliminate the identified significant hazard or reduce it to an acceptable level?	CCP number
		If YES, this step is not a CCP	If YES proceed to Q3	If YES that subsequent step should be a CCP	If YES, this step is a CCP	

Process step	Significant hazard	Q1 Can the significant hazard be controlled to an acceptable level at this step by PRP (e.g. GMPs)?	Q2 Do specific control measures for the identified significant hazard exist at this step?	Q3 Will a subsequent step prevent or eliminate the identified hazard or reduce it to an acceptable level?	Q4 Can this step specifically prevent or eliminate the identified significant hazard or reduce it to an acceptable level?	CCP number
		If NO, proceed to Q2	If NO this step is not a CCP. Subsequent steps should be evaluated for a CCP	If NO, proceed to Q4	If NO, modify the step, process or product to implement a control measure	
1. Meat receival and storage	Growth and toxin production by <i>S. aureus</i> in raw meat	N	Y	N	Y	CCP1
2. Thawing / tempering	Growth and toxin production by <i>S. aureus</i> during thawing/tempering	N	Y	N	Y	CCP1
5a. Jerky Marinating / Salting	Growth of <i>S. aureus</i> due to low salt	Y				
	Addition of correct amount of nitrite	Y				
	Growth of <i>S. aureus</i> due to poor temperature control	N	Y	N	Y	CCP2
5b. Biltong Marinating / Salting	Growth of <i>S. aureus</i> due to low salt or low vinegar addition	Y				
	Addition of correct amount of nitrite	Y				
6a. Jerky Drying	Growth of <i>S. aureus</i> due to poor temperature control	N	Y	N	Y	CCP3
6b. Biltong Drying	Growth of <i>S. aureus</i> due to low vinegar addition	Y				

Process step	Significant hazard	Q1 Can the significant hazard be controlled to an acceptable level at this step by PRP (e.g. GMPs)?	Q2 Do specific control measures for the identified significant hazard exist at this step?	Q3 Will a subsequent step prevent or eliminate the identified hazard or reduce it to an acceptable level?	Q4 Can this step specifically prevent or eliminate the identified significant hazard or reduce it to an acceptable level?	CCP number
7. Cutting / slicing	Contamination by <i>S. aureus</i>	Y				
	Contamination by <i>L. monocytogenes</i>	Y				
8. Packing	Mould growth in packed product	Y				
	<i>S. aureus</i> growth due to high water activity	N	Y	N	Y	CCP4
	Contamination by <i>L. monocytogenes</i>	Y				

CLs

This is a sample of the CLs, monitoring, and corrective actions based on the sample hazard analysis and identification of CCPs. You need to state CLs (step 8) for your CCP, establish a monitoring system (step 9), determine corrective actions (step 10), and procedures for verification (step 11) and record keeping (step 12 of HACCP system development).

CCP number	Significant hazard	CLs	Monitoring				Corrective actions	Verification activities	Records
			What	How	When	Who			
CCP1	<i>S. aureus</i> toxin production	Not greater than 5°C (<i>Australian Standard</i> clause 11.6) * **	Raw meat	Chiller temperature	Twice daily	Stores supervisor	1. Immediately chill product to correct temperature. 2. Assess safety of product for use.	1. Calibration of temperature measuring devices. 2. Weekly check of records.	Chiller log

CCP number	Significant hazard	CLs	Monitoring				Corrective actions	Verification activities	Records
			What	How	When	Who			
CCP2 (Jerky)	<i>S. aureus</i> toxin production	Not greater than 5°C (<i>Australian Standard</i> clause 11.6) * **	Raw meat	Chiller temperature	Twice daily	Stores supervisor	1. Immediately chill product to correct temperature. 2. Assess safety of product for use.	1. Calibration of temperature measuring devices. 2. Weekly check of records.	Chiller log
CCP3 (Jerky)	Growth of <i>S. aureus</i> due to poor temperature control	Raise the temperature above 48°C as quickly as possible	Temperature	Oven gauge	Continuous	Supervisor	1. Immediately heat product to correct temperature. 2. Assess safety of product for use.	Calibration of thermometer. Check every batch record.	Batch production records
CCP4	Growth of <i>S. aureus</i> due to high water activity	$a_w < 0.85$ (<i>Australian Standard</i> , clause 13.14)	a_w or moisture level that has been correlated with water activity	Laboratory test	Every batch	QA staff	1. assess safety of product.	Check every batch record.	Batch production records

* some pathogens will not grow at 5° C. A guideline for CLs for raw meat that will be used in a product intended to be fully cooked by the consumer or processor can be found at [Raw Product Critical Limit Tables \(wisc.edu\)](http://www.wisc.edu/~meathaccp/tables/)

** *S. aureus* does not produce toxin below 10°C and a high level of *S. aureus* is required (Chapter 9.1). A predictive tool can be used to assess the amount of growth that may occur: <https://meathaccp.wisc.edu/therm/> Ingham, S.C., Fanslau, M.A., Burnham, G.M., Ingham, B.H., Norback, J.P., Schaffner, D.W., 2007. Predicting Pathogen Growth during Short-Term Temperature Abuse of Raw Pork, Beef, and Poultry Products: Use of an Isothermal-Based Predictive Tool. *J Food Prot* 70, 1445-1455.

Guidelines on procedures for CCPs and important GMPs can be found in the following places:

Information on CCPs

CCP1	57.1 Receiving and temperature control of raw meat
CCP2	7.5 Massaging, tumbling, injecting and curing
CCP3	7.11 Cooking
CCP4	7.19 Measurements during production

Important GMPs

Step 5,6b	7.3 Formulation and assembly of raw materials
	7.4 Weighing and adding ingredients
Step 7,8	7.17 Packing

8.6.6 Validation

A safe product is one that:

- a high salt level during the early stages of drying
- temperature is controlled throughout the process (Jerky)
- pH/salt concentration is controlled throughout the process (Biltong)
- drying to a very low moisture level.

8.6.7 Verification

There are no microbiological limits for dried meats. As requirements differ from state-to-state check with your controlling authority about testing and approval requirements.

Dried meats (as described in this chapter) and production environments can be excluded from *Listeria* testing because they are shelf stable products. The microbiological criteria for *L. monocytogenes* in the *Food Standards Code* applies only to RTE foods and shelf stable products are not considered RTE foods for the purpose of applying microbiological criteria (as defined in Standards 1.6.1 and 1.1.2 of the *Food Standards Code*).

8.7 Slow cured meats

8.7.1 Description of product

Slow cured meats are whole muscles or portions of muscles that are salted, then dried at low temperature and low relative humidity.

In Australia, slow cured meats, such as Prosciutto, can be prepared from boneless or bone-in legs with a requirement that the pH is not >6.0 before salting. Above this pH the muscle can be watery and sour badly during ageing. Other slow cured products include Speck and Lachschen processed from meat portions, Pancetta (round or flat), Capocollo, Bresaola (most frequently beef), Guanciale (pork jowl/cheek), Iberian Ham, Parma Ham, Serrano Ham. Some products can also be made using beef, lamb, goat, duck, etc.

Meat undergoes a dry salting process followed by drying at low temperatures (for example, around 10–15°C) and low relative humidity (around 70–85%). It may be smoked to varying degrees. Some products are soaked in brine and often washed to remove excess salt before hanging to dry.

The main food safety concern is due to the possible growth and toxin production of *S. aureus*, which can be controlled through a combination of low temperature processing and high salt concentrations at the sites of

concern. The site of microbiological concern is the product surface. Sufficient salt needs to diffuse through the meat, so that the salt content (water activity) reaches the desired level throughout the product. *Salmonella* and *E. coli* are controlled effectively due to an inability to grow and long processing times. Some products require refrigeration to maintain shelf life (i.e. they are not shelf stable) and minimise the growth of *L. monocytogenes*.

You can validate whether your product supports the growth of *L. monocytogenes* following the advice in Chapter 1.8.2. It is possible to reformulate your product so that it does not support the growth of *L. monocytogenes* following the advice in Chapter 9.2.

The following sample description should be reviewed and completed (step 2 in the HACCP system development process)

Ingredients	Pork or other meat species Salt Nitrate/nitrite Smoke Spices and seasoning ingredients such as garlic Starter cultures (moulds) Protective cultures
Primary Packaging	Sealed plastic shrink bag
Storage Conditions	Refrigerated: Store under active refrigeration not more than 5°C.
Shelf Life	Sealed shelf life: x days from production. Use-by date if growth of <i>L. monocytogenes</i> may occur Best-before date if growth of <i>L. monocytogenes</i> cannot occur Shelf life once opened: not more than x days once opened.
Labelling related to product safety	If not shelf stable: Keep refrigerated- Store below 5°C Presence of allergens Allergens that may be present without being listed as ingredients

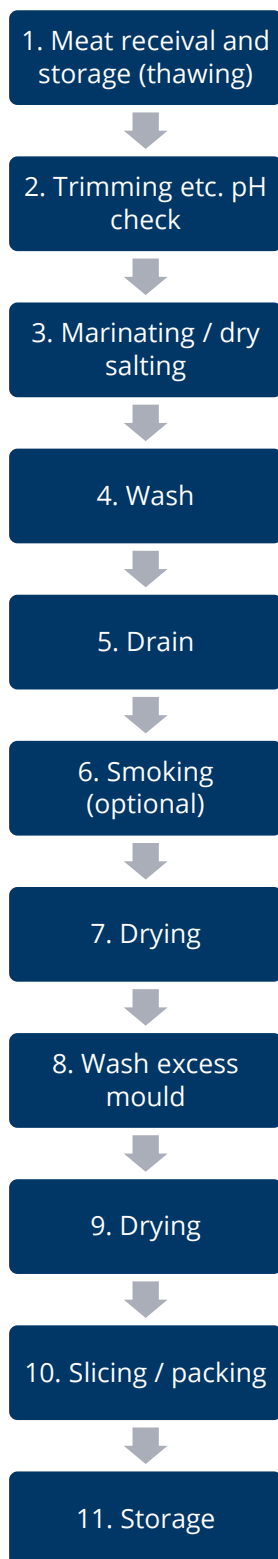
8.7.2 Intended use and users

The following sample description of intended use should be reviewed and completed (step 3 in the HACCP system development process)

Sensitive Consumer	
Customer Preparation	Product is RTE

8.7.3 Flow diagram

The process flow may vary between products and with available equipment. This is a sample flow diagram, used to prepare the sample HACCP analysis. Constructing your own flow diagram and on-site confirmation of the process are two steps (steps 4 and 5) in the HACCP system development.



8.7.4 Potential hazards and control measures

This is a sample hazard analysis based on the sample flow diagram. You need to conduct your own hazard analysis based on your product, production process, and circumstances (Step 6 of HACCP system development)

1	2	3		4	5
Step	Identify potential hazards	Does this potential hazard need to be addressed in the HACCP plan		Justification for decision in column 3	What measure(s) can be applied to prevent or eliminate the hazard or reduce it to an acceptable level
		YES	NO		
1. Meat receipt and storage (thawing)	B	All meat: <i>Salmonella</i> , <i>L. monocytogenes</i> , <i>C. botulinum</i> , <i>C. perfringens</i> Beef: pathogenic <i>E. coli</i> Pork: <i>Y. enterocolitica</i> Lamb: pathogenic <i>E. coli</i> Chicken: <i>Campylobacter</i> sp.	Y	Pathogens may be present on the raw meat and could grow if temperature abuse occurred. Imported pork cannot be used because the process does not meet DAFF Biosecurity requirements (Chapter 7.11).	Purchase to specification from approved supplier. Control of temperature and salt will effectively deal with hazards; <i>S. aureus</i> is the most salt tolerant pathogen. Maintain and monitor storage (and thawing) temperature below 5°C. Careful attention to control of the manufacturing process, particularly, salt concentration. Some products include nitrate/nitrite to control <i>C. botulinum</i> .
	B	<i>S. aureus</i>	Y	<i>S. aureus</i> may grow and produce toxin and these toxins may remain active until consumption.	Temperature control according to the <i>Australian Standard</i> .
	C	Chemical residues		N	Management of chemical residues in Australia is excellent.

1	2	3	4	5
	P	Bone splinters Plastic Foreign objects	N	Purchase to specification from approved supplier. Visual inspection of meat pieces during trimming.
2. Trimming	B			
	C			
	P			
3. Dry curing / brining	B	<i>S. aureus</i> <i>L. monocytogenes</i>	Y	<i>S. aureus</i> may grow and produce toxin if salt is not at a high enough level or temperature is too high. Dry salting with salt covering all external surface below 10°C. Or Brining at below 10°C. The timing of the process is variable, and temperature dependent. The site of microbiological concern is initially, the surface. Sufficient salt needs to diffuse through the meat, so that the salt content (water activity) reaches the desired level throughout the product.
	C			
	P			
4. Wash	B			
	C			
	P			
5. Drain	B			
	C			
	P			

1	2	3	4	5	
6. Smoking (optional)					
7. Dry	B	<i>S. aureus</i> <i>L. monocytogenes</i>	Y	<i>S. aureus</i> able to grow and produce toxin if moisture remains high (low salt concentration).	Drying occurs below 15°C and RH 70-85%. Personnel hygiene prevents contamination with <i>S. aureus</i> . The site of microbiological concern is the product surface. Sufficient salt needs to diffuse through the meat, so that the salt content (water activity) reaches the desired level throughout the product.
	C				
	P				
8. Wash off excess mould	B				
	C				
	P				
9. Dry	B	<i>S. aureus</i> <i>L. monocytogenes</i>	Y	<i>S. aureus</i> able to grow and produce toxin if moisture remains high (low salt concentration).	Drying occurs below 15°C and RH 70-85%. The salt content (water activity) reaches the desired level at the centre of the product. Worker hygiene prevents contamination with <i>S. aureus</i> .
	C				
	P				
10. Slicing / Packing	B	<i>L. monocytogenes</i>	Y	Some products may support the growth of <i>L. monocytogenes</i> .	Attention to hygiene during packing.

1	2	3	4	5	
	B	<i>S. aureus</i>	Y	<i>S. aureus</i> able to grow and produce toxin if moisture remains high (low salt concentration).	Worker hygiene prevents contamination with <i>S. aureus</i> .
	C				
	P				
11. Storage	B	<i>L. monocytogenes</i>	Y	Some products may support the growth of <i>L. monocytogenes</i> .	Ability of product to support the growth of <i>L. monocytogenes</i> must be determined and storage temperatures controlled and maximum shelf life determined.
	B	<i>S. aureus</i>	Y	<i>S. aureus</i> able to grow and produce toxin if moisture remains high (low salt concentration).	Storage temperature below 10°C if product supports the growth and toxin production of <i>S. aureus</i> .
	C				
	P				

8.7.5 CCPs and CLs

CCPs

This is a sample analysis of CCPs based on the sample hazard analysis. You need to determine the CCPs based on your own analysis of hazards (step 7 of HACCP system development)

Process step	Significant hazard	Q1 Can the significant hazard be controlled to an acceptable level at this step by PRP (e.g. GMPs)?	Q2 Do specific control measures for the identified significant hazard exist at this step?	Q3 Will a subsequent step prevent or eliminate the identified hazard or reduce it to an acceptable level?	Q4 Can this step specifically prevent or eliminate the identified significant hazard or reduce it to an acceptable level?	CCP number
		If YES, this step is not a CCP	If YES proceed to Q3	If YES that subsequent step should be a CCP	If YES, this step is a CCP	
		If NO, proceed to Q2	If NO this step is not a CCP. Subsequent steps should be evaluated for a CCP	If NO, proceed to Q4	If NO, modify the step, process or product to implement a control measure	
1. Meat receipt and storage (thawing)	<i>Salmonella, Y. enterocolitica, pathogenic E. coli, or other pathogens</i> may be present on the raw meat	Y				
	<i>S. aureus</i> may be present, and grow and produce toxin during storage or thawing	N	Y	N	Y	CCP1
	Bone, plastic, foreign objects	Y				
3. Dry curing / brining	<i>S. aureus, L. monocytogenes</i> growth (and toxin production by <i>S. aureus</i>) during salting	N	Y	N	Y	CCP2
7. Dry	<i>S. aureus, L. monocytogenes</i> growth (and toxin production by <i>S. aureus</i>) during drying	N	Y	N	Y	CCP3

Process step	Significant hazard	Q1 Can the significant hazard be controlled to an acceptable level at this step by PRP (e.g. GMPs)?	Q2 Do specific control measures for the identified significant hazard exist at this step?	Q3 Will a subsequent step prevent or eliminate the identified hazard or reduce it to an acceptable level?	Q4 Can this step specifically prevent or eliminate the identified significant hazard or reduce it to an acceptable level?	CCP number
9. Dry	<i>S. aureus</i> , <i>L. monocytogenes</i> growth (and toxin production by <i>S. aureus</i>) during drying	N	Y	N	Y	CCP4
10. Slicing / packing	<i>L. monocytogenes</i> contamination at the time of slicing/packing	Y				
	<i>S. aureus</i> may grow and produce toxin	N	Y	N	Y	CCP5
11. Storage	<i>L. monocytogenes</i> may grow in non-shelf stable products	Y				
	<i>S. aureus</i> may grow and produce toxin	N	Y	N	Y	CCP5

CLs

This is a sample of the CLs, monitoring and corrective actions based on the sample hazard analysis and identification of CCPs. You need to state CLs (step 8) for your CCP, establish a monitoring system (step 9), determine corrective actions (step 10), and procedures for verification (step 11 of HACCP system development).

CCP number	Significant hazard	CLs	Monitoring				Corrective actions	Verification activities	Records
			What	How	When	Who			
CCP1	<i>S. aureus</i> may grow and produce toxin during storage or thawing	Not greater than 5°C (<i>Australian Standard</i> clause 11.6) * **	Raw meat	Chiller temperature	Twice daily	Stores supervisor	1. Immediately chill product to correct temperature. 2. Assess safety of product for use.	1. Calibration of temperature measuring devices. 2. Weekly check of records.	Chiller log
CCP2	<i>S. aureus</i> , <i>L. monocytogenes</i> growth during salting	Dry salting: cold room temperature <10°C Validated time for the size of the meat piece	Temp	Cold room gauge	Daily		Move to another location if >10°C	Weekly check of records.	Log book
CCP3	<i>S. aureus</i> growth and toxin production during drying	10-15°C and RH 70-85%	Temp RH	Cold room gauge	Daily		1. Move to another location if >15°C or >85% RH. 2. Assess safety of product for use.	Weekly check of records.	Log book
CCP4	<i>S. aureus</i> growth and toxin production during drying	10-15°C and RH 70-85%	Temp RH	Cold room gauge	Daily		1. Move to another location if >15°C or >85% RH. 2. Assess safety of product for use.	Weekly check of records.	Log book

CCP number	Significant hazard	CLs	Monitoring				Corrective actions	Verification activities	Records
			What	How	When	Who			
CCP5	<i>S. aureus</i> growth and toxin production during slicing/packing or storage	Not greater than 5°C (<i>Australian Standard</i> clause 11.6) **	Product	Chiller temperature	Twice daily	Stores supervisor	1. Immediately chill product to correct temperature. 2. Assess safety of product for use.)	1. Calibration of temperature measuring devices. 2. Weekly check of records.	Chiller log

* some pathogens will not grow at 5° C. A guideline for CLs for raw meat that will be used in a product intended to be fully cooked by the consumer or processor can be found at [Raw Product Critical Limit Tables \(wisc.edu\)](http://www.wisc.edu/~meathaccp/therm/)

** *S. aureus* does not produce toxin below 10°C and a high level of *S. aureus* is required (Chapter 9.1). A predictive tool can be used to assess the amount of growth that may occur: <https://meathaccp.wisc.edu/therm/> Ingham, S.C., Fanslau, M.A., Burnham, G.M., Ingham, B.H., Norback, J.P., Schaffner, D.W., 2007. Predicting Pathogen Growth during Short-Term Temperature Abuse of Raw Pork, Beef, and Poultry Products: Use of an Isothermal-Based Predictive Tool. J Food Prot 70, 1445-1455.

