MEAT & LIVESTOCK AUSTRALIA

GUIDELINES FOR THE SAFE MANUFACTURE OF SMALLGOODS

2ND EDITION

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Acknowledgments

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Disclaimer

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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
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	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, being a minimum of 2.5% salt on water phase and 100 ppm nitrite in-going
FSP	Food Safety Plan
GMP	Good Manufacturing Practice
HACCP	Hazard Analysis 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
Log	Logarithm — used to express microbial counts e.g. log 2 is 100, log 3 is 1,000
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

Glossary of Terms and Abbreviations continued..

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
PRP	Pre-requisite program
QCP	Quality Control Points
QUAT	Quaternary ammonium compounds
RCP	Regulatory Control Point
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 ready-to-eat meat that is susceptible to the growth of pathogens or the production of toxins.
SARDI	South Australian Research and Development Institute
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
SME	Small and medium enterprise
Spoilage bacteria	Bacteria which limit the shelf life of foods by producing objectionable odours, colours or slime
SSOP	Sanitation Standard Operating Procedures
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 compliance with standards
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

Introduction

Introduction

Smallgoods include a wide range of cooked, cured, fermented or dried meat products, using meat and offals from cattle, sheep, pigs and chickens. Packaging for smallgoods varies according to the product, for example, slow cured hams have no packaging but luncheon meats are gas-flushed and vacuum-packed. Shelf lives also vary widely, from a few days for fresh sausage to months for prosciutto. Products such as salamis may be stored at room (ambient) temperature but products such as pâtés and cured meats must be chilled. Some smallgoods are ready-to-eat such as hams while others such as fresh sausages must be cooked before they are eaten.

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 Middle Eastern and Asian countries have been manufactured here. Over the past fifty 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 environmental rooms with computer-controlled temperature, humidity and smoke injection for ripening of fermented meats.

The Guidelines

In 2001 Meat and 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* O111
- Its aftermath, which led to the mandating of HACCP-based Food Safety Plans (FSPs)
- The need for resource materials to facilitate the development of FSPs
- Since the completion of the first edition of the guidelines in 2003 there have been numerous recalls of smallgoods and several outbreaks of food poisoning following smallgoods consumption.

The decade has also seen changes in regulation with the promulgation of Standard 4.2.3 in the *Australia New Zealand Food Standards Code* (*Production and Processing Standard for Meat*), the Regulatory guidelines for the control of *Listeria* and in the Food Standards Code re. microbiological criteria for *Listeria monocytogenes.* There have also been changes to the Australian standard for the hygienic production and transportation of meat and meat products for human consumption (AS 4696: 2007).

In response, the Australian Meat Industry Council (AMIC) and MLA have produced videos, guidelines and written resources to help the industry meet these increased requirements.

There is also a clear need to update the 2003 edition of the Guidelines for the Safe Manufacture of Smallgoods to take into account the changes in the scientific information available to help you to produce a safe product, hence this 2015 edition.

What you need to do after reading these Guidelines

1. Review your work instructions and monitoring forms. Only you can do this for your individual operation and for approval by your controlling authority.
2. Set out how to meet all the provisions of the *Australia New Zealand Food Standards Code* and other relevant standards. You need to do this before your regulator will sign-off on your food safety plan. These include:

    - *Standard 1.2 – Labelling (ingredients, allergens, date marking)*
    - *Standard 1.3.1 – Food Additives*
    - *Standard 1.3.3 – Processing aids*
    - *Standard 1.6.1 – Microbiological limits for food*
    - *Standard 1.6.2 – Processing requirements (definitions for 'heat treated' and 'cooked' fermented meat products)*
    - *Standard 2.2.1 – Meat and Meat Products*
    - *Standard 3.1.1 – Interpretation and Application*
    - *Standard 3.2.1 – Food Safety Programs*
    - *Standard 3.2.2 – Food Safety Practices and General Requirements*
    - *Standard 3.2.3 – Food Premises and Equipment*
    - *Standard 4.2.3 – Production and Processing Standard for Meat*

The Standards can be downloaded from the Food Standards Australia New Zealand (FSANZ) website, www.foodstandards.gov.au

AS 4696: 2007 – *Australian Standard for Hygienic Production and Transportation of Meat and Meat Products for Human Consumption*, downloadable from the CSIRO Publishing website.

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 Food Safety Plan
4. Provide background information so you meet the regulatory requirements for the safe manufacture all your products

If you have a smaller operation you'll also find useful information in MLA's *"Guidelines for the safe retailing of meat and meat products"* – also called the Butchers' Guidelines.