Guidelines on procedures for CCPs and important GMPs can be found in the following places:

Information on CCPs

CCP1	7.5 Massaging, tumbling, injecting, and curing
CCP2	7.14 Maturing
CCP3	7.14 Maturing

Important GMPs

Step 1	7.1 Receiving and temperature control of raw meat
Step 1	4.7 Physical contamination – and foreign body detection
Step 10	3.4 Keeping control of <i>Listeria</i>
	4.8 Protective cultures
	7.17 Packing
Step 11	57.18 Temperature control of finished product

8.7.6 Validation

A safe product is one that has been processed within the established CLs and has the following characteristics:

Water activity ≤ 0.85

8.7.7 Verification

The following microbiological criteria will be applied if there is testing undertaken by the controlling authority. Testing for these microorganisms may not necessarily be part of a regular testing program, but the production process must be designed to meet them.

You can validate whether your product supports the growth of *L. monocytogenes* following the advice in Chapter 1.8.2. It is possible to reformulate your product so that it does not support the growth of *L. monocytogenes* following the advice in Chapter 9.2.

Verification of compliance with the criterion for *L. monocytogenes* (on a single sample) is required by controlling authorities for RTE products.⁸³

	Number of samples (n)	Number of samples allowed to be >m but $\leq M$	Limit (m)	Limit (M)
Coagulase-positive staphylococci	5	1	10 ² /g	10 ³ /g
<i>Salmonella</i>	5	0	Not detected in 25g	
Product in which growth of <i>L. monocytogenes</i> can occur	5	0	Not detected in 25g	
Product in which growth of <i>L. monocytogenes</i> will not occur	5	0	10 ² /g	

⁸³ Australian Meat Regulators Group (2019) Standard 4.2.3 - Guidelines for the Management of Listeria.

8.8 Uncooked comminuted fermented meats (UCFM)

8.8.1 Description of product

UCFM have been made for centuries in many European countries. European salamis originated in the Mediterranean region and are seasoned with spices; they are usually not smoked and usually have Italian or Spanish names. In cooler parts of Europe (e.g. Germany, the Netherlands, Scandinavia), semi-dry sausages emerged which are less spiced. Most are smoked at cool temperatures and typically have Germanic names. While some other cultures have developed their own styles of fermented sausages, those produced and consumed most in Australia are typically derived from established European-style sausages.

UCFM are sausages manufactured by a series of processes which involves fermenting followed by maturing. Some UCFM are also smoked. The range of UCFM covers a wide spectrum of water activity and pH, ranging from the acidic, moist Mettwurst to the dry, high-pH Italian or Spanish sausages. UCFM are made safe by attention to many details of production that result in a combination of factors (addition of starter cultures, meat with low microbiological count, temperature control, pH reduction, water loss, smoke, nitrite/nitrate) being applied which act in together to control pathogens that may be present. A recent, thorough review can be consulted for further details.⁸⁴

Some UCFM have long shelf life at ambient temperature, such as pepperoni and hard Italian salamis, through to semi-dry sausages which require refrigerated storage e.g. Chorizo, and relatively high moisture products like Mettwurst.

In this chapter we will describe the European styles of UCFM. Fermented sausages are also made in Middle Eastern and Asian countries, and these are covered in Chapter 8.10.

In Australia, fermented sausages vary widely in flavour, aroma and texture. This is due in the first instance to the type of meat (beef, pork, lamb) and the fat content, which can range up to 45% when the product has matured.

There are a number of processing variables which also affect the eating quality, and may have an effect on the safety, of the final UCFM:

- curing mix composition, concentration of nitrite/nitrate, salt concentration and spices
- types of starter cultures
- fermentation temperature, which can vary from 30°C (or higher) for soft, spreadable sausages, with semi-dry types being fermented in 20-30°C range
- maturing time and temperature
- sausage diameter
- final pH and water activity.

Commercially available starter cultures (Chapter 6.14) are an essential ingredient in UCFM to ensure a rapid and effective fermentation. It is not acceptable to use some material or product from a previous batch because it may not provide the right kind of fermentation and can magnify the levels of pathogens in the product.

As mentioned above, there are hundreds of types of European-style UCFM, they are often grouped into three main categories.

⁸⁴ Holck, A., Axelsson, L., McLeod, A., Rode, T.M., Heir, E., 2017. Health and Safety Considerations of Fermented Sausages. *Journal of Food Quality* 2017, 9753894.

The first categories can be described as 'sliceable' UCFM. They may be divided into:

- Dry UCFM, which align with the Mediterranean styles traditionally developed in countries such as Italy, Spain and France. Dry UCFM are typically ripened (matured) for more than four weeks and achieve a final $a_w < 0.90$. and $pH < 5.6$.
- Semi-dry UCFM which typically originated in northern European countries. Semi-dry UCFM typically undergo 10 - 20 days of ripening and achieve a final a_w in the range 0.90 to 0.95, and pH in the range 4.9 to 5.2.

The second category can be described as moist/undried/spreadable:

- Moist/undried/spreadable UCFM are found in Germany (e.g. Mettwurst), Italy and France (mortadella), and Spain (sobrasada). Lebanon bologna is another example. These UCFM typically are fermented at higher temperatures in the range 32 – 38°C for from a few days to up to two weeks, to achieve a final $pH < 4.7$, with final a_w in the range 0.94 to 0.97. To increase the safety for consumption they are often heated to an internal end-point temperature in the range 43 to 65°C, for a suitable length of time (see discussion of 'Heat Treatment' in Chapter 5.9).

The third category can be described as 'fast' or 'American style' processes

Immigrants to the USA from Europe brought their UCFM traditions with them and, initially employed them at farm, or local butcher, levels. As commerce and food technology progressed in USA and Canada, in particular, industrial scale manufacture of UCFM was developed. There was a desire to speed up the processing of UCFM to increase productivity. This led to much experimentation and development of starter cultures, beginning in the 1940s.

Over time this led to the development of commercial UCFM starter cultures (typically including multiple strains) that were able to function at higher temperatures and, thus, more quickly. These cultures are called 'thermophilic' cultures (meaning that they prefer warmer temperatures (e.g. in the range 32 – 42°C).

These starter culture mixes are often quite complex and designed to satisfy food technological requirements involving encouragement of the growth of useful fermenting microorganisms, and metabolism of nitrite/nitrate and to generate flavour compounds from the components of the meat and fat. These processes and starter cultures are now described as 'fast' or 'American style' processes. Those processes can be used to produce 'dry' or 'semi-dry' styles of UCFM, but to do so more quickly. Several commentators note that the use of fast or American-style processes reduce the sensory quality and appeal of the UCFM styles based on them. Because of the industrialised nature of the 'fast' and American style' processes there is only a limited range of UCFM types made using them.

The following sections provide additional discussion on different sub-categories of European-style UCFMs.

Short maturing

The short maturing UCFM, such as moist Mettwurst are generally made using higher fermentation temperatures 32-38°C which drops the pH quickly during the first 1-2 days where it ideally reduces the pH to well below 5. The low pH /high organic acid levels and smoke (if applied) and appropriate post-fermentation heating (if applied) enable the product to be stable at ambient temperatures, otherwise refrigeration may be required. The flavour is quite acidic, or "tangy", and is usually in middle width casings.

Semi dry

Semi-dry products generally are made at fermenting temperatures approximately 22-35°C and are frequently made from frozen meats with a finer grain texture through use of a bowl chopper or mincing twice. The final pH should be ≤ 5.6 (some may be below 4.7). These products rely on the combination of pH and water activity to provide shelf stability. This category is often smoked according to regional style. The use of smoke discourages growth of bacteria on the outside of the casing and helps control the moisture loss.

Mould matured

These are fermented in the temperature range 18-30°C, with final pH dependant on the fermentation time and temperature. The rate of pH fall may be inhibited by the lower water activity.

Maturation is typically undertaken at 14-18°C. When the water activity of the salami no longer enables bacterial growth the environmental humidity and surface moisture enables the growth of mould on the surface of the casing until the internal moisture is no longer sufficient to support further growth. Many styles have a white mould. White mould can be brushed or washed off according to preference. Other styles, usually larger diameter, can have growth of moulds that vary from light to darker green depending on the humidity and prevailing strains in the maturation rooms. These are generally washed off before sale. The mould influences the flavour of the salami and helps prevent excess surface drying and loss of lactic acid during maturation that can result in an increase in pH. Products ripened at higher temperatures dry faster so can be sale ready earlier.

Dry

This style of UCFM is traditionally fermented at temperatures in the range 10 to 18°C and relies on a gentle reduction of moisture during maturation for the first couple of days as humidity is reduced from 95 to 85% with very moderate airflow which can vary according to the temperature and humidity of the room but must keep the surface just damp, to enable the mixture to cure, bond and begin the migration of moisture to the surface. This is the most critical time where case hardening can occur.

The environment is designed to encourage weight loss early to discourage the proliferation of bacteria that would encourage the pH to fall below approximately 5 so giving the salami undesirable sour notes. After the initial weight loss of 7-10% the mixture becomes more stable, and lowering of the humidity is important to keep the surface moist but without build-up of a surface layer of microbial growth (biofilm) which inhibits the controlled loss of moisture.

During the long maturation phase the humidity is decreased from 85% to 75% and as low as 70% with almost no airflow, while the salami achieves the desired weight loss. The diameter of the product determines the days required till the product is ready for sale.

This low moisture content of dry UCFM discourages mould growth on the surface so retains the savoury meat and spice characteristics. The water activity from which it is safe is below 0.90 with flavour development occurring with greater weight loss.

Soft Spreadable

These products may not meet the definition of UCFM if they do not use starter cultures. They have high fat content and sometimes spices that result in a soft and spreadable product. They are often made by a method similar to dry salami products.

From a food safety viewpoint, the types of salami can be defined by the temperature of processing, and the typical final pH and water activity (a_w) (Table 25), however not all UCFM neatly fit into these categories. An example is a semi-dry salami product (conforms to pH and a_w) that is fermented at a higher temperature.

Table 25: Characteristics of different types of UCFM

	Fermentation Temperature	pH*	a_w	Weight loss %	Shelf stability
Short-maturing moist e.g. Mettwurst	30°C	< 4.7	0.95	~10%	May be shelf stable due to low pH
Semi-dry salami, German Landjager; Danish	20-30°C	< 5.3	<0.95	25-30%	May not be shelf stable
Dry mould ripened salami; traditional Hungarian	~20°C	5.3-5.6	<0.90	~30%	Probably shelf stable due to low a_w
Long maturation (>4 weeks), Italian salami	~20°C	Up to 5.6	<0.90	~30%	Probably shelf stable due to low a_w
'Fast' or 'American'	26 – 32°C	< 4.5 to 4.8	< 0.92	25-30%	May require heating for safety
	32 – 42°C	< 4.5 to 4.8	< 0.92	25-30%	

* pH of product, not pH after 48 hours of fermentation

In summary, limits for shelf stability for UCFM varies according to the pH and water activity found in each category:

- Moist, spreadable UCFM relies on pH <4.7. It has a short shelf life and may require refrigeration
- Sliceable UCFM are shelf stable when pH is <5.6 if a_w <0.90 or if the pH is < 5.0 and the a_w is < 0.92

A note about guideline values

In these *Guidelines*, and especially for UCFM, we use guideline values, for example, parameters (pH, a_w) predicting shelf stability, or parameters (time and pH) predicting safety. These guideline values are often based on experience, and a consensus from regulator, industry and scientific consultation. Some of them have been established and proven by experience over a long period and therefore we don't have neat and tidy scientific reports to validate the selection of the parameters. Often the values are chosen with the idea of them being 'safe harbours', in other words, values that you can rely on to be safe, but they don't exclude that other values can also deliver safety considering your product and process. This means that if your product or process is outside the parameters, you may need to find some specific information to show that your product is safe, or have a scientific study performed to prove it.

Here are two examples of guideline values relevant to UCFM production, and how they were developed, and how to work with them if your process or product is not conforming to the guideline.

Following from the development of industrial-scale production of UCFM some food safety problems began to emerge related to growth and toxin production by *S. aureus*. Studies were done and it was considered that, in a typical fermentation process achievement of pH 5.3 was the lower limit for *S. aureus* growth, and that achieving pH 5.3 during fermentation provided protection against illness resulting from *S. aureus* growth. However, there is also a temperature effect on the rate of growth of *S. aureus* which means that the time taken to reach pH 5.3 at a particular temperature is also important. A rule of thumb emerged which is that a

safe UCFM process should reach a pH of 5.3 in no more than 48 hours after commencement of fermentation (when the temperature reaches 15-16°C). However, this was based on a 'typical' US fermentation temperature of about 30°C. At lower temperatures, longer times are allowed. Conversely, at high fermentation temperatures, less time is allowed to reach pH 5.3.⁸⁵ In Australia, authorities have required that a pH of 5.2 is achieved in no more than 48 hours, and this was reflected in earlier editions of these *Guidelines*. Even though the US guidelines are well-accepted, we are not aware of the location (e.g. published report) of the original research results, which is a factor in Australian authorities maintaining a requirement for pH 5.2.

Pathogenic strains of *E. coli* surviving the manufacturing process can be a significant public health problem. Research conducted primarily at the University of Tasmania developed an understanding that pH and a_w levels create conditions in the fermenting UCFM that stop the growth of *E. coli* and that after that, temperature of fermentation/maturation could explain most of the subsequent death (higher temperatures lead to more rapid death). Models were developed that predict when *E. coli* stops growth⁸⁶, and the inactivation (death) of *E. coli* once growth ceases.⁸⁷ The *Food Standards Code* previously required a UCFM process to be able to achieve a 3 log reduction in *E. coli* and so the work at the University of Tasmania led to the development of the *E. coli* predictive tool (later in this chapter, and Chapter 9.3). To make the predictive tool easy to use, it does not need data to prove that the conditions stopping the growth of *E. coli* have been met, and it does not consider factors other than temperature that have a relatively minor effect on the death of *E. coli*. The *Food Standards Code* no longer requires you to design a process with a 3 log predicted reduction in *E. coli*, but your controlling authority will probably require you to use the predictive tool because it provides confidence that, with the expected quality of incoming meat, you will be able to achieve the finished product *E. coli* criterion found in the *Food Standards Code*.

Back to the FSP

If you manufacture several kinds of UCFM it is likely that you will have several HACCP Plans. The safety of the product is a result of the design of the process after considering the possible starting pathogen numbers in the raw materials, the microbiological criteria for finished product in the *Food Standards Code* and the likely increases/decreases in pathogen numbers through the process steps.

The following sample description should be reviewed and completed (step 2 in the HACCP system development process).

Ingredients	Meat (frozen, chilled) of the required species Fat and trimmings (frozen, chilled) of the required species Salt Nitrite (and Nitrate) Spices Other ingredients
Primary Packaging	

⁸⁵ American Meat Institute Foundation [Blue Ribbon Taskforce] (1997). Good Manufacturing Practices for Fermented Dry & Semi-Dry Sausage Products. Meat HACCP – Food Safety @ UW-Madison – UW-Madison (wisc.edu). <https://www.localfoodheroes.com/calculating-maximum-fermenting-times/>

⁸⁶ Presser, K.A., Ross, T., Ratkowsky, D.A., 1998. Modelling the Growth Limits (Growth/No Growth Interface) of *Escherichia coli* as a Function of Temperature, pH, Lactic Acid Concentration, and Water Activity. *Applied and Environmental Microbiology* 64, 1773-1779.

⁸⁷ McQuestin, O.J., Shadbolt, C.T., Ross, T., 2009. Quantification of the relative effects of temperature, pH, and water activity on inactivation of *Escherichia coli* in fermented meat by meta-analysis. *Appl Environ Microbiol* 75, 6963-6972.

Storage Conditions	Refrigerated: Store under refrigeration not more than 5°C. (if not shelf stable) Or Store at room temperature (if shelf stable)
Shelf Life	'Best-before' date: x days from production, if product does not support the growth of <i>L. monocytogenes</i> . 'Use-by' date: x days from production if product supports the growth of <i>L. monocytogenes</i> . Shelf life once opened: x days once opened.
Labelling related to product safety	The <i>Food Standards Code</i> (2.2.1 – 9) requires product to be labelled as 'fermented processed meat – heat treated' or 'fermented processed meat – not heat treated' ⁸⁸ Presence of allergens Allergens that may be present without being listed as ingredients

8.8.2 Intended use and users

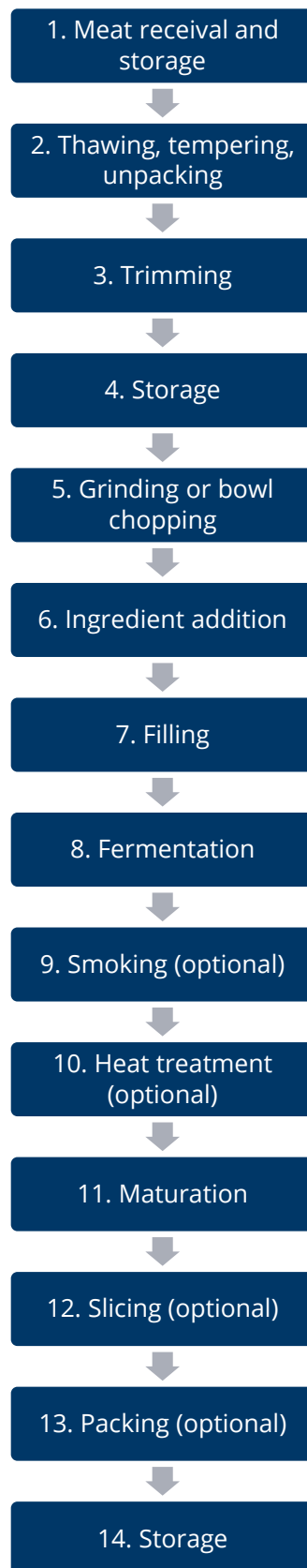
The following sample description of intended use should be reviewed and completed (step 3 in the HACCP system development process)

Sensitive Customer	
Customer Preparation	RTE or intended to be cooked

⁸⁸ There is also a category of 'fermented processed meat – cooked' which is covered in the next chapter

8.8.3 Flow diagram

The process flow may vary between products and with available equipment. This is a sample flow diagram, used to prepare the sample HACCP analysis. Constructing your own flow diagram and on-site confirmation of the process are two steps (steps 4 and 5) in the HACCP system development.



8.8.4 Potential hazards and control measures

This is a sample hazard analysis based on the sample flow diagram. You need to conduct your own hazard analysis based on your product, production process, and circumstances (Step 6 of HACCP system development)

Step	Identify potential hazards (Biological, Chemical, Physical)	Does this potential hazard need to be addressed in the HACCP plan		Justification for decision in column 3	What measure(s) can be applied to prevent or eliminate the hazard or reduce it to an acceptable level		
		YES	NO				
1. Meat receival and storage	B	All meat: <i>Salmonella</i> , <i>S. aureus</i> , <i>L. monocytogenes</i> , <i>C. botulinum</i> , <i>C. perfringens</i> Beef: pathogenic <i>E. coli</i> Pork: <i>Y. enterocolitica</i> , Lamb: pathogenic <i>E. coli</i> Chicken: <i>Campylobacter</i> sp.	Y		The prevalence of these pathogens in Australian meat is low. Imported pork cannot be used in UCFM. UCFM are not heated sufficiently to meet biosecurity requirements (Chapter 7.11).	Purchase from °reliable suppliers. Use inside muscle cuts. Wash surface with lactic acid. Testing program.	
	B	Pathogens such as <i>Salmonella</i> , <i>E. coli</i> ,	Y		Pathogens of concern will be able to grow at greater than 7°C.	Follow the temperature requirements of the <i>Australian Standard</i> .	
	B	<i>S. aureus</i>	Y		Toxin production may occur at greater than 10°C and these toxins may remain active until consumption.	Follow the temperature requirements of the <i>Australian Standard</i> .	
	C	Residues of agricultural and veterinary chemicals		N		The prevalence of these chemicals in Australian meat is low.	
	P	Bone splinters, foreign objects, plastic wrap	Y			May cause injury to consumers.	Physical contamination checks.

Step	Identify potential hazards (Biological, Chemical, Physical)		Does this potential hazard need to be addressed in the HACCP plan		Justification for decision in column 3	What measure(s) can be applied to prevent or eliminate the hazard or reduce it to an acceptable level
			YES	NO		
2. Thawing, tempering, unpacking	B	Pathogens such as <i>Salmonella</i> , <i>E. coli</i> .	Y		Growth of pathogens such as <i>Salmonella</i> , <i>E. coli</i> .	Follow the temperature requirements of the <i>Australian Standard</i> .
	B	<i>S. aureus</i>	Y		Growth and toxin production by <i>S. aureus</i> and these toxins may remain active until consumption.	Follow the temperature requirements of the <i>Australian Standard</i> .
	C					
	P	Plastic may be trapped in between pieces of frozen meat		N	Soft plastic is not a food safety hazard.	Temper for sufficient time for the meat to thaw and allow easy removal of plastic.
3. Trimming	B					
	C					
	P					
4. Storage	B	Pathogens such as <i>Salmonella</i> , <i>E. coli</i> .	Y		Growth of pathogens such as <i>Salmonella</i> , <i>E. coli</i> .	Follow the temperature requirements of the <i>Australian Standard</i> .

Step	Identify potential hazards (Biological, Chemical, Physical)	Does this potential hazard need to be addressed in the HACCP plan		Justification for decision in column 3	What measure(s) can be applied to prevent or eliminate the hazard or reduce it to an acceptable level
		YES	NO		
	B	<i>S. aureus</i>	Y		
				Growth and toxin production by <i>S. aureus</i> and these toxins may remain active until consumption.	Follow the temperature requirements of the <i>Australian Standard</i> .
	C				
5. Grinding or bowl chopping	P				
	B				
5. Grinding or bowl chopping	C				
	P	Fragments of metal	Y	Fragment of metal from machinery may cause injuries to consumers.	Physical contamination checks.
6. Ingredient addition	B				
	C	Nitrites and sulphites can cause adverse reactions in consumers if the level is too high. Too low nitrites, nitrates could allow pathogens such as <i>C. botulinum</i> to grow. Salt must be added at the correct level to inhibit growth of pathogens such as <i>E. coli</i> and <i>Salmonella</i> . Sugar addition helps starter cultures to grow, produce acid and cause rapid fall in pH.	Y	Multiple chemicals must be added at the correct level to produce a chemically safe product, and allow the processing of the product to produce conditions that will produce a shelf-stable product and inactivate pathogens through changes in pH and <i>a_w</i> .	Care taken with the addition of ingredients.

Step	Identify potential hazards (Biological, Chemical, Physical)	Does this potential hazard need to be addressed in the HACCP plan		Justification for decision in column 3	What measure(s) can be applied to prevent or eliminate the hazard or reduce it to an acceptable level
		YES	NO		
	P				
7. Filling	B				
	C				
	P	Fragments of metal	Y	Fragment of metal from machinery may cause injuries to consumers.	Physical contamination checks. Metal detector.
8. Fermentation	B	Pathogens such as <i>Salmonella</i> , <i>E. coli</i>	Y	Slow or incomplete fermentation may allow the growth and/or survival of pathogens.	Monitoring of temperature, water activity (weight loss) and pH. Use of <i>E. coli</i> predictor to assess inactivation. <i>Salmonella</i> is probably controlled adequately by applying the criteria associated with the <i>E. coli</i> predictive model, and the microbiological criterion for <i>E. coli</i> .
	B	Growth and toxin production by <i>S. aureus</i>	Y	Slow or incomplete fermentation may allow the growth and toxin production by <i>S. aureus</i> and these toxins may remain active until consumption.	pH below 5.2 within 48 hours.

Step	Identify potential hazards (Biological, Chemical, Physical)	Does this potential hazard need to be addressed in the HACCP plan		Justification for decision in column 3	What measure(s) can be applied to prevent or eliminate the hazard or reduce it to an acceptable level
		YES	NO		
	C				
	P				
9. Smoking (optional)	B Pathogens such as <i>Salmonella</i> and <i>E. coli</i>	Y		Survive the smoking process.	The <i>E. coli</i> predictor does not consider the effect of smoke on <i>E. coli</i> but can incorporate the time-temperature effect. <i>Salmonella</i> is probably controlled adequately by applying the criteria associated with the <i>E. coli</i> predictive model, and the microbiological criterion for <i>E. coli</i> .
	C				
	P				

Step	Identify potential hazards (Biological, Chemical, Physical)		Does this potential hazard need to be addressed in the HACCP plan		Justification for decision in column 3	What measure(s) can be applied to prevent or eliminate the hazard or reduce it to an acceptable level
			YES	NO		
10. Heat treatment (optional)	B	Pathogens such as <i>Salmonella</i> and <i>E. coli</i>	Y		Survive the heat treatment process.	55°C for 20 minutes, or equivalent at a higher temperature.
	C					
	P					
11. Maturation	B	Survival of pathogens such as <i>Salmonella</i> , <i>E. coli</i>	Y		Changed time or temperature of maturation may allow the survival of pathogens.	Monitoring of temperature, water activity (weight loss) and pH. Use of <i>E. coli</i> predictor. <i>Salmonella</i> is probably controlled adequately by applying the criteria associated with the <i>E. coli</i> predictive model, and the microbiological criterion for <i>E. coli</i> .
	C					
	P					
12. Slicing (optional)	B	<i>S. aureus</i>	Y		Transfer of <i>S. aureus</i> from workers.	Wearing of gloves, face masks

Step	Identify potential hazards (Biological, Chemical, Physical)	Does this potential hazard need to be addressed in the HACCP plan		Justification for decision in column 3	What measure(s) can be applied to prevent or eliminate the hazard or reduce it to an acceptable level	
		YES	NO			
	B	<i>L. monocytogenes</i>	Y		Contamination of the slicing machine, or the environment transfers to product.	Hygienic zoning. Cleaning of environment and equipment. Product may not support the growth of <i>L. monocytogenes</i> .
	C					
	P					
13. Packing (optional)	B	Pathogens other than <i>L. monocytogenes</i>		N	Pathogens are unlikely to contaminate the product. Pathogens are unlikely to be able to grow.	
	B	<i>S. aureus</i>	Y		Transfer of <i>S. aureus</i> from workers.	Wearing of gloves, face masks.
	B	<i>L. monocytogenes</i>	Y		Contamination of the packing machine, or the environment transfers to product.	Hygienic zoning. Cleaning of environment and equipment. Product may not support the growth of <i>L. monocytogenes</i> .
	C					

Step	Identify potential hazards (Biological, Chemical, Physical)	Does this potential hazard need to be addressed in the HACCP plan		Justification for decision in column 3	What measure(s) can be applied to prevent or eliminate the hazard or reduce it to an acceptable level
		YES	NO		
	P				
14 Storage	B Pathogen growth such as <i>S. aureus</i> , <i>L. monocytogenes</i>	Y		Use of ambient storage temperatures for non-shelf stable products could result in growth of surviving pathogens.	Define products as shelf stable based on pH and a_w . Follow the temperature requirements of the <i>Australian Standard</i> .
	C				
	P				

8.8.5 CCPs and CLs

CCPs

This is a sample analysis of CCPs based on the sample hazard analysis. You need to determine the CCPs based on your own analysis of hazards (step 7) and state the validated CLs (step 8 of HACCP system development).

Process step	Significant hazard	Q1 Can the significant hazard by controlled to an acceptable level at this step by PRP (e.g. GMPs)?	Q2 Do specific control measures for the identified significant hazard exist at this step?	Q3 Will a subsequent step prevent or eliminate the identified hazard or reduce it to an acceptable level?	Q4 Can this step specifically prevent or eliminate the identified significant hazard or reduce it to an acceptable level?	CCP number
		If YES, this step is not a CCP	If YES proceed to Q3	If YES that subsequent step should be a CCP	If YES, this step is a CCP	
		If NO, proceed to Q2	If NO this step is not a CCP. Subsequent steps should be evaluated for a CCP	If NO, proceed to Q4	If NO, modify the step, process or product to implement a control measure	
1 Meat receipt and storage	Bacterial pathogens such as Salmonella, E. coli,	Y				
	Growth of pathogens such as Salmonella, E. coli	N	Y	N	Y	CCP1
	Growth and toxin production by <i>S. aureus</i>	N	Y	N	Y	CCP1
	Bone splinters, foreign objects, plastic wrap	Y				
2. Thawing, tempering, unpacking	Growth of pathogens such as <i>Salmonella</i> , <i>E. coli</i> , <i>S. aureus</i>	N	Y	N	Y	CCP2
	Growth and toxin production by <i>S. aureus</i>	N	Y	N	Y	CCP2

Process step	Significant hazard	Q1 Can the significant hazard be controlled to an acceptable level at this step by PRP (e.g. GMPs)?	Q2 Do specific control measures for the identified significant hazard exist at this step?	Q3 Will a subsequent step prevent or eliminate the identified hazard or reduce it to an acceptable level?	Q4 Can this step specifically prevent or eliminate the identified significant hazard or reduce it to an acceptable level?	CCP number
4. Storage	Growth of pathogens such as <i>Salmonella</i> , <i>E. coli</i>	N	Y	N	Y	CCP3
	Growth and toxin production by <i>S. aureus</i>	N	Y	N	Y	CCP3
5. Grinding or bowl chopping	Fragments of metal	Y				
6. Ingredient addition	<p>Nitrites and sulphites can cause adverse reactions in consumers if the level is too high.</p> <p>Too low nitrites, nitrates could allow pathogens such as <i>C. botulinum</i> to grow.</p> <p>Salt must be added at the correct level to inhibit growth of pathogens such as <i>E. coli</i> and <i>Salmonella</i></p> <p>Sugar addition helps starter cultures to grow, produce acid and cause rapid fall in pH.</p>	Y				
7. Filling	Fragments of metal	Y				
8. Fermentation	Growth or survival of pathogens such as <i>Salmonella</i> , <i>E. coli</i>	N	Y	N	Y	CCP4

Process step	Significant hazard	Q1 Can the significant hazard by controlled to an acceptable level at this step by PRP (e.g. GMPs)?	Q2 Do specific control measures for the identified significant hazard exist at this step?	Q3 Will a subsequent step prevent or eliminate the identified hazard or reduce it to an acceptable level?	Q4 Can this step specifically prevent or eliminate the identified significant hazard or reduce it to an acceptable level?	CCP number
	Growth and toxin production of pathogens such as <i>S. aureus</i>	N	Y	N	Y	CCP5
9. Smoking (optional)	Survival of pathogens such as <i>Salmonella</i> , <i>E. coli</i>	N	Y	N	Y	(CCP6)
10. Heat treatment (optional)	Survival of pathogens such as <i>Salmonella</i> , <i>E. coli</i>	N	Y	N	Y	(CCP7)
11. Maturation	Survival of pathogens such as <i>Salmonella</i> , <i>E. coli</i>	N	Y	N	Y	CCP8
12. Slicing (optional)	Transfer of <i>S. aureus</i> from workers	Y				
12. Slicing (optional)	<i>L. monocytogenes</i> contamination of the slicing machine, or the environment transfers to product	Y				
13. Packing (optional)	Transfer of <i>S. aureus</i> from workers	Y				
13. Packing (optional)	<i>L. monocytogenes</i> contamination of the machine, or the environment transfers to product	Y				

Process step	Significant hazard	Q1 Can the significant hazard by controlled to an acceptable level at this step by PRP (e.g. GMPs)?	Q2 Do specific control measures for the identified significant hazard exist at this step?	Q3 Will a subsequent step prevent or eliminate the identified hazard or reduce it to an acceptable level?	Q4 Can this step specifically prevent or eliminate the identified significant hazard or reduce it to an acceptable level?	CCP number
14. Storage	Pathogen growth such as <i>Salmonella</i> , <i>E. coli</i> , <i>S. aureus</i> , <i>L. monocytogenes</i>	Y				

CLs

This is a sample of the CLs, monitoring and corrective actions based on the sample hazard analysis and identification of CCPs. You need to state CLs (step 8) for your CCP, establish a monitoring system (step 9), determine corrective actions (step 10), and procedures for verification (step 11 of HACCP system development).

CCP number	Significant hazard	CLs	Monitoring				Corrective actions	Verification activities	Records
			What	How	When	Who			
CCP1	Growth of pathogens such as <i>Salmonella</i> , <i>E. coli</i> , <i>S. aureus</i>	Not greater than 5°C (<i>Australian Standard clause 11.6</i>). **	Raw meat	Chiller temperature	Continuously	Supervisor	1. Immediately chill product to correct temperature. 2. Assess product for use in a cooked product.	Weekly check of records. Calibration of temperature measuring devices.	Chiller log

CCP number	Significant hazard	CLs	Monitoring				Corrective actions	Verification activities	Records
			What	How	When	Who			
CCP2	Growth of pathogens such as <i>Salmonella</i> , <i>E. coli</i> , <i>S. aureus</i>	Not greater than 5°C (Australian Standard clause 11.6). **	Thawed and tempered raw meat	Chiller temperature	Continuously	Supervisor	1. Immediately chill product to correct temperature. 2. Assess product for use in a cooked product.	Weekly check of records. Calibration of temperature measuring devices.	Chiller log
CCP3	Growth of pathogens such as <i>Salmonella</i> , <i>E. coli</i> , <i>S. aureus</i>	Not greater than 5°C (Australian Standard clause 11.6). **	Trimmed raw meat	Chiller temperature	Continuously	Supervisor	1. Immediately chill product to correct temperature. 2. Assess product for use in a cooked product.	Weekly check of records. Calibration of temperature measuring devices.	Chiller log
CCP4	Survival of pathogens such as <i>Salmonella</i> , <i>E. coli</i> during fermentation	pH over time conforms to approved arrangement* ***	Product	pH meter	Twice per day and at 48h	Fermentation technician	1. Consider cooking the product.	Review records for each lot.	Fermentation log
		Weight loss/water activity over time conforms to approved arrangement * ***	Product	Balance / water activity meter	Every 24 hours	Fermentation technician	1. Consider cooking the product.	Review records for each lot.	Fermentation log

CCP number	Significant hazard	CLs	Monitoring				Corrective actions	Verification activities	Records
			What	How	When	Who			
		Temperature over time conforms to the validated process * ****	Product /ripening room	temperature	continuously	Fermentation technician	Quarantine, and Test finished product for <i>E. coli</i> .	Review records for each lot. Calibration of temperature measuring devices.	Fermentation log
CCP5	Growth and toxin production by <i>S. aureus</i> during fermentation	pH ≤5.2 after 48h ⁸⁹	Product	pH meter	at the end of fermentation	Fermentation technician	2. Assess the product for compliance with <i>S. aureus</i> microbiological criterion in finished product.	Review records for each lot. Calibration of pH meter	Fermentation log

⁸⁹ Australian controlling authorities have used pH 5.2 in this simplification of a US criterion .In the US calculation, a fermentation at 30°C (85°F, which is 25°F above 60°F (15.5°C)) achieving a pH of 5.3 in 48h will ‘accumulate’ 48 x 25 = 1200 degree-hours, which is the guideline limit. American Meat Institute Foundation [Blue Ribbon Taskforce] (1997). Good Manufacturing Practices for Fermented Dry & Semi-Dry Sausage Products. Meat HACCP – Food Safety @ UW-Madison – UW-Madison (wisc.edu).

<https://www.localfoodheroes.com/calculating-maximum-fermenting-times/>

pH 5.3 is referred to by FSIS as the ‘pH at which *S. aureus* growth is controlled’ in fermented meats. FSIS-GD-2023-0002: FSIS Ready-to-Eat Fermented, Salt-Cured, and Dried Products Guideline (usda.gov). In a shelf stability study, in a fermented sausage, pH ≤5.1 (pH 5.3 was not tested) and aw ≤0.96 (the highest aw tested) were sufficient prevent the growth of *S. aureus*. Tilkens, B.L., King, A.M., Glass, K.A., Sindelar, J.J., 2015. Validating the Inhibition of *Staphylococcus aureus* in Shelf-Stable, Ready-to-Eat Snack Sausages with Varying Combinations of pH and Water Activity. *Journal of Food Protection* 78, 1215-1220.

CCP number	Significant hazard	CLs	Monitoring				Corrective actions	Verification activities	Records
			What	How	When	Who			
(CCP6)	Survival of pathogens such as <i>Salmonella</i> , <i>E. coli</i>	Temperature and time conform to the validated process * ****	Smoking cabinet	Temperature probe	Continuously	Supervisor	1. Quarantine, and Test finished product for <i>E. coli</i> .	Check of records for each lot. Calibration of temperature measuring devices.	Temperature log
(CCP7)	Survival of pathogens such as <i>Salmonella</i> , <i>E. coli</i>	Heat treatment * 55°C for 20 minutes or equivalent (<i>Food Standards Code</i> 1.6.2)	Oven	Temperature probe	Continuously	Supervisor	Repeat the process.	Check of records for each lot. Calibration of temperature measuring devices.	Temperature log
CCP8	Survival of pathogens such as <i>Salmonella</i> , <i>E. coli</i>	Temperature over time conforms to the validated process * ****	Product /maturation room	Temperature	Continuously	Supervisor	1. Quarantine, a Test finished product for <i>E. coli</i> .	Check of records for each lot. Calibration of temperature measuring devices.	Temperature log

* The monitoring and recording of these parameters (if the optional steps are performed), and retention of the records, are required by the *Food Standards Code* Standard 4.2.3 Production and Processing Standard for Meat 5(6). Additional records are also required.

** *E. coli* does not grow below 7°C.. *S. aureus* does not produce toxin below 10°C and a high level of *S. aureus* is required (Chapter 9.1). A predictive tool can be used to assess the amount of growth that may occur: <https://meathaccp.wisc.edu/therm/> Ingham, S.C., Fanslau, M.A., Burnham, G.M., Ingham, B.H., Norback, J.P.,

Schaffner, D.W., 2007. Predicting Pathogen Growth during Short-Term Temperature Abuse of Raw Pork, Beef, and Poultry Products: Use of an Isothermal-Based Predictive Tool. *J Food Prot* 70, 1445-1455.

*** Assess whether conditions prevent the growth of *E. coli* (prerequisite for using the *E. coli* predictor. Presser, K.A., Ross, T., Ratkowsky, D.A., 1998. Modelling the Growth Limits (Growth/No Growth Interface) of *E. coli* as a Function of Temperature, pH, Lactic Acid Concentration, and Water Activity. *Applied and Environmental Microbiology* 64, 1773-1779

**** Assess using the *E. coli* predictor (Chapter 9.3)

Guidelines on procedures for CCPs and important GMPs can be found in the following places:

Information on CCPs

CCP 1, CCP 2, CCP 3 7.1 Receiving and temperature control of raw meat

CCP4, CCP6, CCP7 Design of fermentation and maturation temperature over time

The *Food Standards Code* requires that the production method used will reduce the concentration of *E. coli* in raw meat to the required level in finished product. To demonstrate this, you need to have two pieces of information:

1. The highest level of *E. coli* likely to be found in your raw meat. You may be able to obtain data from your supplier or send samples of meat from the start of your process to a laboratory for testing.
2. A prediction of *E. coli* reduction during your process. The easiest way to predict *E. coli* reduction is to use the *E. coli* Predictive tool (<https://www.mla.com.au/globalassets/mla-corporate/research-and-development/documents/e.coli-inactivation-model-v-2.2b-.xlsx>). The following information is required to enter into the Predictor:
 - temperature of the batter
 - temperature of fermentation
 - duration of fermentation (hours)
 - temperature and duration of smoking (if performed)
 - temperature at each stage of maturing
 - temperature and duration of heat treatment (if performed)
 - length of each stage (hours)

Instructions on using the *E. coli* predictor can be found in Chapter 9.3.

A prediction of *E. coli* reduction during the process can also be determined through a challenge study, in which *E. coli* is added to the batter and inactivation is monitored through the process by testing. This is an expensive method which requires a high level of technical competence.

You must be sure that your process is capable of reducing the *E. coli* concentration in your raw materials to meet the microbiological criterion in the *Food Standards Code* (less than 3.6/g, see below). If it is not capable of achieving that outcome, then you must change your process. Fermenting or maturing at a higher temperature will increase the reduction of *E. coli*. You may also consider heat treatment.

CCP5 7.13 Fermenting

CCP7 7.8 Smoking

CCP8 7.10 Heat treatment

Important GMPs

- | | |
|--------|--|
| Step 1 | 4.3 Control of raw materials |
| Step 5 | 4.7- Physical contamination – and foreign body detection |
| Step 6 | 7.3 Formulation and assembly of raw materials,
4.5 Allergen management,
4.3 Control of raw materials |
| Step 7 | 4.7- Physical contamination – and foreign body detection |

- Step 12, 13 3.4 Keeping control of *Listeria*
 6.8 Protective cultures
 7.17 Packing
- Step 14 4.10 Product traceability and recall,
 7.18 Temperature control of finished product

8.8.6 Validation

Just as there are a large variety of UCFM products, and there may be several HACCP plans, the validation of the process must be done multiple times.