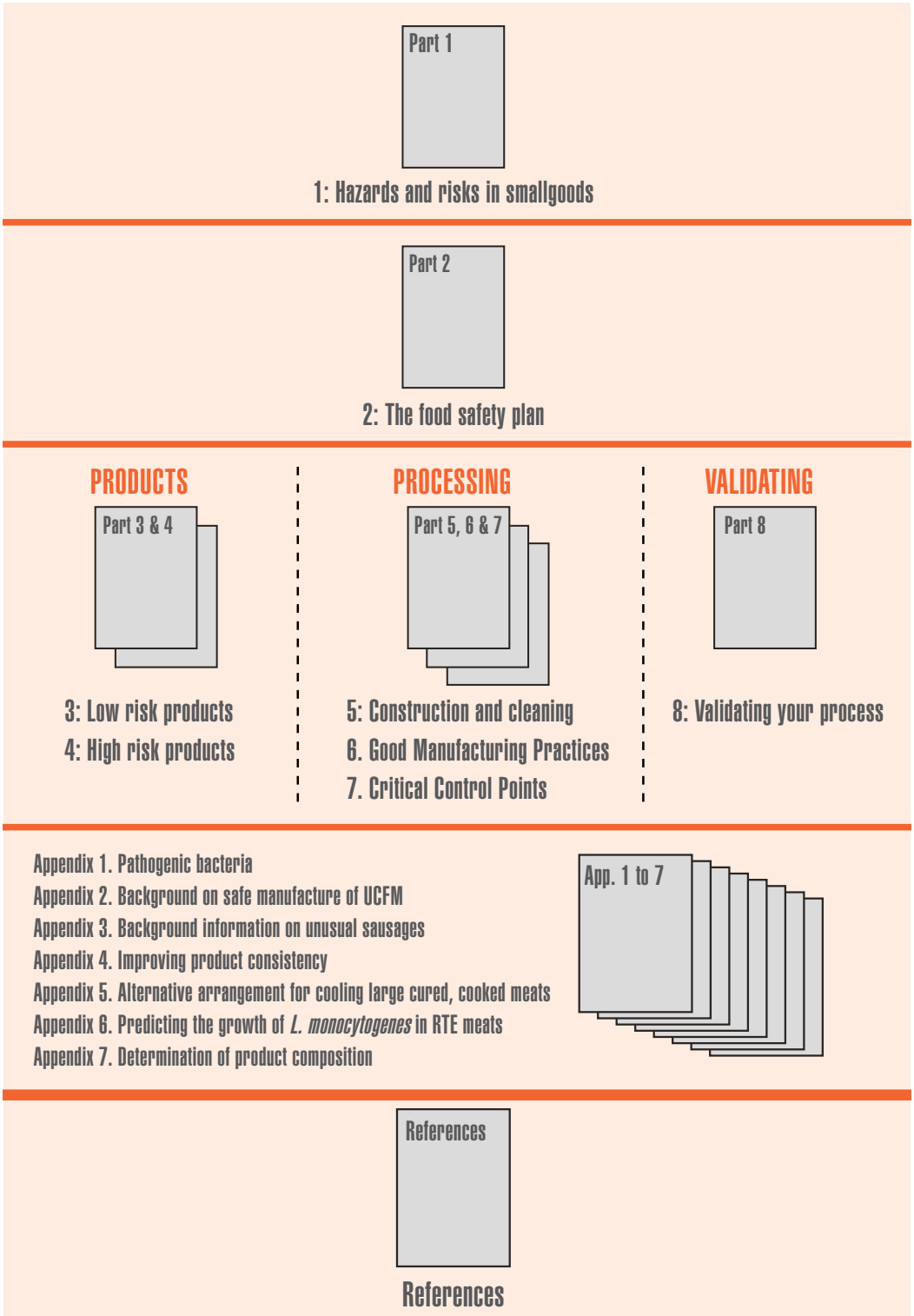
Roadmap to these Guidelines

The following diagram shows you how this manual is arranged.

The first two parts tell you how to think about the risks associated with your product and how to think about controlling them.

Parts 3-8 give you specific information relevant to the product(s) you manufacture.

The appendices provide background information and more detail for when you need it.



Part 1: Hazards and Risks in Smallgoods

1.1 Hazards in smallgoods

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 humans. Given the large range of smallgoods there are many hazards you need to control in your business.

One way to identify which hazards are the most important is by looking at:

- Food poisoning outbreaks from meat
- Recalls of meat and meat products

1.1.1 Food poisonings involving meat

Table 1.1 lists meat products which have caused food poisoning in Australia over recent years, and the hazards which caused the problems, using data collected by state authorities and OzFoodNet.

In 1995, mettwurst made in Adelaide was contaminated with *Escherichia coli* O111 *(E. coli)*. Around 150 people became ill, more than 20 of them seriously and one young girl died. In 2005, corned beef contaminated with *Listeria monocytogenes* caused serious illness in five hospital patients in South Australia, three of whom died.