A safe product is one where:

- the batter is fermented using a starter culture to produce a controlled reduction in pH of the meat
- nitrite / nitrate is added at the required level to control *C. botulinum*
- the process can inactivate the highest *E. coli* counts of in-going raw materials to levels that comply with Standard 1.6.1 (Microbiological limits in food – see below)
- the number of *E. coli* in the final product complies with Standard 1.6.1 (Microbiological limits in food – see below).

8.8.7 Verification

Records are kept of each batch of UCFM manufactured for 12 months after the use-by or best-before date of the product

The following microbiological criteria will be applied if testing is performed.

The *Food Standards Code* requires testing for *E. coli* in raw meat and in finished product.

You can validate whether your product supports the growth of *L. monocytogenes* following the advice in Chapter 1.8.2. It is possible to reformulate your product so that it does not support the growth of *L. monocytogenes* following the advice in Chapter 9.2.

Verification of compliance with the criterion for *L. monocytogenes* (on a single sample) is required by controlling authorities for RTE products.⁹⁰

Testing for other microorganisms may not necessarily be part of a regular testing program, but the production process must be designed to meet them.

	Number of samples (n)	Number of samples allowed to be >m but ≤M	Limit (m)	Limit (M)
Coagulase-positive staphylococci	5	1	10 ³ /g	10 ⁴ /g
<i>E. coli</i>	5	1	3.6/g	9.2/g
<i>Salmonella</i>	5	0	Not detected in 25g	
SPC*	5	2	10 ⁵ /g	10 ⁶ /g
Product in which growth of <i>L. monocytogenes</i> can occur	5	0	Not detected in 25g	

⁹⁰ Australian Meat Regulators Group (2019) Standard 4.2.3 - Guidelines for the Management of Listeria.

	Number of samples (n)	Number of samples allowed to be >m but ≤M	Limit (m)	Limit (M)
Product in which growth of <i>L. monocytogenes</i> will not occur	5	0	10 ² /g	

* It is possible that the SPC will detect starter cultures that have survived the production process

8.9 Fermented then cooked meats (CFM)

8.9.1 Description of product

In the 1990s, following outbreaks of illness from consumption of UCFM, manufacturers developed fermented sausages which receive a cooking step.

Many manufacturers use a cooking step where fermented sausages receive 65°C for 10 minutes or a temperature/time which gives an equivalent killing effect. The *Food Standards Code* requires these products to be labelled as “fermented cooked”.

There are certain advantages in using a cooking step:

- The level of inactivation of *E. coli* means there is no requirement for testing raw meat or the final product for *E. coli*.
- The process allows manufacturers to get the product on the market more quickly.

If the product achieves shelf stability because of its pH and/or water activity it may be stored at ambient temperature. Otherwise, it is stored under refrigeration.

The manufacturing process is similar to that of UCFM, except that a cooking step is introduced following fermentation or after maturation.

If products receive a lesser heat treatment than 65°C for 10 minutes (or equivalent) then they are considered ‘heat treated’ and these products are included in the UCFM chapter.

The following sample description should be reviewed and completed (step 2 in the HACCP system development process)

Ingredients	Meat (frozen, chilled) of the required species Fat and trimmings (frozen, chilled) of the required species Salt Nitrites Spices Starter culture Other ingredients
Primary Packaging	x
Storage Conditions	depends on whether the product is shelf stable
Shelf Life	‘Use-by’ date (if <i>L. monocytogenes</i> is able to grow): x days from production ‘Best-before’ date (if <i>L. monocytogenes</i> is not able to grow): x days from production. Shelf life once opened: x days once opened.
Labelling related to product safety	All allergens must be included in the ingredients list using the format prescribed in the <i>Food Standards Code</i> .

8.9.2 Intended use and users

The following sample description of intended use should be reviewed and completed (step 3 in the HACCP system development process)

Sensitive Customer	
Customer Preparation	RTE

8.9.3 Flow diagram

The process flow may vary between products and with available equipment. This is a sample flow diagram, used to prepare the sample HACCP analysis. Constructing your own flow diagram and on-site confirmation of the process are two steps (steps 4 and 5) in the HACCP system development.



8.9.4 Potential hazards and control measures

This is a sample hazard analysis based on the sample flow diagram. You need to conduct your own hazard analysis based on your product, production process, and circumstances (Step 6 of HACCP system development)

Step	Identify potential hazards	Does this potential hazard need to be addressed in the HACCP plan		Justification for decision in column 3	What measure(s) can be applied to prevent or eliminate the hazard or reduce it to an acceptable level	
		YES	NO			
1. Meat receipt and storage	B	All meat: <i>Salmonella</i> , <i>S. aureus</i> , <i>L. monocytogenes</i> , <i>C. botulinum</i> , <i>C. perfringens</i> Beef: pathogenic <i>E. coli</i> Pork: <i>Y. enterocolitica</i> , Lamb: pathogenic <i>E. coli</i> Chicken: <i>Campylobacter</i> sp.	Y		The prevalence of these pathogens in Australian meat is low. Imported pork can be used in CFM subject to the biosecurity requirements (Chapter 7.11).	Purchase from reliable suppliers. Use inside muscle cuts. Wash surface with lactic acid. Testing program.
	B	Pathogens such as <i>Salmonella</i> , <i>E. coli</i> ,	Y		Pathogens of concern will be able to grow at greater than 7°C.	Follow the temperature requirements of the <i>Australian Standard</i> .
	B	<i>S. aureus</i>	Y		Toxin production may occur at greater than 10°C and these toxins may remain active until consumption.	Follow the temperature requirements of the <i>Australian Standard</i> .
	C	Residues of agricultural and veterinary chemicals		N	The prevalence of these chemicals in Australian meat is low.	
	P	Bone splinters, foreign objects, plastic wrap	Y		May cause injury to consumers.	Physical contamination checks.

Step	Identify potential hazards		Does this potential hazard need to be addressed in the HACCP plan		Justification for decision in column 3	What measure(s) can be applied to prevent or eliminate the hazard or reduce it to an acceptable level
			YES	NO		
2. Thawing, tempering, unpacking	B	Pathogens such as <i>Salmonella</i> , <i>E. coli</i> .	Y		Growth of pathogens such as <i>Salmonella</i> , <i>E. coli</i> .	Follow the temperature requirements of the <i>Australian Standard</i> .
	B	<i>S. aureus</i>	Y		Growth and toxin production by <i>S. aureus</i> .	Follow the temperature requirements of the <i>Australian Standard</i> .
	C					
	P	Plastic may be trapped in between pieces of frozen meat		N	Soft plastic is not a food safety hazard.	Temper for sufficient time for the meat to thaw and allow easy removal of plastic.
3. Trimming	B					
	C					
	P					
4. Storage	B	Pathogens such as <i>Salmonella</i> , <i>E. coli</i>	Y		Growth of pathogens such as <i>Salmonella</i> , <i>E. coli</i> .	Follow the temperature requirements of the <i>Australian Standard</i> .

Step	Identify potential hazards		Does this potential hazard need to be addressed in the HACCP plan		Justification for decision in column 3	What measure(s) can be applied to prevent or eliminate the hazard or reduce it to an acceptable level
			YES	NO		
	B	<i>S. aureus</i>	Y		Growth and toxin production by <i>S. aureus</i> .	Follow the temperature requirements of the <i>Australian Standard</i> .
	C					
	P					
5. Grinding or bowl chopping	B					
	C					
	P	Fragments of metal	Y		Fragment of metal from machinery may cause injuries to consumers.	Physical contamination checks.
6. Ingredient addition	B					
	C	Nitrites and sulphites can cause adverse reactions in consumers if the level is too high. Too low nitrites, nitrates could allow pathogens such as <i>C. botulinum</i> to grow. Salt must be added at the correct level to inhibit growth of pathogens such as <i>E. coli</i> and <i>Salmonella</i> . Sugar addition helps starter cultures to grow, produce acid and cause rapid fall in pH.	Y		Multiple chemicals must be added at the correct level to produce a chemically safe product, and allow the processing of the product to produce conditions that will produce a shelf-stable product and inactivate pathogens through changes in pH and <i>a_w</i> .	Care taken with the addition of ingredients.
	P					
7. Filling	B					

Step	Identify potential hazards		Does this potential hazard need to be addressed in the HACCP plan		Justification for decision in column 3	What measure(s) can be applied to prevent or eliminate the hazard or reduce it to an acceptable level
			YES	NO		
	C					
	P	Fragments of metal	Y		Fragment of metal from machinery may cause injuries to consumers.	Physical contamination checks. Metal detector.
8. Fermentation	B	Pathogens such as <i>Salmonella</i> , <i>E. coli</i>	Y		Slow or incomplete fermentation may allow the growth and/or survival of pathogens.	Monitoring of temperature, water activity (weight loss) and pH. Use of <i>E. coli</i> predictor to assess inactivation. <i>Salmonella</i> is probably controlled adequately by applying the criteria associated with the <i>E. coli</i> predictive model, and the microbiological criterion for <i>E. coli</i> .
	B	Growth and toxin production by <i>S. aureus</i>	Y		Slow or incomplete fermentation may allow the growth and toxin production by <i>S. aureus</i> .	pH below 5.2 within 48 hours.
	C					

Step	Identify potential hazards		Does this potential hazard need to be addressed in the HACCP plan		Justification for decision in column 3	What measure(s) can be applied to prevent or eliminate the hazard or reduce it to an acceptable level
			YES	NO		
9. Smoking	B	Pathogens such as <i>Salmonella</i> and <i>E. coli</i>	Y		Survive the smoking process.	The <i>E. coli</i> predictor does not consider the effect of smoke on <i>E. coli</i> but can incorporate the time-temperature effect. <i>Salmonella</i> is probably controlled adequately by applying the criteria associated with the <i>E. coli</i> predictive model, and the microbiological criterion for <i>E. coli</i> .
	C					
	P					
10. Cooking	B	Pathogens such as <i>Salmonella</i> and <i>E. coli</i>	Y		Survive the cooking process.	Follow the temperature requirements of the <i>Australian Standard</i> . Cooking will effectively reduce <i>E. coli</i> to safe levels.
	C					

Step	Identify potential hazards	Does this potential hazard need to be addressed in the HACCP plan		Justification for decision in column 3	What measure(s) can be applied to prevent or eliminate the hazard or reduce it to an acceptable level	
		YES	NO			
	P					
11. Cooling	B	Growth and toxin production due to the growth of <i>C. perfringens</i> during cooling		N	The pH of the sausage and possibly the water activity will be too low to allow <i>C. perfringens</i> growth.	
	C					
	P					
12. Storage	B	Pathogen such as <i>Salmonella</i> , <i>E. coli</i> , <i>S. aureus</i> , <i>L. monocytogenes</i>		N	Products are expected to be shelf stable and conditions on the surface are not expected to support the growth of pathogens.	Define products as shelf stable based on pH and a_w for a cooked product.
	C					
	P					

8.9.5 CCPs and CLs

CCPs

Process step	Significant hazard	Q1 Can the significant hazard be controlled to an acceptable level at this step by PRP (e.g. GMPs)?	Q2 Do specific control measures for the identified significant hazard exist at this step?	Q3 Will a subsequent step prevent or eliminate the identified hazard or reduce it to an acceptable level?	Q4 Can this step specifically prevent or eliminate the identified significant hazard or reduce it to an acceptable level?	CCP number
		If YES, this step is not a CCP	If YES proceed to Q3	If YES that subsequent step should be a CCP	If YES, this step is a CCP	
		If NO, proceed to Q2	If NO this step is not a CCP. Subsequent steps should be evaluated for a CCP	If NO, proceed to Q4	If NO, modify the step, process or product to implement a control measure	
1. Meat receipt and storage	Bacterial pathogens such as <i>Salmonella</i> , <i>E. coli</i> , <i>S. aureus</i> , <i>Y. enterocolitica</i> , <i>C. perfringens</i> , <i>C. botulinum</i>	Y				
	Growth of pathogens such as <i>Salmonella</i> , <i>E. coli</i> , <i>Y. enterocolitica</i> , <i>C. perfringens</i> , <i>C. botulinum</i>	N	Y	Y (10. cooking)		
	<i>S. aureus</i> producing a heat stable toxin	N	Y	N	Y	CCP1
2. Thawing, tempering, unpacking	Growth of pathogens such as <i>Salmonella</i> , <i>E. coli</i>	N	Y	Y (10. Cooking)		
	<i>S. aureus</i> producing a heat stable toxin	N	Y	N	Y	CCP2

Process step	Significant hazard	Q1 Can the significant hazard be controlled to an acceptable level at this step by PRP (e.g. GMPs)?	Q2 Do specific control measures for the identified significant hazard exist at this step?	Q3 Will a subsequent step prevent or eliminate the identified hazard or reduce it to an acceptable level?	Q4 Can this step specifically prevent or eliminate the identified significant hazard or reduce it to an acceptable level?	CCP number
4. Storage	Growth of pathogens such as <i>Salmonella</i> , <i>E. coli</i>	N	Y	Y (10. Cooking)		
	<i>S. aureus</i> producing a heat stable toxin	N	Y	N	Y	CCP3
5. Grinding or bowl chopping	Fragments of metal	Y				
6. Ingredient addition	<p>Nitrites and sulphites can cause adverse reactions in consumers if the level is too high.</p> <p>Too low nitrites, nitrates could allow pathogens such as <i>C. botulinum</i> to grow.</p> <p>Salt must be added at the correct level to inhibit growth of pathogens such as <i>E. coli</i> and <i>Salmonella</i>.</p> <p>An appropriate starter culture must be added at an appropriate level.</p> <p>Sugar addition helps starter cultures to grow, produce acid and cause rapid fall in pH.</p>	Y				
7. Filling	Fragments of metal	Y				
8. Fermentation	Survival of pathogens such as <i>Salmonella</i> , <i>E. coli</i>	N	Y	Y (10. Cooking)		

Process step	Significant hazard	Q1 Can the significant hazard be controlled to an acceptable level at this step by PRP (e.g. GMPs)?	Q2 Do specific control measures for the identified significant hazard exist at this step?	Q3 Will a subsequent step prevent or eliminate the identified hazard or reduce it to an acceptable level?	Q4 Can this step specifically prevent or eliminate the identified significant hazard or reduce it to an acceptable level?	CCP number
	<i>S. aureus</i> producing a heat stable toxin	N	Y	N	Y	CCP4
9. Smoking	Survival of pathogens such as <i>Salmonella</i> , <i>E. coli</i>	N	Y	Y (10. Cooking)		
10. Cooking	Survival of pathogens such as <i>Salmonella</i> , <i>E. coli</i> , <i>C. perfringens</i>	N	Y		Y	CCP5

CLs

This is a sample of the CLs, monitoring and corrective actions based on the sample hazard analysis and identification of CCPs. You need to state CLs (step 8) for your CCP, establish a monitoring system (step 9), determine corrective actions (step 10), and procedures for verification (step 11 of HACCP system development) and record keeping (step 12).

CCP number	Significant hazard	CLs	Monitoring				Corrective actions	Verification activities	Records
			What	How	When	Who			
CCP1	Growth and toxin production by <i>S. aureus</i>	Not greater than 5°C (<i>Australian Standard</i> clause 11.6) *	Raw meat	Chiller temperature	Continuously	Supervisor	1. Immediately chill product to correct temperature. 2. Assess safety of product for use.	Weekly check of records. Calibration of temperature measuring devices.	Chiller log

CCP number	Significant hazard	CLs	Monitoring				Corrective actions	Verification activities	Records
			What	How	When	Who			
CCP2	Growth and toxin production by <i>S. aureus</i>	Not greater than 5°C (<i>Australian Standard</i> clause 11.6) *	Thawed and tempered raw meat	Chiller temperature	Continuously	Supervisor	1. Immediately chill product to correct temperature. 2. Assess safety of product for use.	Weekly check of records. Calibration of temperature measuring devices.	Chiller log
CCP3	Growth and toxin production by <i>S. aureus</i>	Not greater than 5°C (<i>Australian Standard</i> clause 11.6) *	Trimmed raw meat	Chiller temperature	Continuously	Supervisor	1. Immediately chill product to correct temperature. 2. Assess safety of product for use.	Weekly check of records. Calibration of temperature measuring devices.	Chiller log
CCP4	Growth and toxin production by <i>S. aureus</i>	pH ≤5.2 after 48h ⁹¹	Product	pH meter	At the end of fermentation	Fermentation technician	2. Assess the product for compliance with <i>S. aureus</i> microbiological criterion in finished product.	Review records for each lot. Calibration of pH meter.	Fermentation log

⁹¹ Australian controlling authorities have used pH 5.2 in this simplification of a US criterion. In the US calculation, a fermentation at 30°C (85°F, which is 25°F above 60°F (15.5°C)) achieving a pH of 5.3 in 48h will 'accumulate' 48 x 25 = 1200 degree-hours, which is the guideline limit. American Meat Institute Foundation [Blue Ribbon Taskforce] (1997). Good Manufacturing Practices for Fermented Dry & Semi-Dry Sausage Products. Meat HACCP – Food Safety @ UW-Madison – UW-Madison (wisc.edu).

<https://www.localfoodheroes.com/calculating-maximum-fermenting-times/>

pH 5.3 is referred to by FSIS as the 'pH at which *S. aureus* growth is controlled' in fermented meats. FSIS-GD-2023-0002: FSIS Ready-to-Eat Fermented, Salt-Cured, and Dried Products Guideline (usda.gov). In a shelf stability study, in a fermented sausage, pH ≤5.1 (pH 5.3 was not tested) and aw ≤0.96 (the highest aw tested) were sufficient prevent the growth of *S. aureus*. Tilkens, B.L., King, A.M., Glass, K.A., Sindelar, J.J., 2015. Validating the Inhibition of *Staphylococcus aureus* in Shelf-Stable, Ready-to-Eat Snack Sausages with Varying Combinations of pH and Water Activity. *Journal of Food Protection* 78, 1215-1220.

CCP number	Significant hazard	CLs	Monitoring				Corrective actions	Verification activities	Records
			What	How	When	Who			
CCP5	Survival of pathogens such as <i>Salmonella, E. coli</i>	65°C for 10 minutes or equivalent according to the <i>Australian Standard</i> clause 13.5 **	Slowest heating point of sausage	Temperature probe	Continuously	Supervisor	1. Recook. 2. Consider labelling as 'heat treated'.	Check records every batch.	Temperature log book

* *S. aureus* does not produce toxin below 10°C and a high level of *S. aureus* is required (Chapter 9.1). A predictive tool can be used to assess the amount of growth that may occur: <https://meathaccp.wisc.edu/therm/> Ingham, S.C., Fanslau, M.A., Burnham, G.M., Ingham, B.H., Norback, J.P., Schaffner, D.W., 2007. Predicting Pathogen Growth during Short-Term Temperature Abuse of Raw Pork, Beef, and Poultry Products: Use of an Isothermal-Based Predictive Tool. J Food Prot 70, 1445-1455.

** imported pork must be cooked to also meet DAFF biosecurity requirements

Guidelines on procedures for CCPs and important GMPs can be found in the following places:

Information on CCPs

CCP 1, CCP 2, CCP 3 7.1 Receiving and temperature control of raw meat

CCP 4 7.13 Fermenting

CCP 5 7.11 Cooking

Important GMPs

Step 1,2,3,4 4.3 Control of raw materials

Step 5 4.7 Physical contamination – and foreign body detection

Step 6 4.3 Control of raw materials,
4.5 Allergen management,
7.3 Formulation and assembly of raw materials

Step 7 4.7 Physical contamination – and foreign body detection

8.9.6 Validation

A safe product is one where:

- raw meat is held at the correct temperature
- the batter is fermented using a starter culture to produce a controlled reduction in pH of the meat
- nitrite / nitrate is added at the required level
- product is cooked according to the requirements of the *Australian Standard*
- product is cooled according to the requirements of the *Australian Standard*
- non shelf-stable product is held under refrigeration

8.9.7 Verification

There are no microbiological criteria in the *Food Standards Code* for CFM.

Verification of compliance with the criterion for *L. monocytogenes* (on a single sample) is required by controlling authorities for RTE products.⁹²

8.10 Other Smallgoods Products

8.10.1 How to make your product safely

Just because your product is considered 'unusual' to the Western European consumers, and Australian regulators, doesn't mean that it is unsafe, but also you cannot assume that it is acceptable to make the product according to the traditional family recipe and practices. There are many examples of how traditional products made by traditional practices are no longer safe when they are made on a large scale, under different circumstances, and then held, transported, sold, and consumed under different conditions.

This chapter is about how to think about your product and consult these *Guidelines* (maybe with some help) to work out what you need to do to produce your product safely for Australian consumers.

⁹² Australian Meat Regulators Group (2019) Standard 4.2.3 - Guidelines for the Management of Listeria.

The first five chapters of these *Guidelines* are important to read and understand. These chapters describe how to set up your manufacturing and how to plan to make a safe product. This chapter suggests some of the main points you need to think about.

Have a look at Chapters 8.1 through to 8.9 describing different product types. You will notice that each chapter has the same headings, and the same tables. The text and the tables in those chapters are a template to guide manufacturers of those products to produce a FSP for their product. They will need to edit those templates so that they accurately describe their product and process, and to help them think about the product's safety. You will need to do the same, using Chapters 5 (HACCP) and 7 (processes) to help you understand how to analyse and design the safety of your process, with some additional guidance in this chapter.

In the sections below we have attempted to describe the 'unusual' products and how they are usually made, identify which 'conventional' product type (Chapters 8.1-8.9) it is most like, and the hazards and likely main points that need to be addressed to make the product safe. This advice is very general, because there are many ways that these products may be made. After reading, it may be necessary for you to make your product in a different way to be sure it is safe.

8.10.2 Dry Chinese Sausage, including Lap Cheong

Description of Product

There are numerous types of dried, unfermented sausage that are intended to be eaten after cooking. Different ingredients are used such as pork, and pork fat but they can also be made with pig and poultry livers. Other ingredients include rice wine, soy sauce, salt, rose water, and spices, particularly chili.

There are also other types of sausages made in China, or other Asian countries that are not dried, or not intended to be eaten only after cooking, and they are not discussed in this section.

Process

Lap Cheong is typically made by heating in a controlled environment at a minimum of 45–50°C at low relative humidity (65–75%). After initial drying, the moisture content of the product is 30–35% and the salt content is 11–12%, as the salt becomes more concentrated with less moisture in the product. The air-drying process causes the sausage to lose approximately 40–55% of its initial weight, with reduction in water activity.

These sausages are dried quickly (i.e., not slow cured). The high temperatures used in air drying dry the product but may not cook it (see the definition of cooking in Chapter 7.11). They do not rely on a natural fermentation for preservation, so they should not be required to follow the regulations for UCFM products.

Even though the ingredients may be different, and the product is formed into a sausage, when thinking about the safety of the product it seems similar to jerky. You should read Chapter 8.6 Dried Meats to see whether this chapter is a useful starting point for producing a FSP for your product.

Hazards

S. aureus is a particular hazard. *S. aureus* may grow in the early stages while the product has a lot of water and the temperature is in the range 15-40°C. If *S. aureus* is able to grow it may produce a toxin which will not be destroyed when the product is cooked and will make people sick (See Chapter 9.1.4).

Bacteria such as *Salmonella* (Chapter 9.1.1) and pathogenic *E. coli* (Chapter 9.1.2) are often a hazard in these types of products, though the final cooking should kill them. However, it is not acceptable to sell a product that may be consumed without cooking to have *Salmonella* or pathogenic *E. coli* in it. The good news is that the drying process at high temperatures will be expected to kill these bacteria if they are present in the raw meat. The University of Tasmania model for inactivation of *E. coli* in UCFMs can be used to assess processes (Chapter 9.3). It is important to know at which point in the process the sausage has a combination of pH and

water activity that will prevent the growth of *E. coli*⁹³ because *E. coli* will only be inactivated after the time that growth is prevented. The tool predicts that some Lap Cheong processes provide a >8-10 log reduction of *E. coli* which is more than enough to make the product safe.

Product characteristics

The good shelf life without refrigeration of traditional dried Chinese sausage is due mainly to the rapid reduction in water activity (a_w). Dried meat must be dried to a water activity of no more than 0.85 to be safe. You should get the water activity tested in a laboratory (Chapter 7.19.2), to make sure it meets this requirement. Sausages like Lap Cheong usually have a very low water activity which will also prevent the growth of moulds.

The product may still be shelf stable at slightly higher water activity (see Table 6 in Chapter 1.8.1), but the acidity level (measured as pH) may then become important.

The shelf life of the product is typically two to three months without refrigeration and if vacuum packaged, four to five months. The use of double laminate with low oxygen and moisture transmission rates, and possibly an oxygen/moisture scavenger, aids in the maintenance of product quality and preventing mould growth. Refrigeration may also improve the shelf life of the product even if it is shelf stable.

Defining a safe product

A safe product is one that has:

- a high salt level during the early stages of drying
- temperature controlled throughout the process to achieve quick drying
- a low final water activity (and, if necessary, pH) to be shelf stable
- drying to a very low moisture level (water activity) to prevent mould growth.

Verification of product safety

The process of drying should be verified on a continual basis through monitoring and recording of the drying times and temperatures, and periodic verification through measurement of weight loss and a_w of the finished product.

There are no microbiological limits in the *Food Standards Code* for dried meats (water activity of no more than 0.85 that are not slow dried cured meat). As requirements differ from state-to-state, check with your controlling authority about testing and approval requirements.

Dried meats (water activity of no more than 0.85 that are not slow dried cured meat) and production environments can be excluded from *Listeria* testing because they are shelf stable products. The microbiological criteria for *L. monocytogenes* in the *Food Standards Code* applies only to RTE foods and shelf stable products are not considered RTE foods for the purpose of applying microbiological criteria (as defined in Standards 1.6.1 and 1.1.2 of the *Food Standards Code*).

⁹³Presser, K.A., Ross, T., Ratkowsky, D.A., 1998. Modelling the Growth Limits (Growth/No Growth Interface) of *Escherichia coli* as a Function of Temperature, pH, Lactic Acid Concentration, and Water Activity. *Applied and Environmental Microbiology* 64, 1773-1779)

8.10.3 Turkish and Western Asian sausages

Description of Product

There are many names for the popular Turkish sausage sucuk (soudjuk). It is also consumed in South Eastern Europe, in Lebanon, and through to central Asia.

The sausage is spicy-hot, semi-dry and made from only ruminant meat (beef, buffalo, mutton), with salt, nitrite and paprika which may undergo fermentation.

Traditionally, sucuk is eaten cooked as a breakfast sausage, though some people dry and consume it without cooking.

Process

In addition to the ruminant meat, salt (around 2% wt/wt), nitrite (150-200 mg/kg) and paprika are added in the mincing stage.

There are several production methods.

In one method, the sausages are hung for around seven days at 8-9°C in a room at 70% relative humidity), and 20–25% of the moisture is lost. There may be some natural fermentation and the pH falls to 5.0 - 5.5. The moisture content is low (around 40%) and usually no heat treatment or smoking is applied.

In another method, salt and nitrite are added to minced meat, before adding fat, spices, dextrose and starter cultures and filling into casings. Fermentation is performed at 22-23°C at fairly high relative humidity (RH) and then the temperature and RH are gradually decreased until the third day of fermentation.

At the end of this fermentation stage the pH of the product must have dropped to 4.9–5.0. In the post-fermentation stage sucuk is matured and dried until the moisture content of the sausage is under 40%.

Whether starter cultures are added or not, the product does seem to rely on a fermentation. The production sounds most like a semi-dry salami, as described in Chapter 8.8 UCFM. The *Food Standards Code* requires UCFM to be made using starter cultures; allowing a natural fermentation or adding some of the previous batch to the next batch are too risky for food safety.

Hazards

Since there is no step in the production process, such as cooking that will kill pathogenic bacteria, a number of pathogens that can be found in raw meat are hazards that need to be controlled by the process. *Salmonella*, pathogenic *E. coli* and *S. aureus* are the major pathogens that are of concern. As with UCFM, the safety of the product is a result of the design of the process including process hygiene, and how well it is controlled. Even if the product is intended to be consumed only after cooking, it is not wise to depend on all consumers to cook the product. As a result, it is not acceptable to sell a product that may be consumed without cooking to have *Salmonella* or pathogenic *E. coli* in it. The University of Tasmania model for inactivation of *E. coli* in UCFMs can be used to assess processes (Chapter 9.3). It is important to know at which point in the process the sausage has a combination of pH and water activity that will prevent the growth of *E. coli*⁹⁴ because *E. coli* will only be inactivated after the time that growth is prevented.

If safety of the process depends on fermentation, then all of the regulatory requirements for UCFM should be complied with (Chapter 8.8 focuses on food safety, but there are also other regulatory requirements).

⁹⁴ Presser, K.A., Ross, T., Ratkowsky, D.A., 1998. Modelling the Growth Limits (Growth/No Growth Interface) of *Escherichia coli* as a Function of Temperature, pH, Lactic Acid Concentration, and Water Activity. *Applied and Environmental Microbiology* 64, 1773-1779)

Product characteristics

At the end of the production, the pH of the product must be 4.9-5.0 (see Chapter 7.19.1) and the water activity should be measured (see Chapter 7.19.2).

The final pH and water activity (a function of the moisture level, but which needs to be measured) determine whether the finished product must be refrigerated for safety during its shelf life (see Table 6 in Chapter 1.8.1).

Defining a safe product

A safe product is one that:

- has a rapid reduction in pH to avoid growth and toxin production by *S. aureus* and growth of *E. coli* and *Salmonella*
- nitrite is added to control *C. botulinum* and other pathogenic spore forming bacteria
- the predicted death of *E. coli* is at least 2 logs assuming that the pH and water activity reduction rapidly prevent growth
- the number of *E. coli* in the final product complies with Standard 1.6.1 (Microbiological limits in food – see below)

Verification of product safety

Even though you may be intending that the product is cooked before consumption, you should comply with the verification requirements of UCFM:

The *Food Standards Code* requires testing for *E. coli* in raw meat and in finished product.

Verification of compliance with the criterion for *L. monocytogenes* (on a single sample) is required by controlling authorities if the product is sold as RTE.⁹⁵

Testing for other microorganisms may not necessarily be part of a regular testing program, but the production process must be designed to meet them. The following microbiological criteria, applicable to UCFMs, would address likely hazards that may be associated with the product and production method.

	Number of samples (n)	Number of samples allowed to be >m but ≤M	Limit (m)	Limit (M)
Coagulase-positive staphylococci	5	1	10 ³ /g	10 ⁴ /g
<i>E. coli</i>	5	1	3.6/g	9.2/g
<i>Salmonella</i>	5	0	Not detected in 25g	
SPC*	5	2	10 ⁵ /g	10 ⁶ /g
Product in which growth of <i>L. monocytogenes</i> can occur	5	0	Not detected in 25g	
Product in which growth of <i>L. monocytogenes</i> will not occur	5	0	10 ² /g	

* It is possible that the SPC will detect starter cultures that have survived the production process

⁹⁵ Australian Meat Regulators Group (2019) Standard 4.2.3 - Guidelines for the Management of Listeria.

8.10.4 Cured, dried, pork belly

Description of Product

This product of Chinese origin is cured, marinated, dried, cooked and smoked. It is shelf stable and used as an ingredient in cooked meals. The product seems moist and spongy because of the layer of fat and the marinated pork muscle.

Process

Pork middles are marinated before rinsing and drying at ambient temperature. Cooking is achieved at a temperature high enough to control vegetative pathogens. Product is packed in vacuum and stored at ambient temperatures with a shelf life of a few months.

The process is somewhat like the process for Biltong (see Chapter 8.6, Dried Meats) except it uses a whole piece of meat with layers of muscle and fat. Biltong is a dried meat with low moisture which is cured with salt and vinegar and is air dried. Both the *Food Standards Code* and the *Australian Standard* define dried meats in terms of the final water activity (a_w) of the product being below 0.85. Biltong relies on a series of controls each of which only partially address food safety concerns.

Hazards

In the early stages of production the product is susceptible to growth of pathogens, and marinating must occur at low temperatures. The pH of the marinade/product at this time is important. When the product commences drying at ambient temperatures, it must have a pH and water activity that prevents the growth and toxin product by *S. aureus*. Cooking is sufficient to destroy vegetative pathogens. At the end of cooking the water activity is too low to support the growth of *C. perfringens* so it is not necessary to cool rapidly.

Product characteristics

The product has a low water activity, sufficiently low to meet the definition of dried meat. At this low water activity, the pH of the final product is not important.

Defining a safe product

A safe product will:

- be marinated at a low temperature
- have a high salt level (low water activity) during the early stages of drying
- have pH/salt concentration (water activity) controlled until it becomes shelf stable
- have temperature controlled throughout the process to achieve quick drying
- have a final water activity to make the final product shelf stable
- be dried to a very low moisture level (water activity) to prevent mould growth.

Verification of product safety

There are no microbiological criteria for dried meats in the *Food Standards Code*. As requirements differ from state-to-state check with your controlling authority about testing and approval requirements.

Dried meats (water activity of no more than 0.85 that are not slow dried cured meat) and production environments can be excluded from *Listeria* testing because they are shelf stable products. The microbiological criteria for *L. monocytogenes* in the *Food Standards Code* applies only to RTE foods and shelf stable products are not considered RTE foods for the purpose of applying microbiological criteria (as defined in Standards 1.6.1 and 1.1.2 of the *Food Standards Code*).

8.10.5 Soft, spreadable sausages

Description of Product

Soft, spreadable sausages vary from having a coarse texture, often described as 'steak tartare in a casing' to being a paste. The water activity is high because the sausage must be easy to spread. The pH is also high (>5.0) for two reasons. Firstly, the meat protein must not set, as in a firm salami and secondly, the taste must be sweet.

Products such as Teewurst, Braunschweiger and 'Nduja fit are soft spreadable sausages, but 'Nduja is discussed separately (Chapter 8.10.6). Depending on the particular product, they may undergo some kind of natural fermentation for a short period and may be smoked. Usually pork (and bacon) is used, but beef may also be used. Nitrite, salt, mineral salts, spices or other ingredients may be added.

The sausages are manufactured for quick sale in delis, manufacturers' shops etc. They are not intended for long shelf life in supermarkets. The product is considered RTE.

Process

Spreadable sausages may be processed by two methods:

- Unsmoked, vacuum packed to maintain moisture and sold refrigerated.
- Blended with a starter culture, packed in a cellulose casing, smoked (cold at 15°C for 3 to 12 hours) then hung at ambient temperature for one to two days.

Given that the product must have a pH above 5.2 to prevent the meat protein changing its form, the starter does not appear to have any function. It may be possible to find starter cultures that do not lower the pH too significantly, and protective cultures (see Chapter 6.8) may be useful. Starter cultures may be used and fermentation allowed to proceed over 7-10 days, but this is likely to produce a harder product which is now longer spreadable.

If starter cultures are used, and the product depends on achieving a low pH to contribute to food safety, then Chapter 8.8 UCFMs would provide a useful guide to making a safe product.

Hazards

Products like Teewurst are consumed widely in Europe and have been implicated in outbreaks of illness due to both pathogenic *E. coli* and *Salmonella* in recent years. This is not surprising because the process is unlikely to reduce *Salmonella*, *E. coli* or other pathogens. High levels of antimicrobial compounds (e.g. phenols) from smoke may retard growth of these bacteria rather than reduce numbers.

There is probably limited opportunity for *S. aureus* to grow if the sausage is cold smoked at low temperatures. Ability to grow during subsequent storage probably depends on how much water is lost (measured as water activity), whether the pH is reduced and whether other bacteria are present to out-compete the staphylococci.

Product characteristics

The high moisture and high pH of typical product results in a short shelf life, even if smoking is included as a processing step.

Defining a safe product

It is not possible to define steps that will guarantee a safe product because there are no processing steps that will effectively eliminate hazards or reduce them to a safe level. If the pH and water activity do not fall to a level that will stop of the growth of *E. coli*⁹⁶, then *E. coli* (and probably *Salmonella*) will be able to grow.

The safety of the product can be improved by:

- making the sausage with cuts of meat that are likely to have high standards of hygiene (Chapter 6.9)
- adding nitrite at the required level to control *C. botulinum*
- having a process that can inactivate the highest *E. coli* counts of in-going raw materials to levels that comply with Standard 1.6.1⁹⁷
- ensuring that the number of *E. coli* in the final product complies with Standard 1.6.1 (Microbiological limits in food – see below).

Verification of product safety

While microbiological testing is not a satisfactory method for controlling your process (Chapter 1.10), repeated demonstration of compliance with microbiological criteria will increase assurance that each lot of product is safe. The following criteria for UCFM in the *Food Standards Code* is a useful guide:

	Number of samples (n)	Number of samples allowed to be >m but ≤M	Limit (m)	Limit (M)
Coagulase-positive staphylococci	5	1	10 ³ /g	10 ⁴ /g
<i>E. coli</i>	5	1	3.6/g	9.2/g
<i>Salmonella</i>	5	0	Not detected in 25g	
SPC*	5	2	10 ⁵ /g	10 ⁶ /g
Product in which growth of <i>L. monocytogenes</i> can occur	5	0	Not detected in 25g	
Product in which growth of <i>L. monocytogenes</i> will not occur	5	0	10 ² /g	

* It is possible that the SPC will detect starter/protective cultures that have survived the production process

8.10.6 'Nduja and similar products

Description of Product

'Nduja is a spicy, soft-textured spreadable pork sausage from Italy, cured in a casing and spreadable at room temperature because of the very high fat content. Chillies are used to give the product its red colour and spicy taste.

Sobrassada is a similar product made in parts of Spain. It is made with similar ingredients and process.

The product is considered RTE.

⁹⁶ Presser, K.A., Ross, T., Ratkowsky, D.A., 1998. Modelling the Growth Limits (Growth/No Growth Interface) of *Escherichia coli* as a Function of Temperature, pH, Lactic Acid Concentration, and Water Activity. *Applied and Environmental Microbiology* 64, 1773-1779

⁹⁷ If conditions prevent the growth of *E. coli* then Chapter 8.8.5 CCPs and CLs, 9.3 *E. coli* predictor for UCFM may be useful

Process

'Nduja is made with meat from the trimmings from various fatty pork cuts and backfat and chilli which give 'nduja its characteristic fiery taste. These are minced together, then stuffed in large sausage casings and smoked, creating a soft large sausage, which is then aged for 3-6 months at 12-15°C.

Product characteristics

An analysis of samples of commercially-produced 'Nduja collected throughout Italy, found that the pH was always lower than 5.3 (as low as 4.44) and water activity (due to the high fat content) in the range of 0.73-0.90, suggesting that the product is almost certainly shelf stable (Chapter 1.8.1). In some experimentally produced 'Nduja with and without chilli, the initial water activity was 0.83-0.90 (without/with chilli).

Since the pH is low, and lactic acid bacteria (lactobacilli, which are not usually used in UCFM) are found in the product, fermentation may be part of the initial preservation, so UCFMs (Chapter 8.8) may provide a way of thinking about producing a safe product. The preservation of the product seems to rely on dryness, similar to dry salami or uncured, dried meat (Chapter 8.7, though preservation relies on fat (low water activity) and possibly chilli, rather than salt).

Hazards

Pathogens such as *E. coli*, and *Salmonella* will die during the maturation of the product because the initial water activity is low. *L. monocytogenes* is unlikely to grow and may die.

There is probably limited opportunity for *S. aureus* to grow if the sausage is matured at low temperatures. The ability of *S. aureus* to grow probably depends on the initial water activity, and how quickly the water activity and pH are reduced.

Defining a safe product

A safe product may be defined by:

- initial pH and water activity
- how long, and under what conditions (e.g. holding temperature) the product reaches a pH and water activity that makes it shelf stable
- the addition of nitrite to control *C. botulinum* and other spore formers
- the potential for potential pathogens to grow or die under these conditions.

Verification of product safety

If the product is considered to be a dried meat because of its low water activity, no microbiological criteria are found in the *Food Standards Code*. As requirements differ from state to state, check with your controlling authority about testing and approval requirements.

If there are concerns about the microbiological quality of raw materials, and the ability of pathogens to grow or survive early stages of production, verification for UCFM may be applicable, as a RTE product. The following criteria for UCFM in the *Food Standards Code* is a useful guide:

	Number of samples (n)	Number of samples allowed to be >m but ≤M	Limit (m)	Limit (M)
Coagulase-positive staphylococci	5	1	10 ³ /g	10 ⁴ /g
<i>E. coli</i>	5	1	3.6/g	9.2/g
<i>Salmonella</i>	5	0	Not detected in 25g	

	Number of samples (n)	Number of samples allowed to be >m but ≤M	Limit (m)	Limit (M)
SPC	5	2	10 ⁵ /g	10 ⁶ /g
Product in which growth of <i>L. monocytogenes</i> can occur	5	0	Not detected in 25g	
Product in which growth of <i>L. monocytogenes</i> will not occur	5	0	10 ² /g	

8.10.7 Droewors

Description of Product

This South African dried sausage is made traditionally from ruminant meat (beef, lamb, goat and deer). It is made with a moderate level of fat and has coriander, vinegar and possibly soy sauce added. The sausage is thin to allow quick drying and can then be stored without refrigeration.