When *Escherichia coli* O111 caused the South Australian poisoning in fermented sausage, food scientists were shocked. The fermentation process was supposed to eliminate pathogens, however, these dangerous types of *E. coli* were shown to be more acid resistant and capable of surviving the fermentation methods used in many countries.

Table 1.1 Selected outbreaks of illness associated with meat in Australia

Year	Meat product	Hazard	Number of cases (deaths)
1993	Roast beef	*Clostridium perfringens*	37 (1)
1994	Pork sausage	*Salmonella*	14
1995	Mettwurst	*E. coli* O111	173 (1)
1997	Pork rolls	*Salmonella*	808
1997	Ham, corned beef	*Salmonella*	25
2005	Corned beef	*Listeria monocytogenes*	3 (3)
2008	Chicken	*Campylobacter*	4
2008	Chicken	*Staphylococcus aureus*	7

The examples listed above identify target bacteria – hazards you must control through your food safety plan. Appendix 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 vulnerability of some consumers.

1.1.2 Product recalls

There is a list of all meat recalls on the Australian Competition & Consumer Commission (ACCC) website (http://www.recalls.gov.au). From 2000-2013 there were 70 recalls of smallgoods:

- 56% were from large manufacturers and 44% were from small and medium enterprises (SMEs)
- 23 recalls (33%) were for raw meats, mainly mince and sausages, with foreign matter (metal, rubber and plastic) causing 18 and allergens causing five recalls
- 47 recalls (67%) were for RTE meats, with UCFM contributing eight, cooked sausages four and the remainder mostly sliced, vacuum packed meats
- The hazards prompting the recalls of RTE meats were: *L. monocytogenes (*37), foreign matter (three), process failure/spoilage (two each) and *Salmonella, S. aureus* and an infected food handler (one each)

1.2 Risks associated with smallgoods

Risk involves:

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 fermented (Pointon *et al*. 2005; Sumner *et al*. 2005a, 2005b). The results are summarised in Table 1.2.

Researchers from the University of Tasmania rated smallgoods product types according to the risk of becoming ill (Ross *et al*. 2009). This rating made assumptions that raw products were properly cooked and that fermented meats were manufactured in accordance with Standard 4.2.3.

The researchers found that the highest risk was associated with cured, cooked meats, especially when these were sliced and vacuum packed (Ross *et al*. 2009a). This risk rating reflected the seriousness of illness caused by *Listeria monocytogenes*, which results in death in 20-30% of cases.

Figure 1.1 Risk rating of various meat products

Product type	Risk rating
Fresh sausage*	0
Ground products*	0
Cooked sausages (franks etc)**	0
Cooked fermented meats	8
Uncooked fermented meats	8
Slow cured hams (prosciutto)	20
Cooked sausages (franks etc) eaten raw	40***
Roast meats (unsliced)	46
Sliced hams	49
Sliced vacuum packed meats	49

** Assumes cooked thoroughly before eating*
*** Assumes reheated properly before eating*
**** Ranking 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, 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. In these guidelines we focus heavily on controlling handling of cooked meat during slicing and packing.

Food Safety Plans are needed for all products – whether the risk is high or low. We have divided the chapters about products into two sections: low risk and high risk, so as to be clear that you may be manufacturing a product that has a high risk. In general, products that are cooked just before consumption are low risk, and those that are consumed without cooking just before consumption are considered high risk.

If you feel bulletproof, think again. Here are two tales of woe concerning butchers who made the same products you do. They don't any more – find out why.

1.3 Manufacturers just like you – shocking tales!

In 1996 John Barr, a butcher in Scotland, grew from a modest retail operation to an SME producing RTE meats for a range of customers and venues. Steak pies became contaminated with *E. coli* O157 and killed six old aged pensioners. More fell ill at the local pub following consumption of a range of RTE meats. In all, Mr Barr's products caused 279 illnesses and 20 deaths. Mr Barr had recently been named Scottish Butcher of the Year. He avoided serious charges when his legal team brokered a deal and was fined £2250 (about $3500).

Speaking to the press, Mr Barr confessed that, until the disastrous outbreak, he had barely even heard of the *E. coli* bug and would be "haunted" by the deaths for the rest of his days. He'd been close to a nervous breakdown and was still on medication for depression. He added: "You go from being Scottish butcher of the year to mass murderer of the year."

Professor Hugh Pennington, a UK expert on microbiology and food safety, led an inquiry into the incident and made many recommendations aimed at ensuring such an incident wouldn't happen again. But it did.