Traditionally, it is considered an easily preserved product because it's seasoned with vinegar and salt and hung out to dry in the open dry air.

The product is considered RTE.

Process

Meat is minced with the addition of salt, vinegar, coriander, and possibly other spices. Nitrite is not traditionally used but would be considered an essential ingredient for a commercial product. It is filled into narrow casings, then dried at around 30°C with a relatively dry airflow that promotes water loss without hardening the exterior. This process can take a few days.

The ingredients and process are somewhat like the ingredients and process for Biltong (see Chapter 8.6, Dried Meats). Biltong is a dried meat with low moisture which is cured with salt and vinegar and is air dried. Both the *Food Standards Code* and the *Australian Standard* define dried meats in terms of the final water activity (a_w) of the product being below 0.85. Biltong relies on a series of controls each of which only partially address food safety concerns.

Product characteristics

The water activity may be very low (0.60–0.70).

Hazards

Pathogens such as *E. coli*, and *Salmonella* will die during the maturation of the product once the water activity is low. The *E. coli* predictor (Chapter 9.3) may be used to determine the predicted death of *E. coli*. *L. monocytogenes* is unlikely to grow and may die.

There is probably limited opportunity for *S. aureus* growth and toxin production providing the initial drying is rapid.

C. botulinum has been found in dried products, explaining why nitrite is considered essential.

Defining a safe product

A safe product is one that has:

- a high salt level (low water activity) during the early stages of drying
- pH/salt concentration controlled throughout the process
- temperature controlled throughout the process to achieve quick drying

- a final water activity to make the final product shelf stable
- drying to a very low moisture level (water activity) to prevent mould growth.

Verification of product safety

There are no microbiological criteria for dried meats in the *Food Standards Code*. As requirements differ from state-to-state check with your controlling authority about testing and approval requirements.

Dried meats (water activity of no more than 0.85 that are not slow dried cured meat) and production environments can be excluded from *Listeria* testing because they are shelf stable products. The microbiological criteria for *L. monocytogenes* in the *Food Standards Code* applies only to RTE foods and shelf stable products are not considered RTE foods for the purpose of applying microbiological criteria (as defined in Standards 1.6.1 and 1.1.2 of the *Food Standards Code*).

8.10.8 Kypriaka loukanika (Cyprus smoked sausage)

Description of Product

This sausage is traditionally produced in autumn when pigs are killed. The special aroma and flavour come from the addition of dry red wine and shino (lentisk seeds). These seeds are the black whole spices seen through the sausages, which look like peppercorns but have a unique taste.

Cypriot loukanika are grilled over hot coals or pan fried.

Process

Pork is coarsely chopped, salted, spiced and allowed to drain overnight. It is then covered with wine and stirred over five days adding more wine. Remaining spices, including the shinos are added, then it is filled into lengths of hog casings, pricked and drained. Sausages are smoked cool for a day then dried with moderate ambient temperature with a low airflow (traditionally they are dried in the sun for 15 days). They can also be just dried.

Product characteristics

The product is intended to be cooked prior to consumption. From the process description, it appears that the product is quite dry.

Hazards

It is not clear whether the salt and ethanol (from wine) is sufficient to inhibit or even result in the death of pathogens in the early stages of production. Ethanol and salt can act synergistically (having greater effect together than expected by their effect alone) to inhibit *E. coli*, *Salmonella* and *S. aureus*.

In the later stages (smoking and drying) it is not clear how low the water activity becomes and how that makes the product safe and shelf stable.

Defining a safe product

The process needs to be carefully monitored for temperature, pH, water activity, and the effects of possible initial fermentation on bacterial growth, and behaviour of pathogens considered (by predictive modelling or challenge studies (Chapter 1.8)).

Verification of product safety

Once the process is defined, then verification activities should follow.

8.10.9 Sous vide cooked meats / prepared meals

Description of Product

Sous vide is a method of cooking foods by vacuum packing, fully or partially cooking them, and usually storing them at refrigeration temperatures. When they are required, they are either reheated or the cooking is completed. Cooking is carried out in hot water, well below the boiling point, for long periods of time, to maintain the quality of the ingredients. Smallgoods manufacturers may be interested in these manufacturing these products, because they often have most, or all, of the equipment required.

Producing sous vide products requires specialist skills and knowledge. The Australian Institute of Food Science and Technology has published an e-book:

Karen Ferres and Gary Kennedy (2024) *Cook Chill for Foodservice and Manufacturing; Guidelines for safe production, storage and distribution*. 2nd. Ed. Australian Institute of Food Science and Technology.

8.10.10 Dry Aged Meats

Description of Product

Dry aging is the traditional method of aging meat. Dry aging is done by hanging meat in a controlled, refrigerated environment. It is more tender and flavourful because the meat enzymes break down the hard connective tissue in meat, and also break down the proteins and fats to form new flavours. Some water evaporates, concentrating the flavour.

Dry aged meat is a raw product and is not RTE. Smallgoods manufacturers may be interested in manufacturing these products, because they often have most, or all, of the equipment required, and the product may be of great interest to customers.

The Australian Butchers' Guild (ABG) is an initiative of MLA and is the face of the Australian beef, veal, lamb and goat farmers in the independent retail butcher sector. It provides advice on the ageing of meat.

MLA has produced *Guidelines for the safe production of dry aged meat* ([guidelines-for-the-safe-production-of-dry-aged-meat.pdf](#)). These guidelines provide advice on dry ageing and avoiding microbial spoilage and potential safety problems.

9 APPENDICES

9.1 Pathogens

Disease-causing organisms are called pathogens; most of the concerns in smallgoods are from bacteria, but parasites and moulds may also be a concern. Some organisms are pathogenic because they grow within the gut, others because they produce toxins (chemicals) that are poisonous to humans, and which they release into the food as they grow. Toxins can be a big problem as many are heat resistant and cannot be destroyed by cooking so even if we destroy the bacterium, if it has already produced a toxin, then the food is unsafe.

In this Chapter we summarise knowledge about selected food-borne pathogens, including limits for growth relevant to processed meats, and rates of inactivation (death) due to higher temperatures. The limits and rates given are representative of the response of most strains of the nominated pathogen.⁹⁸

9.1.1 *Salmonella*

There are several thousand types of *Salmonella*, called serovars, with names that may suggest an animal association (e.g. *Salmonella* Bovismorbificans = *Salmonella* associated with sickness in cows) or the place where it was found (*Salmonella* Dublin), but they are all a single species. Many *Salmonella* serovars cause illness in humans. Some types cause mild gastroenteritis. Others cause much more severe infections which can be fatal, such as typhoid fever caused by *Salmonella* Typhi or by infection with serovars that are more likely to spread from the gut into the bloodstream. Salmonellae are commonly found in the gut of animals and birds and is therefore sometimes found on meat, or ingredients that have come from animal sources, or been contaminated by animals.

Causing disease

For some types of *Salmonella* in some foods, as few as 100 organisms can cause a large number of consumers to become ill, e.g. when eaten in contaminated chocolates. The fat in some foods protect bacteria against the acidity of the stomach as the food passes through on its way to the intestine. Salamis have a high fat content that can help bacteria survive passage through highly acidic environment in the stomach.

Growth

Salmonella grows over a wide range of environmental conditions (temperature, pH and water activity) commonly found in the meat and smallgoods industries. The tolerance ranges for these factors are shown in Table 26.

Table 26: Limits for growth of *Salmonella* spp. when other conditions are near optimum

	Minimum	Optimum	Maximum
Temperature (°C)	> 5	35-43	49.5
pH	3.8	7-7.5	9.5
a_w	0.94	~ 0.99	>0.995

⁹⁸ International Commission on Microbiological Specifications for Foods (ICMSF). 1996. Microorganisms in Foods 5: Characteristics of Microbial Pathogens Springer New York, NY

Another useful and succinct source is the New Zealand Ministry of Primary Industries web-site (<https://www.mpi.govt.nz/science/food-safety-and-suitability-research/food-risk-assessment/foodborne-hazard-data-sheets/>) or FSANZ [Agents of Foodborne Illness](#) | [Food Standards Australia New Zealand](#)

Death

Salmonella are good survivors and can survive for a long time on dry surfaces, or in low moisture foods.

In food products, such as UCFM, conditions which stop them growing appear to cause them to die. For example, the combination of low pH, lactic acid and water activity that develops during the fermentation and maturation of salamis eventually prevents growth which means that any *Salmonella* in the salami gradually die. The higher the temperature, the faster they die.

Salmonella cells are affected by heat alone. At 65°C, they die quickly and it takes from 1 – 5 minutes to reduce the number present by 90%. This time is referred to as the D value, and usually indicates the temperature as well, e.g. D₆₅ for *Salmonella* is 1- 5 minutes (some strains are quite heat tolerant, but an 'average' may be about 2 minutes). If you extend the heating time to 2 x D₆₅, you kill off 99% of the *Salmonella*, if you use 3 x D₆₅ you kill off 99.9% of the *Salmonella* and so on. Thus, suppose an emulsified sausage such as Strasbourg has a count of one million *Salmonella*/gram. After bringing the temperature of the sausage to 65°C and holding for 12 minutes (i.e., 2 minutes x 6 x D₆₅), less than one *Salmonella*/gram would remain alive.

Relevance in smallgoods

Salmonella is a target organism for all smallgoods processes because it can be a contaminant on raw meat.

Products like UCFM require a combination of factors (low pH from fermentation, low a_w from drying) to stop the growth of *Salmonella*, and maturation at time and temperature combinations that result in sufficient death to make sure there aren't enough *Salmonella* left to cause illness. High fat in some products will protect any *Salmonella* consumed from stomach acids and allow them to cause disease once they reach the gut.

Cooking is effective in destroying *Salmonella*.

9.1.2 Pathogenic *E. coli*

E. coli grows in the gut of all warm-blooded animals and large numbers are excreted in the faeces. Most types of *E. coli* are harmless and, in fact, even contribute to our health. These harmless types of *E. coli* are called 'generic' *E. coli*. One gram of our faeces may contain 10 million generic *E. coli*. When we find *E. coli* in foods it may be an indication of faecal contamination (poor hygiene) from contaminated water, soil or hands, and can be a hint that other pathogens that live in the gut may be present.

Importantly, there are also pathogenic types of *E. coli* and they have caused severe food poisoning outbreaks, and sometimes deaths. These pathogenic types are grouped in different ways with complex different names: Shiga toxin-producing *E. coli* (STEC) and Enterohaemorrhagic *E. coli* (EHEC) describe *E. coli* that produce a toxin that acts on the gut wall to cause diarrhoea (STEC), and additionally have factors that can cause the *E. coli* to invade the gut wall, causing bleeding (EHEC). *E. coli* O157:H7 is a type that most frequently causes severe illness and death. Animal meat (from cattle, pigs, sheep, deer and other mammals used in smallgoods manufacture can carry pathogenic types of *E. coli*.

Causing disease

Pathogenic *E. coli* may cause different symptoms:

- diarrhoea
- bloody diarrhea (this is Haemorrhagic Colitis or HC)
- kidney failure (this is called Haemolytic Uraemic Syndrome or HUS)
- blood clots which may lead to brain damage (this is called Thrombotic Thrombocytopenic Purpura or TTP).

The type of illness depends on the type of *E. coli* strain and also on the person. Younger people (e.g. preschool children) tend to have more serious disease.

The number of *E. coli* healthy adults need to consume to cause illness is probably thousands to tens of thousands of cells. However, in the very young and very old, less than 100 cells could lead to severe illness.

The testing required to be able to predict whether an *E. coli* is a harmless generic strain, or is pathogenic, is complex and time consuming, which is why regulations usually just have requirements for generic *E. coli*. If your process deals with generic *E. coli* then it will also deal with the pathogenic types.

Growth

E. coli grows over a wide range of environmental conditions (temperature, pH and water activity) commonly found in the meat and smallgoods industries. The tolerance ranges for these factors are shown in Table 27.

Table 27: Limits for growth of *E. coli* when other conditions are near optimum

	Minimum	Optimum	Maximum
Temperature (°C)	> 7	35-40	46
pH	>4	6-7	10.0
a_w	>0.95	0.995	> 0.995

Death

Once conditions exist in smallgoods which prevent growth, *E. coli* begins to die. The combination of pH and water activity in the maturation of salamis will gradually kill it. Pathogenic *E. coli* are vulnerable to heat and, at 65°C, they die very quickly, with a D value of 0.1-0.25 minutes (or roughly 5 –15 seconds) but possibly up to about 1 minute. In emulsified sausages a centre temperature of 65°C for 6 minutes means that there is only a one-in-a-million chance that a pathogenic *E. coli* would be able to survive. Normal cooking processes for processed meats will eliminate any *E. coli* that might be present and recontamination in a food factory is unlikely.

Relevance in smallgoods

Among smallgoods, EHEC survival in fermented meats is a big risk.

Because it is a contaminant on raw meat, EHEC are a target for all smallgoods processes. The UCFM process has the most problems in making sure the pathogen is made inactive. There are several critical stages in the UCFM process. These include adding salt to minimise *E. coli* growth during fermentation, and inactivation, which occurs during maturation. Under certain conditions *E. coli* can survive for long times in dry environments. The high fat content of salamis may protect EHECs from the acid conditions of the stomach. This is why regulations for UCFM are very stringent and why good quality meat with no or very low generic *E. coli* must be used as raw materials for UCFM manufacture. The seriousness of EHEC infections is why UCFM manufacturers are closely scrutinised and checked by your controlling authority.

9.1.3 *Y. enterocolitica*

Y. enterocolitica seems to be particularly associated with pigs and therefore, possibly found in pork and pork products. It is not frequently identified as a foodborne pathogen.

Causing disease

Y. enterocolitica can cause an enteritis (inflammation of the gut) associated with fever, pain and diarrhoea that can be mistaken for acute appendicitis, and sometimes children suffering from a *Y. enterocolitica* infection have their appendix removed. The dose that will cause consumers to become infected and to show symptoms of illness is not known with certainty. It is widely considered that the number consumed for an average adult to show symptoms is in the range 10^7 to 10^9 cells (10 million to one billion) in a serve of food, which roughly translates to 10^5 - 10^7 cells/g of the food. Others, including US-based health authorities,

estimate the number to be lower: in the range 10^4 to 10^6 cells. Children and old people or those with weakened immune systems, however, are more susceptible to infection from lower doses. There is a wide diversity of pathogenicity between strains.

Growth

Y. enterocolitica can grow at refrigeration temperatures. It is likely to be inactivated during the production process and finished products may not support growth. It is not tolerant of low water activity (see Table 27).

Table 28: Limits for growth of *Y. enterocolitica* when other conditions are near optimum

	Minimum	Optimum	Maximum
Temperature (°C)	~ -1	25 - 37	42
pH	> 4.2	7-8	9.6 - 10
a_w	>0.96	~ 0.99	> 0.995

Death

Y. enterocolitica is relatively susceptible to heat. Studies performed in milk demonstrate that standard pasteurisation conditions are adequate to eliminate levels of the bacterium that might reasonably be expected. The D_{65} is a few seconds, meaning it is much more sensitive to heat than many other food-borne pathogens.

Y. enterocolitica can, however, better tolerate freezing and thawing than many other enteric pathogens.

Relevance in smallgoods

Disease caused by *Y. enterocolitica* is infrequently recorded in Australia and smallgoods products are not recognised as vehicles for its transmission. However, it is a pathogen that can be found in pigs and pork, so product safety plans need to consider it.

9.1.4 *S. aureus*

The most common type of *S. aureus* has a yellow colour if present in high concentrations. That's why its common name is 'golden staph'. It causes boils and pimples but also a common form of food poisoning due to production of a heat stable toxin. However, it is commonly found on the skin of humans, and food handlers can become a source of contamination of foods that leads to food poisoning outbreaks, including from some processed meat products.

Causing disease

While growing, *S. aureus* makes a toxin which is released into the food that it is growing in. The effects of the toxin upon ingestion are rapid, usually two to six hours after eating the contaminated food and causes severe vomiting that can last for hours. High numbers of *S. aureus* are needed before food becomes toxic, at least 100,000 (10^5) per gram. The toxin is extremely heat stable, so it is possible for *S. aureus* to produce toxin prior to cooking, and that subsequent consumption of the food results in illness, even though no *S. aureus* can be detected in the food.

Growth

The bacterium grows at similar temperatures to *Salmonella* and *E. coli* and is also controlled by refrigeration. Unlike *Salmonella* and *E. coli*, however, it tolerates high levels of salt and can grow at salt concentrations as high as 20% (salt in the water phase of the food). It grows relatively slowly and so usually becomes overgrown by other, faster growing bacteria so that foods often spoil before *S. aureus*, if present, grows sufficiently to produce high levels of the toxin. However, in cooked foods in which spoilage bacteria are initially eliminated

and in high-salt foods in which it has a competitive advantage, it can grow to high numbers, and without any signs of spoilage, particularly at warmer temperatures.

The conditions in which *S. aureus* will produce toxin is more restricted than the conditions which will allow growth, but it is much easier to test for the presence of *S. aureus* in foods than it is to test for the presence of toxin (Table 28)

Table 28 Limits for growth of *S. aureus* and enterotoxin production when other conditions are near optimum

	<i>S. aureus</i> growth			Staphylococcal toxin production		
	Minimum	Optimum	Maximum	Minimum	Optimum	Maximum
Temperature (°C)	7	37	48	10	40-45	48
pH	4	6-7	10	4.5	7-8	9.6
<i>a_w</i>	0.86	0.98	>0.99	0.87	0.98	>0.99

Death

S. aureus is relatively easy to kill by heating and cooking. Programs for control of *L. monocytogenes* by heating or cooking will also eliminate high populations of *S. aureus*. Its $D_{65^{\circ}\text{C}}$ value is in the range ~0.2 to 1 minute, but it tolerates heat a little better at lower water activities, such as are found in some processed meats.

Importantly, however, the toxin produced by *S. aureus* is extremely heat-stable and no heat treatment used in food processing will eliminate it. In other words, even if you eliminate the living cells, any toxin they have already produced will remain.

Relevance in smallgoods

S. aureus lives on 40% of healthy adults in our noses, ears and mouths, without causing any harm. It is also found on the skin, particularly in warm moist parts of the body. Food handlers can transfer the bacterium when they handle food which is why regulations do not allow bare hands to contact foods that are RTE. *S. aureus* may also be present on raw meat. They often come from the hands of operators, but also from diseased animals. Cows with mastitis may have large numbers of *S. aureus* in the udder and in abscesses. This is part of the reason for veterinary inspections of animals intended for slaughter. The tonsils of pigs may also harbour the organism in high numbers. Active refrigeration at the abattoir followed by effective cold-chain handling will prevent the organism multiplying to levels where toxin might become a problem for the smallgoods manufacturer.

In UCFM, *S. aureus* has a competitive advantage before fermentation starts because the salt concentration prevents spoilage bacteria from overgrowing it. It is likely that there is some growth of *S. aureus* until the starters begin producing lactic acid. However, if the original level of *S. aureus* in the batter is low, and the fermentation proceeds as intended, it will not grow to levels to produce toxin where the toxin has caused illness to consumers. Additionally, this is why you need to ensure that fermentation proceeds as expected to set up levels of acidity and lactic acid that prevents growth of *S. aureus* and other pathogens. Under these conditions the risk of illness is low (Chapter 1).

Historically, *S. aureus* has caused many outbreaks of food poisoning from salamis because of its unusual tolerance of salty conditions. In UCFM manufacture *S. aureus* is controlled through use of starter cultures which outcompete it. The organism is controlled in cured, cooked meat, because of refrigeration and the use of gloves to handle cooked foods.

When testing for *S. aureus*, laboratories usually test for 'coagulase-positive staphylococci' which provides a good estimate of the numbers of *S. aureus* that are thought to have the potential to cause human illness. As noted above, high numbers ($\geq 10^5$ cfu/g) are required to produce sufficient toxin to cause illness. Testing for

coagulase-positive staphylococci is an option if the product has not been heat treated, but if it has, then a test for staphylococcal toxins must be performed.