William Tudor, of South Wales, had grown his business and was supplying lunches to 44 schools in addition to his retail shop. In 2005, 157 people, almost all of them children, became ill, 30 were hospitalised and one boy, aged five years, died. The lunches had been contaminated with *E. coli* O157. Mr Tudor pleaded guilty to seven food hygiene offences and was jailed for 12 months.

Professor Pennington again led an inquiry – the second in less than a decade. His recommendations for industry and regulators included:

1. All food businesses must ensure that their systems and procedures are capable of preventing the contamination or cross-contamination of food with E. coli O157.
2. Food businesses must get to grips with food safety management based very clearly on the seven key HACCP principles, ensuring it is a core part of the way they run their business.
3. Additional resources should be made available to ensure that all food businesses understand and use the HACCP approach and have in place an effective, documented, food safety management system which is embedded in working culture and practice.
4. Discussion with employees must be a standard part of food hygiene inspection visits.

It's easy to dismiss these incidents, but both operations were licensed by their local authorities and audited regularly – just like yours.

However, these businesses also:

- Processed and packed RTE meats in the same room as raw meats
- Stored carcases and RTE meats in the same chiller
- Weighed raw and RTE meats on the same scales before packing
- Used the same vacuum packing machine for raw and RTE meats
- Had staff without adequate skills and knowledge
- Had grown their business and were manufacturing much larger volumes from the same premises

All these are trigger points for increased risk. Ask yourself "How many of these triggers apply to my operation?"

If any of them rate a 'Yes' you should be thinking about how you can better protect your customers.

You may remember the Garibaldi mettwurst illnesses in 1995. 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 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

There are some early-warning signs when a business is building up risk. Check the list in Table1.2 which applies to both large and small businesses.

Table 1.2 Checklist of early-warning signs for companies causing illness in consumers

DANGER SIGNALS	YES
Things are going great – we're making heaps more products	
I've had to take on new staff – must get around to sending them on a training course	
I'm making some great new products – must remember to find out what this allergen business is all about	
Pub across the road wants a heap of fancy stuff for weekend lunches	
We're flat out - I'll have to think about another slicer and vacuum machine	
The aged care home's asking for another week's use-by on the vac-pack sliced meats – no problem	
Due for an audit soon – must get the paperwork up to date	
We're that busy, the chillers are never empty – we give them a mop each week though	
What's the cleaning gang up to? The pre-ops are terrible	
Marketing have okayed a new low-salt product with the customer – that's a worry, we haven't done the R&D yet	
We're taking on extra staff for Christmas production – hope on-the-job training works	
New manager's really pushing it – wants to clean the bacon line every other day – save on downtime	
Sure we're flat out but I'm not going to miss that hospital tender	
That new company's selling pre-mixes real cheap – I'll be in that!	

If you answer 'Yes' to any of these, you're moving into danger territory.

In later sections we focus on how you can protect your customers and your business from a food safety incident.

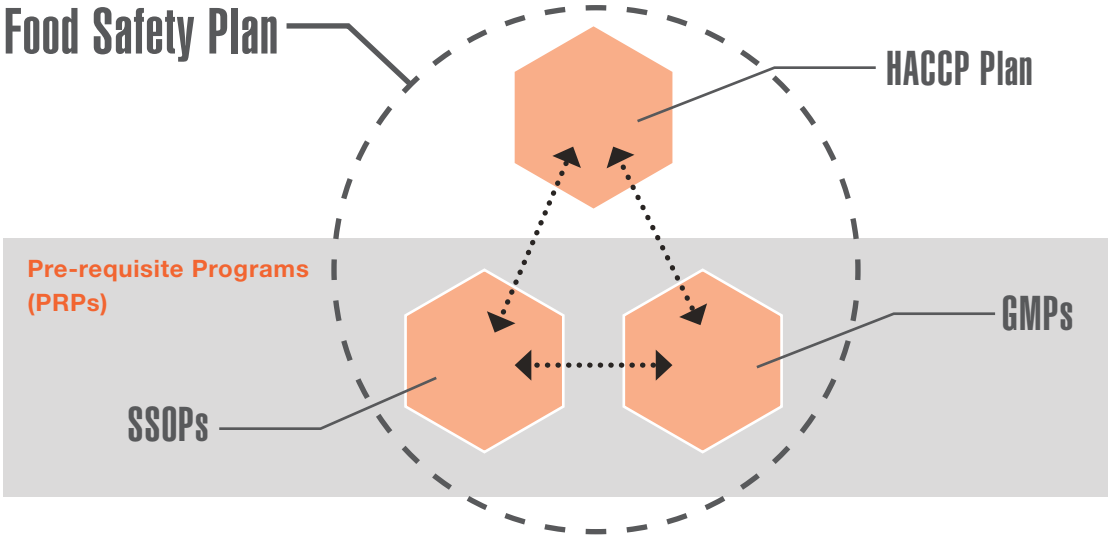
Part 2: The Food Safety Plan

A food safety plan has three parts:

- Good Manufacturing Practices (GMPs)
- Sanitation Standard Operating Procedures (SSOPs)
- Hazard Analysis Critical Control Points (HACCP)

The first two are sometimes called pre-requisite programs (PRPs) because they need to be under control before HACCP can successfully ensure a safe product. The interrelation between the three elements of a Food Safety Plan are shown in Fig. 2.1.