9.1.5 *L. monocytogenes*

L. monocytogenes has been known for over 70 years as a pathogen of small animals (including sheep). During the 1980s *L. monocytogenes* became known as a foodborne pathogen as a result of several very large outbreaks, some involving scores of deaths. Among the species of *Listeria*, the only pathogenic species is *L. monocytogenes*.

Causing disease

For most people more than 100 billion *L. monocytogenes* must be swallowed before they become ill. The illness is usually a short, two to four day bout of gastroenteritis, with flu-like symptoms. For other consumers, the infectious dose may be less than 100,000 organisms. In these consumers the illness progresses sometimes with flu-like symptoms to meningitis (infection in the brain) or septicaemia (blood poisoning). In 20-30% of exposures that lead to active infections the patient will die, even with treatment. These consumers are almost exclusively the elderly, the pregnant and their foetus or new-born baby (up to a few months of age), and people whose immune system is low or compromised e.g. because they had antibiotics or cancer treatment, post-transplant drug therapy, or because their liver is damaged.

In response to the recognition of *L. monocytogenes* as a significant pathogen in many foods, many regulatory authorities have a policy of 'zero tolerance' (i.e. not detected in five samples of 25g of the food product) similar to the requirements for *Salmonella*. There is now a recognition that usually, high numbers of *L. monocytogenes* need to be consumed to cause illness and that only some foods support the growth of the pathogen. International regulations (such as in the EU or those issued by Codex Alimentarius) now allow up to 100 cells per gram in foods that do not permit the growth of *L. monocytogenes* (e.g. fermented meats).

Growth

L. monocytogenes grows over a wide range of environmental conditions commonly found in meat and smallgoods products and processing plants and operations (Table 29).

Table 29: Limits for growth of *L. monocytogenes* when other conditions are near optimum

	Minimum	Optimum	Maximum
Temperature (°C)	-1.5	30-37	45
pH	4.0	6-8	9.6
a_w	0.92	0.99	>0.99

There are two reasons why *L. monocytogenes* is a very robust organism in the smallgoods environment. First, it can grow at refrigeration temperatures. At 4–5°C in long shelf life products - like vacuum-packed or MAP sliced luncheon meats or pâté - it doubles its population every few days. So, over the typical four to six week shelf life of these products there is the potential for it to grow to very high numbers. Second, it is also salt-tolerant so it is also able to grow on cured meats such as hams and corned beef, even at refrigeration temperatures.

Death

L. monocytogenes is not unusually heat resistant. Temperatures of 65°C for about 9 minutes or 75°C for about 30 seconds will reduce population levels in food by a million-fold in every gram of product (see Chapter 7.11 Cooking).

Relevance in smallgoods

L. monocytogenes has caused a number of serious outbreaks of food poisoning from smallgoods in several countries around the world, including Australia (see Chapter 1).

In those cases, all the products went through a heat process which was enough to eliminate even huge populations of *L. monocytogenes* in the product. So how did these products become contaminated? *L. monocytogenes* is common in the environment and can enter food premises in many ways. The most critical situation for a food plant, however, is if *L. monocytogenes* sets up permanent residence on, or in, equipment in the slicing and packing area, particularly places that stay cool, and wet, and that are contaminated.

9.1.6 *Campylobacter* sp.

Campylobacter spp. are comma or S-shaped bacteria that cause diarrhoea in humans. The two species most commonly associated with human are *C. jejuni* (~80%) and *C. coli* (~20%). In Australia, *Campylobacter* is one of the most common causes of bacterial gastroenteritis and is frequently associated with the consumption of contaminated poultry.

Causing disease

Campylobacter spp. are bacteria that cause the gastrointestinal disease campylobacteriosis, with diarrhoea cramps and abdominal pain. Infection with *Campylobacter* spp. has also been associated with Guillain-Barré syndrome, which results in progressive muscle weakness or paralysis. Low doses of some *Campylobacter* strains are likely to cause disease.

Growth

Campylobacter spp. grow in the 30–45°C temperature range. the number of *Campylobacter* spp. will not increase in foods held at room temperature (20–25°C) (Table 30). *Campylobacter* spp. survive at temperatures as low as 4°C under moist conditions.

C. jejuni grows best at a sodium chloride concentration of 0.5% and does not grow in the absence of sodium chloride or in the presence of 2% or higher concentrations of sodium chloride (Table 30).

Most strains of *Campylobacter* do not grow in the presence of air. Optimal growth occurs at 5% oxygen and 2–10% carbon dioxide

Table 30: Limits for growth of *Campylobacter* sp. when other conditions are near optimum

	Minimum	Optimum	Maximum
Temperature (°C)	32	42-43	45
pH	4.9	6.5-7.5	9.5
a_w	0.987	0.997	

Death

Campylobacter are sensitive to heat and are readily inactivated by pasteurisation treatment or domestic cooking.

Campylobacter are highly sensitive to loss of moisture and do not survive well on dry surfaces.

Relevance in smallgoods

There is a high likelihood that the use of raw chicken in smallgoods will introduce *Campylobacter* to the process, but there are limited opportunities for it to survive or grow during the process and ample opportunities for it to be controlled.

9.1.7 *C. perfringens*

C. perfringens produces spores, a kind-of resting stage of bacteria that provides much greater resistance to otherwise lethal environmental conditions, and the spores therefore can survive cooking. It grows in the absence of oxygen, and it grows very fast, especially at very warm temperatures such as in the range 40–45°C.

Causing disease

The organism usually causes mild food poisoning symptoms, diarrhoea which clears up within 24 hours. The cause is a toxin made by the organism which passes into the gut. Among processed meat, outbreaks are almost always associated with cooked meat dishes which have been cooled slowly. As the meal cools and the temperature declines to the growth range (50°C and lower) it allows the spores of the organism which have survived the cooking process to germinate and to grow rapidly to high numbers.

High numbers (more than one million/g) are usually needed to produce enough toxin to cause symptoms of food poisoning.

Growth

C. perfringens grows very rapidly at temperatures between 40-46°C but not under acid conditions, or at low water activity. It is anaerobic and will only grow in foods where there is very little or no oxygen (Table 31).

Table 31: Limits for growth of *C. perfringens* when other conditions are near optimum

	Minimum	Optimum	Maximum
Temperature (°C)	12	43 - 47	50
pH	5.1	6 - 7	9.7
a_w	0.93	0.95 - 0.96	> 0.97

Death

C. perfringens is a spore former. The spores survive boiling/cooking so when the temperature of the food falls to 50°C the spores germinate, and vegetative cells begin to grow rapidly. The spores are more heat resistant than those of *C. botulinum*, meaning that heat treatment times and temperatures for *C. botulinum* will not reliably eliminate spores of *C. perfringens*. For vegetative cells, the $D_{65^\circ\text{C}}$ is in the range of 0.5 to 1 minutes, while the $D_{100^\circ\text{C}}$ for spores is in the range 5 - 15 minutes. As such, control of cooling is very important to minimise the risk of germination and outgrowth, but this is less relevant to smallgoods that contain nitrite.

Nitrite is effective in delaying spores from germinating. Nitrite is important in those smallgoods which have an anaerobic atmosphere, or deep in the meat, where *C. perfringens* could otherwise grow. The effect of salt, nitrite and rapid cooling through the growth range leads to a low risk of illness from cured meats.

Relevance in smallgoods

C. perfringens is of most concern in products which have been cooked and then slowly cooled. When foods are cooked the oxygen inside them is also removed. As the food cools, oxygen gradually diffuses back into it from the surfaces exposed to air. But in a mass of cooked food the centre will remain anaerobic, allowing growth of *C. perfringens*. The cooling provisions of the *Australian Standard* are intended to control *C. perfringens* in a two-stage cooling regime.

9.1.8 *C. botulinum*

This bacterium produces a toxin that is the most powerful natural toxin known. It specifically interferes with nerve signal transmission leading to paralysis of the respiratory muscles, the lungs and heart. It has

traditionally been the most feared foodborne organism because it was almost inevitably fatal, and many food safety regulations, particularly in thermal processing, are aimed specifically at *C. botulinum*.

Causing disease

If ingested the toxin principally affects the autonomous nervous system and, typically, initially causes double vision, slurred speech and loss of control of facial muscles, and progresses to paralysis of the respiratory muscles leading to the inability to breathe. The fatality rate is currently at about 40% but, if medical aid is provided soon after symptoms develop, patients in urban areas generally survive if they can be given an antiserum and mechanical ventilation. The effects of the paralysis can last for many months, requiring ongoing respiratory support.

The toxin is very potent (the most potent toxin known of all toxin classes) and a very small amount - less than one millionth of a gram - is fatal for an adult if untreated. It is thought that relatively high numbers of bacteria are required to produce enough toxin to cause botulism. The toxin is now used commercially as a cosmetic aid and called 'botox'

Growth

C. botulinum is a term for a group of organisms that all produce various forms of botulinum toxin, but they are (technically) several distinct species. Some types of *C. botulinum* can grow under refrigeration if the food is anaerobic and is not very acidic. Other types are mildly salt tolerant. As with *S. aureus*, it does not grow particularly quickly at lower than ambient temperatures and many foods will spoil from the growth of other bacteria before *C. botulinum* levels are high enough to lead to significant toxin production (e.g. vacuum packed beef and lamb).

Death

Spores of the organism are not killed by any heating regime used in smallgoods manufacture. Control of spore germination is the same as that for *C. perfringens*. Using nitrite is important in those products with an anaerobic atmosphere e.g. large hams, pâtés and terrines.

Relevance in smallgoods

The growth of *C. botulinum* may cause serious illness and death. The toxin itself is destroyed by cooking but with such a high consequence if toxin is consumed, cannot be relied upon to make a product safe. Equally, many smallgoods are considered RTE. The effect of salt, nitrite and rapid cooling through the growth range, however, are needed to minimise risk of severe human illness.

9.1.9 Moulds

Fungi are significant to human health because under certain conditions they are able to produce toxins (mycotoxins). Only two genera of moulds (*Penicillium*, *Aspergillus*) found on meat, are capable of producing mycotoxins. Non-toxicogenic strains of *Penicillium* are used in production of mould-ripened cheeses and some salami.

Causing disease

Mycotoxins usually affect the functioning of the liver and kidney which leads to a range of symptoms including induction of cancers, and sometimes may lead to death in both animals and man. However, unless mould levels are extremely high (unlikely in processed meats), they will not cause immediate human illness. Most concerns about the risks to human health from mycotoxins are from long-term, low level exposure but, these exposures usually arise from other food types, not processed meats.

Growth

Aspergillus and *Penicillium* may produce toxins at, or above, 10°C. Growth of *Penicillium* may occur at <5°C

Death

Mould growth is noticed during the production of some UCFM products that are matured over a long period, and on dry cured meats. There is no practical process to destroy them or their mycotoxins other than by physical removal (washing) when required.

Relevance in smallgoods

Some moulds found on cured meats are capable of mycotoxin production, but there is no suggestion that mycotoxin production occurs or that there is a risk to consumers. The use of starter cultures of mould species is probably the best protection against an undesirable mould growing. These quickly colonise the production environment and successfully compete with any other moulds that may be present. If other (undesirable) moulds are noted on product, attention should be paid to environmental and equipment hygiene to eliminate them.

9.1.10 *T. spiralis*

T. spiralis is a small, roundworm that is a parasite of pigs, humans, rodents and some other mammals. It lives in the intestine, but also invades, and forms cysts in muscle tissue. Reproduction occurs in the pig.

Causing disease

Humans usually become affected by the parasite by consumption of muscle containing *Trichinella* cysts. The parasite invades the intestines, which may be accompanied by diarrhoea, abdominal pain and vomiting. It later migrates to muscle tissues where it may cause fever, muscle pain, rashes, swelling and a number of other symptoms depending on the part of the body affected.

Australia is free of *T. spiralis* in its animal population, though other species of *Trichinella*, that do not affect humans, can be found.

Growth

The parasite only multiplies in its animal host, so there is no growth in smallgoods production.

Death

Trichinella is sensitive to heat, freezing and curing. The Food Safety Inspection Service of the US Department of Agriculture⁹⁹, provides the following was of eliminating *T. spiralis*:

- heating to 60°C for 1 minute, or equivalent
- freezing at -15°C for 20-30 days (depending on thickness of meat) or equivalent
- various curing processes
- high pressure (483 MPa for 1 minute)
- irradiation (0.4-0.6 kGy).

Relevance in smallgoods

Trichinella is only an issue when imported pork is used. In addition to any process required to eliminate the risk from *Trichinella* it is necessary to cook the pork to meet biosecurity requirements (Chapter 7.11)

⁹⁹ https://www.fsis.usda.gov/sites/default/files/media_file/2021-02/Compliance-Guidelines-Trichinella.pdf

9.2 Predicting the growth of *L. monocytogenes* in RTE meats

The *Food Standards Code* (Standard 1.6.1 - Microbiological limits for foods) applies different microbiological requirements for RTE foods depending on whether growth of *L. monocytogenes* will occur in the food. FSANZ has issued a document 'Guidance on the application of microbiological criteria for *L. monocytogenes* in RTE food'¹⁰⁰ which should be consulted for further information.

9.2.1 Validating your formula

One way to prove your product does not support the growth of *Listeria* is to submit samples to a specialist laboratory for what's called a challenge test in which the lab deliberately contaminates packages of your product with a known number of *L. monocytogenes*. They store the deliberately contaminated product at a constant temperature (usually 4-5°C) and test the samples periodically over the expected shelf life, and check whether *L. monocytogenes* has grown. No growth means your product has passed the challenge test because it prevents growth of the pathogen over the entire shelf life. The *Food Standards Code* allows not more than 0.5 log cfu/g growth for at least the expected shelf life, and still define the RTE food as one in which growth will not occur.

An alternative to challenge testing is to use a validated predictive model.

9.2.2 The *L. monocytogenes* growth model

An alternative to challenge testing is the predictive growth model. It's a piece of software into which you enter a number of key parameters about your product and it predicts how long it can prevent the growth of *L. monocytogenes*. The model described here is the *L. monocytogenes* Growth Model which is part of the Food Spoilage and Safety Predictor (FSSP) software package and has been developed and peer reviewed by international experts).¹⁰¹

MLA has road tested the FSSP in Australian smallgoods and verified that it is an effective *L. monocytogenes* management tool. The FSSP is downloadable from – [Food Spoilage & Safety Predictor](#). It is free.

Another available model, which has commercial support is the Corbion *Listeria* Control Model ([Listeria Control Model \(corbion.com\)](#)). Models are also available through ComBase.

To use the *Listeria* growth tool in the FSSP you'll need to know the following information about your product:

1. storage temperature
2. shelf life
3. salt content in the water phase
4. pH
5. lactic acid in the water phase
6. diacetate in the water phase
7. nitrite level
8. phenol content if you use smoke.

¹⁰⁰ Food Standards Australia New Zealand. [Microsoft Word - Guidance on the application of limits for Listeria monocytogenes FINAL \(foodstandards.gov.au\)](#)

¹⁰¹ Mejlholm, O., Gunvig, A. Borggaard, C., Blom-Hanssen, J., Mellefont, L., Ross, T., Leroi, F. Else, T., Visser, D. & Dalgaard, P. (2010) Predicting growth rates and growth boundary of *Listeria monocytogenes* - An international validation study with focus on processed and ready-to-eat meat and seafood. *International Journal of Food Microbiology*, 141:137-150.

Entering values into the *L. monocytogenes* Growth Model

L. monocytogenes initial cell level (cfu/g) – we have to choose a number, so choose 1 cfu/g (makes it easy to see how much growth is expected to occur).

Temperature you select should always be 5°C, unless you have accurate data for the whole supply chain. The experts who worked with MLA on the use of the model agreed that 5°C is a good estimate of the average temperature over the whole of the shelf life (manufacturer's store, transport, distribution centre, supermarket and homes).

NaCl (Salt) in water phase % is calculated as % salt divided by % moisture x 100 You can also do this calculation using the calculator symbol on the screen - except you use dry matter (100- % moisture). Press the 'cog' icon to calculate, then use the 'apply' button to add the answer to the Model.

pH – as measured by the laboratory

Smoke components (from wood smoke) – phenol (ppm) – as measured by the laboratory. Phenol originating from smoke extracts may not have strong anti-listerial effects. At levels where control might be achieved the smoke taste would simply be much too strong. Therefore, while smoke can contribute to the control of *L. monocytogenes* growth in foods, it is inadequate on its own to control growth of this pathogen.

% CO₂ in headspace gas at equilibrium – as measured by the laboratory, or as calculated using the calculator on the *L. monocytogenes* Growth Model. To use the calculator, you need to know storage temperature, initial gas/product ratio, and initial % CO₂ in headspace gas.

Nitrite, mg/kg as measured by the laboratory

Storage period is the shelf life that you have given to the product.

Include lag time for *L. monocytogenes* – tick the box

Organic acids in water phase of product (ppm) - You can use the calculator symbol on the screen - except you use dry matter (100 - %moisture). Press the "cog" icon to calculate. Using acetic acid as the example, you need to enter:

- Dry Matter (%)
- Acetic acid and acetate in product (%) OR
- Sodium acetate in product (%).

Then enter 'acetic acid in water phase of the product mg/L' into the model by using the 'Apply' button.

But this leaves you with a lot of calculations still to do because you have to take account of the purity and concentration of your product, and whether it's sodium or potassium.

If you're a small/medium manufacturer you won't have a laboratory, so you'll need to send your product for analysis to a lab approved by your regulator. You should also check with your local regulator for other validation record requirements to support your claim. In Chapter 5 we list the tests and methods the lab will need to use.

Using the *L. monocytogenes* growth model to validate a product formulation

Here is a guide to the steps that need to be taken to validate your formula using the model.

Step 1: What's the composition of my product and how does it vary?

Your first job is to send samples from five different batches (not five samples from the same batch) to a laboratory. For each batch you will need to find out:

1. salt content

2. moisture content
3. pH
4. nitrite level.

You might also want to get tests done for phenols (from smoke), lactate and/or diacetate, if you use these in your production.

You can calculate the carbon dioxide level (CO₂) in headspace at equilibrium using the method in above.

Step 2: Determine the worst-case batch

In this step you use the results from the lab to determine what would be the worst-case product you will make – the batch in which *L. monocytogenes* will grow the best. This batch will have the highest moisture, lowest salt, lowest nitrite and highest pH.

Step 3: Enter data into the *L. monocytogenes* Growth Tool

Enter your product composition data into the tool.

- *L. monocytogenes* (cfu/g) - insert 1 cfu/g – this makes it easy to see how much growth has occurred.
- Storage period is the shelf life that you have given to the product.
- Storage temperature is 5°C, unless you have accurate data for the whole supply chain.
- Include lag time for *L. monocytogenes* - tick this box. It's valid to assume that *L. monocytogenes* will take some time to adapt to the new environment in your product.

There are two important things to look at on the screen (Figure 5):

The number of days for a 0.5 log increase in *L. monocytogenes*. The Food Standards Code (Standard 1.6.1 - Microbiological Limits for Foods) allows a 0.5 log increase - If you inserted 1cfu/g as the initial cell level then your graph will start at 0 (the log of 1cfu/g = 0) and you can easily see when the level gets to 0.5 log. If this is greater than the shelf life of your product, then your product already meets the criteria for a safe product, and the less stringent requirement of <100cfu/g *L. monocytogenes* applies, rather than 'zero tolerance'.

The concentration of *L. monocytogenes* (in log cfu/g) at the end of shelf life. You'll see that your worst-case product does support the growth of *L. monocytogenes* (red line), and the pathogen starts to grow after six days storage. At the end of shelf life (five weeks) one cell present at Day 1 will have been able to grow to log 6 (1,000,000) cfu/g, which makes it a potentially dangerous product.

The FSSP result should prompt you to review your work practices to reduce variability in salt and nitrite concentration and improve the safety of your worst-case products.

You may conclude that you should reformulate your product by using ingredients which inhibit *Listeria*. If you do, proceed to Step 4.

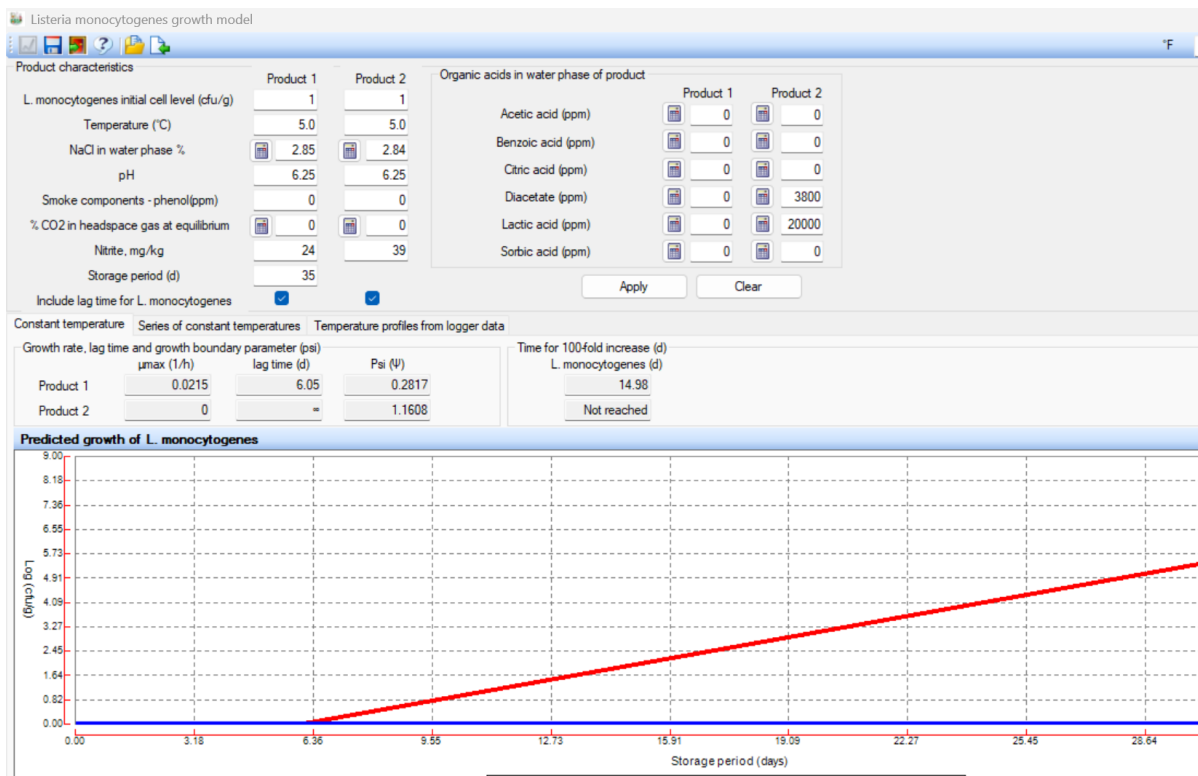


Figure 4: Screen shot of *L. monocytogenes* growth model showing the growth of *L. monocytogenes* in product before (red line) and after reformulation (blue line)

Step 4: Reformulate product

You reformulate by adding the anti-*Listeria* ingredient at the lowest concentration to prevent growth over the shelf life. Many companies use either lactate on its own, or in combination with diacetate – there are many products and advice about their use. In our example we'll use a brand which contains diacetate and lactate. The FSSP is very useful because it allows you to test 'what-if' scenarios. You don't have to make any product and get it tested, just insert realistic values for lactate and diacetate and the FSSP will tell you whether the formulation stops *L. monocytogenes* growing.

- Keep the lab data for your existing, worst-case product in the left-hand column of the *L. monocytogenes* Growth Model.
- Put zero for smoke (phenol) unless your supplier can give you some solid information.
- If you're vacuum-packing, put zero for CO₂.
- Now put some values in for lactate and diacetate until the tool shows you that growth flat-lines over the entire shelf life. To prevent growth of *L. monocytogenes* (Figure 5) requires addition of 20,000 ppm of lactate and 4,000 ppm of diacetate to do the job (Table 32).

Table 32: Reformulation with lactate and diacetate to prevent growth of *L. monocytogenes*

	Existing product	New product
<i>L. monocytogenes</i> (cfu/g)	1	1
Storage period (days)	35	35
Storage temperature (°C)	5	5
Salt in water phase (%)	2.85	2.84
pH	6.25	6.25

	Existing product	New product
Lactate in water phase (ppm)	0	20000
Diacetate in water phase (ppm) ^b	0	3800
Smoke components (phenol, ppm)	0	0
CO ₂ in headspace (%)	0	0
Nitrite (ppm)	24	39
Day growth begins	6	After the end of shelf life

Whichever proprietary brand you decide, you're using a lot of inhibitor, which may affect the sensory quality of your product. In Step 5 you can see how reducing variability will mean you can reduce the amount of lactate and/or diacetate.

Step 5: Reducing product variability

A major problem may be your process control with variability occurring from batch to batch. Check out Chapter 7 and descriptions of process; there are many ways listed there to reduce variability and improve your process control.

Step 6: Consolidation

If you've made changes to your production process, you will want to collect additional data to demonstrate that your process now has tighter control, and that *L. monocytogenes* is being controlled.

Step 7: Amend your FSP

In the FSP for your reformulated product your regulator or their auditing agent will need to see how you ensure lactate, salt and nitrite are all added at the correct concentration. You also need to amend your work instructions. Injection rate now becomes important, and you'll need to check each batch by weighing before and after injection and you'll need to record the weights.

Step 8: Submit your validation to your regulator

You've validated a process for a new, reformulated product. Now you need to document:

1. The results from the samples you sent to the lab.
2. How you changed the formulation using the *L. monocytogenes* Growth Model.
3. How you amended your: a. Work instructions, for example, lactate addition and monitoring of injection rate b. SSOPs for example, cleaning injectors c. HACCP plan.
4. Batch sheets and monitoring, for example, for injection rate.

If you have certification to other standards such as SQF2000 or ISO 22000 then you will also have to address product development and formulation. If you have reformulated to use new additives, such as lactate, then you will need to change the ingredient label on your product.

Step 9: Now you're ready to go

So, you're operating under a newly approved arrangement – improving the safety of your product and reducing the chance of getting involved in a recall. And remember, adding an ingredient to stop *Listeria* growing is just one part of your operation. You still need all those procedures aimed at stopping *Listeria* getting into your premises and product, especially when you're packing.

Instructions

1. Download and open the *E. coli* inactivation model/predictor - <https://www.mla.com.au/globalassets/mla-corporate/research-and-development/documents/e.coli-inactivation-model-v-2.2b-.xlsx>

This page will appear.

Click on the 'Go to: "Advanced" Calculations' button.

INSTRUCTIONS: This is the "quick" calculator. You simply need to enter the time and temperature of your fermentation, and the time and temperature of your maturation conditions, and the expected log kill of *E. coli* will be automatically calculated.

Use Celsius temperatures and type in the appropriate box.

Type the fermentation time and maturation time in EITHER days OR hours (your choice), into the appropriate boxes. The fermentation time to use is the time from when the product gets to the desired fermentation temperature, or when the pH of the batter falls below 5.

Use the "TAB" key to move between the boxes to enter the times and temperatures.

	Temperature (°C)	Time (hours / days)		Time final	Rate (logCFU.h-1)	Log Kill
Fermentation:	25		5	0 120	0.0110	1.32
Maturation:	14	11		0 11	0.0034	0.04
Total Log Kill						1.35

[Return to: Introduction](#) [Go to: "Advanced" Calculations](#)

Note: The 'quick' calculator option only allows entry of one temperature and time for fermentation and one temperature and time for maturation. For most processes, this is not suitable for use.

Concerns about food safety arise because *C. perfringens* is recognised as the fastest growing living thing in the known universe and can double itself every 9-10 minutes¹⁰² under optimal conditions, e.g. at 42°C in a moist, nutritious, environment, and absence of nitrite. Products like meat!

This section explains how to validate an alternative cooling arrangement that will be equivalent to the food safety outcome intended in the *Australian Standard*.

9.4.1 Effect of ingredients

The combination of sodium chloride and sodium nitrite in curing inhibits germination and outgrowth of *C. perfringens* spores. Zaika¹⁰³ found that salt levels of >2% (wt/wt), roughly equal to 2.5% salt in the aqueous (water) phase, prevented growth of *C. perfringens* during 'slow' cooling.

The *Australian Standard* defines 'cured' (for use in determining cooling requirements) as having a minimum 2.5% salt in water phase and 100ppm nitrite in-going.

The pH of the cured meat has a great influence on growth of *C. perfringens*; as pH falls and salt concentration increases, the inhibitory effect of nitrite on *C. perfringens* germination and outgrowth is enhanced. Other ingredients, such as organic acids also contribute to inhibiting the growth of *C. perfringens*.

9.4.2 What you need to know before predicting *C. perfringens* growth

You need to have the following information on your product (from several lots of product so you also know how variable the results are):

- pH of final product
- salt added and moisture content of cooked product (which enables salt concentration in the aqueous phase of cooked product to be calculated).
- the level of nitrite added to the product.

There is advice on how to measure these properties in the measurement section of the Process Chapter (Chapter 7.19).

You need to know about the changes in temperature during cooling. The process should be monitored over several days of full production, when the chiller is fully loaded with product. You will need to generate temperature:time records for large products (make a note of the weight) placed at different points in each chiller when loaded to its fullest, as well as data for pH and salt concentrations.

9.4.3 Prediction of *C. perfringens* growth

The ComBase Perfringens Predictor can be accessed from:

https://combasebrowser.errc.ars.usda.gov/Perfringens_Predictor.aspx.

You will need to create an account. Creating an account is simple and free. Once your account is set up you can access the database with your email address and password. Once you have logged on, select Perfringens Predictor from the tab on the left of the screen, by first clicking on the tab: "Food models", and enter data for:

- pH
- salt (% salt-in-moisture, see Chapter 7.19.7)

¹⁰² This means that if you had one cell of *C. perfringens* in a 100g piece of meat being held at 42°C, after one hour, their concentration would be 64 cells per 100g. After another two hours, the numbers would be enough to almost certainly make the consumer quite ill.

¹⁰³ Zaika, L. (2003) Influence of NaCl content and cooling rate on outgrowth of *Clostridium perfringens* spores in cooked ham and beef. *Journal of Food Protection*, 66:1599-1603.

- whether the product is uncured or cured (ComBase assumes cured products have ≥ 100 ppm nitrite ingoing and ≥ 10 ppm residual)
- your temperature:time data; note that your time data must start at 0, as in the example provided by ComBase when you open the Predictor. You need to enter time in hours and temperatures from the end of cooking until the product is $< 15^{\circ}\text{C}$.

When you press the PREDICT button the log increase in *C. perfringens* in your product for your process is estimated in the graph.

Other cooling models have been developed. However, a published evaluation of the utility of those models, with co-authors involved in their development, considered that Perfringens Predictor was the most suitable for regulatory purposes.¹⁰⁴ Only the ComBase Perfringens Predictor has the option to enter pH and salt concentration. A full description of the development of the ComBase Perfringens Predictor for uncured products has been published,¹⁰⁵ and in the notes to the on-line model states that the version in ComBase was improved based on a published articles reviewed in Mohr et al (2015)¹⁰⁶. The model for cured products (assuming cured products have ≥ 100 ppm nitrite ingoing and ≥ 10 ppm residual) was added, but choosing not to consider nitrite concentration, based on an unpublished report.¹⁰⁷

A 1 log₁₀ increase in *C. perfringens* during cooling is considered to be the acceptable performance standard since it is specified in US guidance.^{108,109} The reasoning for this performance standard is that in that US guidance the assumed level of *C. perfringens* spores in raw meat is 2-3 log₁₀/g. Allowing 1 log₁₀ growth would result in levels of up to 4 log₁₀/g after cooling, with a 2 log₁₀ margin of safety to account for variability in the product and process before reaching 6 log₁₀/g which is considered the level of public health concern. These regulations in the US are based on a raw material survey that did not differentiate between spores and vegetative *C. perfringens* on meat, so are considered unnecessarily conservative.¹¹⁰

9.4.4 Additional considerations

If the ComBase Perfringens Predictor predicts more than 1 log₁₀ of *C. perfringens* growth during cooling, there are additional steps you can take which may allow you to validate product safety.

Adjusting the pH and/or salt concentration

The pH and salt concentration of product have a great influence on growth of *C. perfringens* during cooling. If you do not achieve a satisfactory prediction you may need to reduce the pH of your product or increase the

¹⁰⁴ Mohr, T.B., Juneja, V.K., Thippareddi, H.H., Schaffner, D.W., Bronstein, P.A., Silverman, M., Cook, L.V., 2015. Assessing the Performance of Clostridium perfringens Cooling Models for Cooked, Uncured Meat and Poultry Products. J Food Prot 78, 1512-1526.

¹⁰⁵ Le Marc, Y., Plowman, J., Aldus, C.F., Munoz-Cuevas, M., Baranyi, J., Peck, M.W., 2008. Modelling the growth of Clostridium perfringens during the cooling of bulk meat. Int J Food Microbiol 128, 41-50.

¹⁰⁶ Mohr, T.B., Juneja, V.K., Thippareddi, H.H., Schaffner, D.W., Bronstein, P.A., Silverman, M., Cook, L.V., 2015. Assessing the Performance of Clostridium perfringens Cooling Models for Cooked, Uncured Meat and Poultry Products. J Food Prot 78, 1512-1526.

¹⁰⁷ Peck, MW, Baranyi, J, Plowman, J, LeMarc, Y, Aldus, CF and Munoz-Cuevas, M (2007) Expansion of the Perfringens Predictor Model to include pH, NaCl and NaNO₂. Final Report of Food Standards Agency Project B13005.

¹⁰⁸ [FSIS. 2017. Compliance Guideline for Stabilization \(Cooling and Hot-Holding\) of Fully and Partially Heat-Treated RTE and NRTE Meat and Poultry Products Produced by Small and Very Small Establishments and Revised Appendix B \(usda.gov\)](#)

¹⁰⁹ [FSIS. 2021. Compliance Guideline for Stabilization \(Cooling and Hot-Holding\) of Fully and Partially Heat-Treated RTE and NRTE Meat and Poultry Products Produced by Small and Very Small Establishments and Revised Appendix B \(usda.gov\)](#)

¹¹⁰ Taormina PJ (2018) [Revised USDA Cooking and Cooling Compliance Guidelines: Impact on Validation and Process Deviation | Food Safety \(food-safety.com\)](#)

salt concentration. You can use the Predictor to work out the targets for pH and salt that are required for your cooling performance.

Microbiological quality of raw meat

The U.S. Department of Agriculture, Food Safety and Inspection Service (FSIS) currently requires that establishments meet performance standards for producing certain RTE meat and poultry products (i.e. RTE roast beef; cooked beef and corned beef products; fully cooked, partially cooked, and char-marked meat patties; and certain partially cooked and RTE poultry products) to address *C. perfringens* risk to consumers. The requirements specify no more than 1-log increase of *C. perfringens* within the product). The FSIS has recommended that producers of meat and poultry products that are not covered under this performance standard design their processes so that no more than a 2-log₁₀ growth of *C. perfringens* occurs subject to demonstrating that the *C. perfringens* spore levels in the product are low (≤ 100 cfu/g).¹¹¹

The prevalence and concentration of *C. perfringens* (spores plus vegetative cells) on meat in Australia is very low. A survey of (the limit of detection was 10 cfu/g) detected *C. perfringens* in 0/94 samples of ground beef and in 1/92 samples of diced lamb purchased from supermarkets and butcher shops (Phillips et al. 2008).¹¹² No data could be found for *C. perfringens* in Australian pork.

You could conduct a survey of your raw materials to determine the level of *C. perfringens* that would justify a performance standard of 2 log₁₀ growth (or even more).

Effect of other ingredients

Many manufacturers use lactate in cured, cooked meats to extend shelf life and also to inhibit growth of *L. monocytogenes*. Lactate also inhibits outgrowth of any *C. perfringens* spores which germinate during cooling.¹¹³

Nitrite inhibits germination and growth of *C. perfringens*. Several studies have involved deliberate inoculation of cooked meats with *C. perfringens* to evaluate survival and potential for outgrowth under commercial conditions. Taormina et al.¹¹⁴ did challenge trials on various cured meat products. They inoculated raw material with a mixture of *C. perfringens* spores at a concentration of 1000 spores/g and then cooked and cooled them slowly. Populations of *C. perfringens* were recovered but remained relatively unchanged during chilling from 54.4°C to 7.2°C and declined slightly during refrigerated storage, also as observed by Kalinowski et al.¹¹⁵ Marquez-Gonzalez et al.¹¹⁶ studied spore survival during cooling of inoculated cured ground pork. The population decreased by 1.1 log cfu/g during cooling over 20 h from 54.4°C to 36.3°C and then increased by 0.9 log cfu/g until the product reached 7.2°C, reinforcing that cooked, cured meats are relatively resistant to growth of *C. perfringens* during cooling.

¹¹¹ FSIS. 2017. Compliance Guideline for Stabilization (Cooling and Hot-Holding) of Fully and Partially Heat-Treated RTE and NRTE Meat and Poultry Products Produced by Small and Very Small Establishments and Revised Appendix B (usda.gov)

¹¹² Phillips, D., Jordan, D., Morris, S., Jenson, I., Sumner, J., 2008. A national survey of the microbiological quality of retail raw meats in Australia. J Food Prot 71, 1232-1236.

¹¹³ Bates J. & Bodnaruk P. (2003) Clostridium perfringens. In: Foodborne Microorganisms of Public Health Significance. 6th edition. Ed: AD Hocking. Australian Institute of Food Science and Technology Inc., Food Microbiology Group, Waterloo NSW. pp505-542.

¹¹⁴ Taormina, P.J., Bartholomew, G.W. & Dorsa, W.J. (2003) Incidence of Clostridium perfringens in commercially cured raw meat mixtures and behaviour in cooked products during chilling and refrigerated storage. Journal of Food Protection, 66:72-81

¹¹⁵ Kalinowski, R., Tompkin, B., Bodnaruk, W. et al. (2003) Impact of cooking, cooling and subsequent refrigeration on the growth or survival of Clostridium perfringens in cooked meat and poultry products. Journal of Food Protection, 66:1227-1232.

¹¹⁶ Marquez-Gonzalez, M., Cabrera-Diaz, E., Hardin, M.D., et al. (2011) Survival and germination of Clostridium perfringens spores during heating and cooling of ground pork. Journal of Food Protection, 75:682-689.

Kalinowski et al. (2003) measured a 2-3 log reduction in count during seven days storage at chill temperatures. Industry knowledge indicates that the minimum time between production and consumption is likely to be one week, and the maximum time up to six weeks. Similar observations on declines in *C. perfringens* during chilled storage, although less pronounced, were made by Taormina et al. (2003).

Since the ComBase Perfringens Predictor doesn't include the concentration of these other ingredients in its model, you have two options: using the scientific literature (if appropriate measurements were taken on a product like yours, under time:temperature conditions like yours), or conducting a challenge study which would involve adding *C. perfringens* spores to your product and measuring the effect of the cooking and cooling process on the level of those spores (difficult and expensive). If you are operating outside the requirements of the *Australian Standard* you will need to find out whether *C. perfringens* has grown to high levels in your product. Samples (around 50g) should be taken from near the centre of large cuts of final, cooked product, then placed in a sterile bag or container, labelled, and sent to an approved laboratory for testing for the presence and concentration of *C. perfringens*. Keep a record of the temperature:time regime until you have established that your alternative arrangement is adequate to limit *C. perfringens* to safe levels. As a guide, many meat microbiologists consider that performance of a process can be evaluated by testing 20-25 samples.

Risk Assessment

A 2007 risk assessment conducted by USDA suggests that cooling accounted for less than 1% of illnesses due to *C. perfringens* in cooked meats. It was estimated that assuming a 10- or 100-fold increase from the currently assumed 1-log (maximal allowable) growth of *C. perfringens* results in a 1.2- or 1.6-fold increase of *C. perfringens*-caused illnesses. Retail and consumer refrigeration failure was estimated to account for 90% of illnesses predicted by the model, whereas cooling accounted for less than 1% of illnesses. USDA concluded that efforts to reduce illnesses from *C. perfringens* in RTE and partially cooked meat and poultry products should focus on retail and consumer storage and preparation methods.¹¹⁷

¹¹⁷ Golden, N.J., Crouch, E.A., Latimer, H., Kadry, A.-R., Kause, J., 2009. Risk Assessment for Clostridium perfringens in Ready-to-Eat and Partially Cooked Meat and Poultry Products. *J Food Prot* 72, 1376-1384.



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