Figure 2.1 Elements of a food safety plan



2.1 Pre-requisite programs

Pre-requisite programs underpin the Food Safety Plan. They contain all the steps and procedures that control the operations within the food plant, together with the documents needed and the records that have to be kept. Often divided into SSOPs and GMPs, these programs include:

1. Premises, both inside and outside must be properly constructed, lit and ventilated (Part 5). Employees need toilets and hand wash stations. The water supply must be potable.
2. Premises need to be cleaned at various stages of the day and as necessary (see Part 5) and kept free from pests.
3. Transport vehicles must be properly constructed and kept clean.
4. Suppliers should be approved and products stored according to regulations for ambient, chilled and frozen storage (Part 6.2).
5. Staff should be trained with the skills and knowledge sufficient to do their tasks.
6. An allergen program (see Part 6.5) and a recall program are needed.

Only when you have these pre-requisite programs set up can you operate a Food Safety Plan. Part 5: Construction and Cleaning and Part 6: Good Manufacturing Practices provides the detailed information that you will need to develop your pre-requisite programs.

2.2 Hazard Analysis and Critical Control Points (HACCP)

HACCP is a system that identifies and evaluates hazards (Hazard Analysis) and controls those hazards at Critical Control Points. The HACCP system, which is science-based and systematic, 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 prevention rather than relying mainly on end-product testing.

A Critical Control Point (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. These points need to be monitored. When measurements are taken at a CCP a Critical Limit (CL) is defined that tells you whether the CCP is being controlled - and therefore, whether the product produced is acceptable or not.

For an operation to fulfil the definition for a CCP it must achieve one of the following:

1. Prevent the hazard
   or
2. Eliminate the hazard from the product
   or
3. Reduce the hazard to an acceptable level

Here are some examples of how this can be achieved.

1: Prevent the hazard being consumed

Example 1: Chilling

If chilling is done according to the Australian Standard (AS 4696: 2007), *C. perfringens* spores are prevented from germinating and growing to a level of concern.

The CLs are prescribed in a two-stage process which must take cured meat through the growth zone in seven and a half hours and uncured meat in six hours and then to 5°C within 24 hours after completing cooking.

Example 2: Nitrite addition

The addition of nitrite to the formulation prevents growth of *C. botulinum* by inhibiting spores from germinating.

The CL is that nitrite is present to the legal limit of 125 mg/kg in all products except Uncooked Comminuted Fermented Meats (UCFM) in which is up to 500 mg/kg of a combination of nitrate and nitrite.

Or

2: Eliminate the hazard from the product

Example: Cooking

In cured, cooked meats the cook step must eliminate all target bacteria.

The CL is that the slowest heating point of meat receives 65°C/10 minutes or an equivalent process as set out in Table 6.4.

Or

3: Reduce the hazard to an acceptable level

Example: Metal. Passage of final product through a metal detector reduces the contaminant to an acceptable level.

The CL is based on the capability of the detector to detect metal of a specific size and type (stainless, ferrous and non-ferrous).

2.3 HACCP Plan

The HACCP plan controls food safety hazards at all stages of food production; it is based on a series of steps developed by the Codex Alimentarius Commission:

Step 1: HACCP team roles and responsibilities

Step 2: Description of each product type and packaging format

Step 3: Intended use of each product

Step 4: Process flow diagram

Step 5: Verify the flow diagram

Step 6: Identify all hazards

Step 7: Determine Critical Control Points (CCPs)

Step 8: Establish Critical Limits (CLs) for each CCP

Step 9: Set up a monitoring and checking system at each CCP

Step 10: Establish Corrective Actions

Step 11: Establish a verification system

Step 12: Maintain records

The HACCP plan is integrated into the overall Food Safety Plan (FSP) as part of the company's pre-requisite programs.

To construct a HACCP plan, hazard control worksheets, which describe how hazards are controlled at each stage of the process, need to be developed (Table 2.1). Some worksheets include a form of risk rating based on the likelihood of a hazard occurring and its severity when it does. Appendix 1 specifies risk ratings for each microbiological hazard.

Table 2.1 Outline of a hazard control worksheet

Process step	Hazard	What can go wrong	Hazard control
	BIOLOGICAL		
	CHEMICAL		
	PHYSICAL		

Step 7 of the HACCP plan determines whether a particular stage is a CCP, defined as: *"A step at which control can be applied and is essential to prevent or eliminate a food safety hazard or reduce it to an acceptable level."*

Unit operations which are CCPs are important parts of the process and require rigorous monitoring to ensure that the process stays in control and does not breach a Critical Limit - a criterion which separates acceptability from unacceptability. CCPs are monitored using a HACCP audit table similar to Table 2.2.

Table 2.2 Outline of a HACCP audit table

Critical Operation	Hazard	Critical Limit	Monitoring				Corrective Action	Records	Verification
			What	How	When	Who			

Part 7: Process Control provides details on all the CCPs required for the manufacture of smallgoods, plus how to validate them.

Part 3: Low-risk products which are cooked before consumption

Smallgoods manufacturers typically have a raw and a cooked side to their operation. In the former, unit operations include: thawing, tempering, trimming, grinding, comminuting, stuffing into casings and packing for retail.

Products such as sausages are intended to be thoroughly cooked before eating, a process which inactivates all microbiological hazards, making them low-risk products. However, there are non-microbial hazards, such as foreign matter and allergens which must be prevented from entering retail-ready products.

3.1 Fresh sausage

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

Fresh sausages are made from comminuted meat extruded into a casing; they are intended to be cooked.

A valid process is one in which:

- The meat emulsion contains no more than 500 mg/kg sulphur dioxide
- The product label declares presence of sulphite and any other allergens
- The temperature of product in process and in storage and transport, is maintained at no warmer than 5°C

3.1.1 GMPs

At large manufacturers, cartons of frozen trim are the predominant raw material; blocks of meat are tempered in a chiller overnight to soften slightly prior to chipping into small flakes of frozen meat. Chilled or flaked frozen meat is then ground. The degree of comminution varies according to the required texture and some operations use a combination of grinding and bowl chopping to produce a sausage emulsion. Ingredients including water, wheat flour, rice flour, mineral salt, sulphite, dextrose, spices and flavours are mixed with meat in grinder/blenders.

Small manufacturers make batches of the order of 20-50 kg and weigh out a premix to give the correct level of ingredients in the finished batter.

Finally, in both large and small-scale operations, the sausage emulsion is extruded from the filling orifice into collagen casings and the end of each sausage is linked. The process flow is presented in Figure 3.3.

Figure 3.1 Emulsifying meat in a bowl chopper

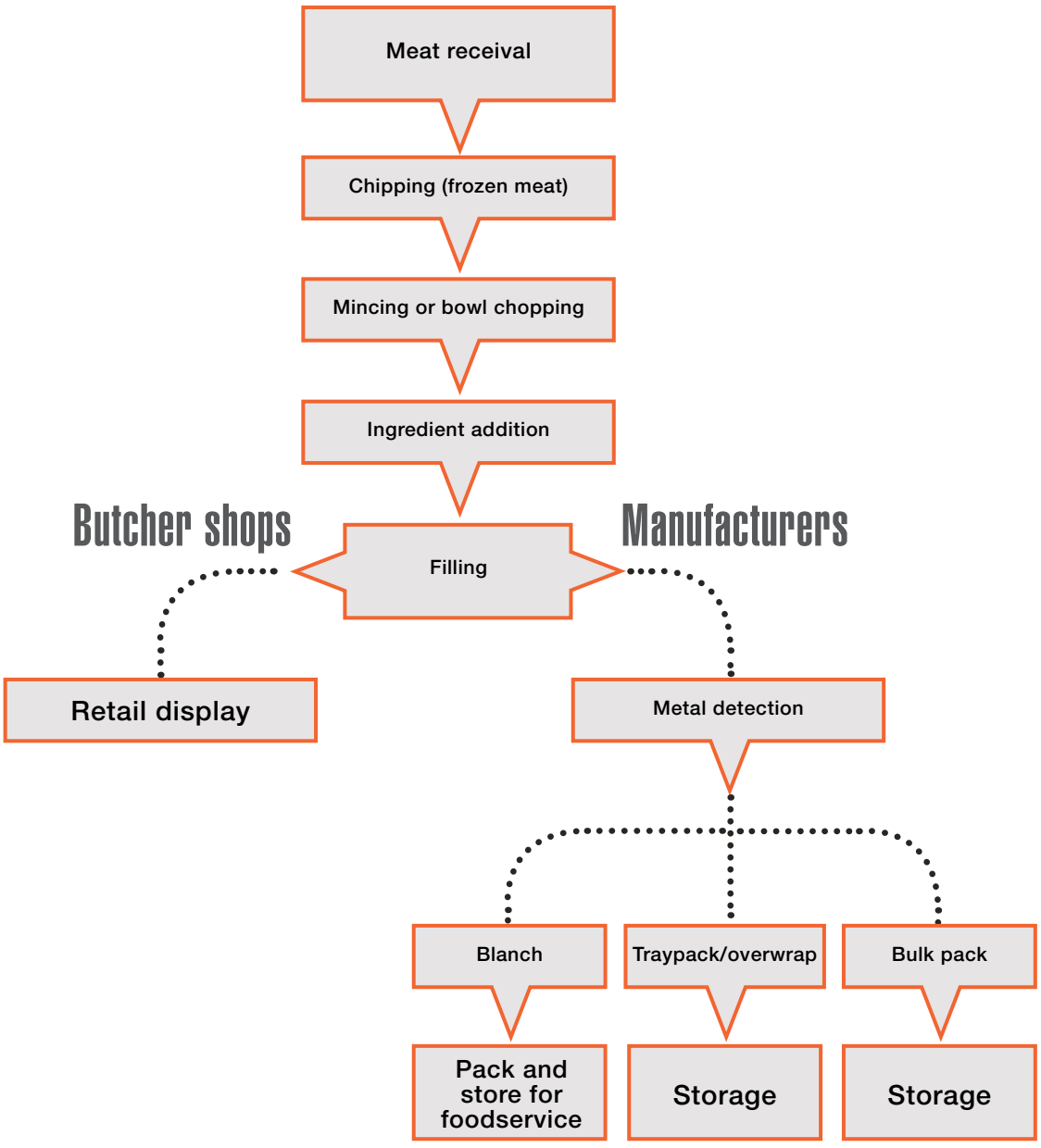
GMPs include:

- Maintaining storage temperatures during processing, especially where 'bench trim' (external meat) is taken from carcases and primals is used
- Work instructions for preventing foreign matter such plastic film, insects, string etc from entering the product

See Part 6 for more detail.

Figure 3.2 Vacuum seal sausage

Figure 3.3 Process flow diagram for sausage manufacturer



3.1.2 Microbiological profile of fresh beef sausage

Researchers from the South Australian Research and Development Institute (SARDI) sampled beef sausages from butcher shops and supermarkets in five capital cities in Australia (Hamilton *et al*. 2009). As shown in Table 3.1, total viable counts (log TVC/g) on average had lower total bacterial counts when purchased from supermarkets. *E. coli* was isolated from 6/10 (60%) samples from butcher shops and from 7/43 samples (16%) from supermarkets. The higher counts in sausages from butcher shops probably reflects the increased proportion of surface trim used in their manufacture.

Table 3.1 Total viable counts (TVC log cfu/g) of fresh sausage

	Butcher shops	Supermarkets
Mean	5.96 (912,000)	4.27 (18,600)
Maximum	7.15 (14,000,000)	7.63 (42,600,000)

3.1.3 HACCP controls

There are four CCPs in the manufacture of fresh sausage:

- Storage temperature of incoming meats and finished product
- Sulphite control
- Control of other ingredients which are allergenic
- Metal detection

More detail on the scientific basis for these CCPs and their validation is presented in Parts 7 and 8, respectively.

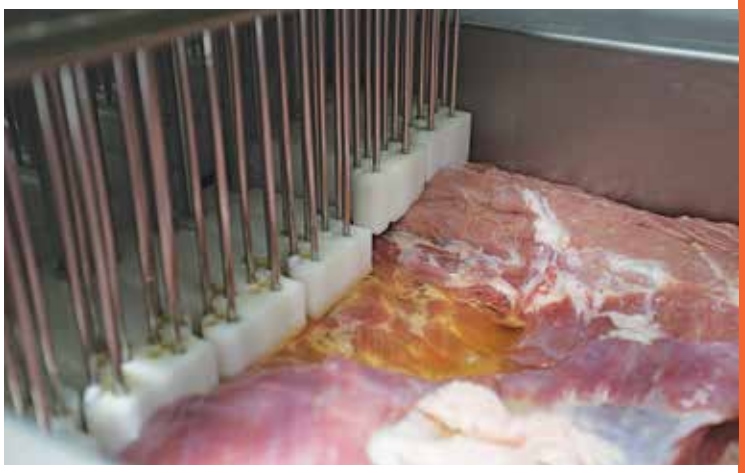
3.2 Bacon

Bacon middles are cured by injecting with curing brine, soaking in pickle, then drying and smoking before chilling and slicing. 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.

A valid process for bacon manufacture involves:

- Correct addition of nitrite to prevent growth of *Clostridium botulinum* and to prevent consumers ingesting a toxic dose
- Storing at a temperature no warmer than 5°C

Figure 3.4 Injectors pumping brine into pork during bacon production



3.2.1 Microbiological criteria – regulatory limits

There are no microbiological limits in the Food Standards Code for bacon.

3.2.2 GMPs

Bacon manufacture involves injecting brine into pork 'middles'. It's important that the correct injection rate is achieved across the entire middle and across the entire batch. Consistency in injection and massaging is covered in detail in Part 6.8.

After brining, middles are 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 in a smoke generator and smoke flavour is taken up. Steam is added to the atmosphere to raise the internal temperature of the 'eye' (the back muscle) to enhance the pink colour of the lean portions of the bacon.

Figure 3.5 A slicing machine producing sliced bacon

Middles 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 middle to 0° to –1°C. Tempered bacon slices satisfactorily because the meat holds together well. If the middle is sliced untempered the belly portion may not slice consistently, causing fat smearing and lower yields.

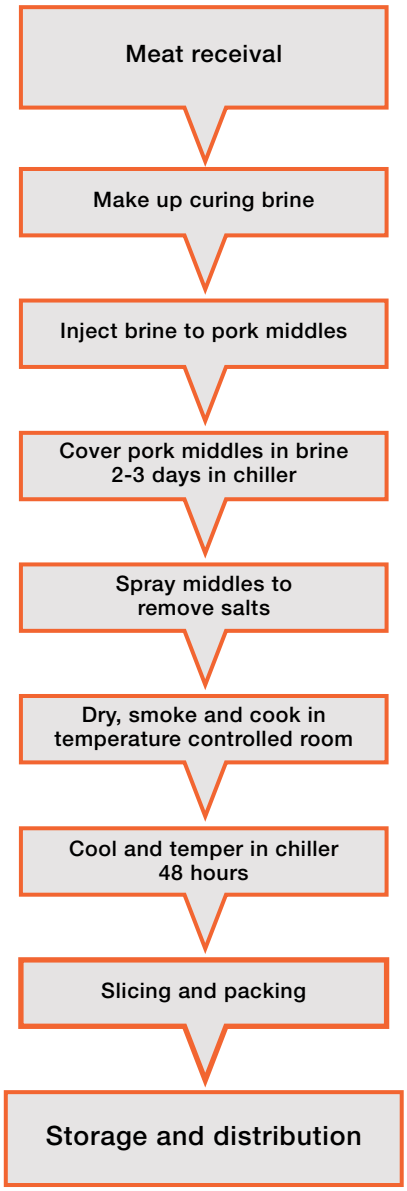
Storage and distribution

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*.

3.2.3 HACCP controls

The process has only one CCP at curing – addition of nitrite at the correct concentration. See Part 7.3 for more detail on the scientific basis for nitrite use.

Figure 3.6 Process flow diagram for bacon



Part 4: High-risk products – ready to eat meats

4.1 Roast meats

Cuts and joints of meat are cooked in an oven or in a water bath, after which they are chilled. Some are injected with seasonings; note that injecting changes the site of microbiologcal concern to the centre of the muscle.

A valid process for the manufacture of roast meats involves:

- A cooking process which delivers at least 65°C for 10 minutes or an equivalent process (see Table 6.4)
- Cooling at the site of microbiological concern which conforms with Standard AS 4696:2007
- Storage, distribution and retail temperatures no warmer than 5°C
- A high standard of hygiene at slicing and packing

4.1.1 Basic types

Cuts and joints of meat (particularly beef) are typically injected with salt, soluble seasonings and vegetable protein, cooked then chilled. Roast meats may be sliced for sandwich making or used in the catering sector for meal preparation.

A typical process flow diagram is shown. If a steamer is used for cooking the roasts, a bagging step will also be included.

4.1.2 Microbiological limits

For roast meat products to achieve a satisfactory food safety status they must conform with the microbiological limits in the Food Standards Code (see Table 4.1). These limits will be applied if there is testing undertaken by the regulator. They may not necessarily be part of a regular testing program, but if the production process is not designed to meet them, the product should not be being made.

Table 4.1 Microbiological limits for roast meats

	Number of samples (n)	Number of samples (c) allowed to be >m but <M	Limit (m)	Maximum (M)
Coagulase-positive *staphylococci*	5	1	100*	1,000*
Products in which growth of *L. monocytogenes* will not occur	5	0	100	
Products in which growth of L. monocytogenes can occur	5	0	0**	
Salmonella	5	0	0**	

* Count per gram of product
** Not detected in 25g samples

What do limits mean

When five samples are tested for coagulase-positive staphylococci four must have a count not more than 100/g while one can have a count between 100 and 1,000/g; no sample can have more than 1,000/g.

For *Salmonella* the limits mean that when five samples, each of 25 g (total 125 g) are tested this pathogen should not be detected.

There should be no problem passing the *Salmonella* test because the cooking requirements can kill high *Salmonella* loadings.

For *L. monocytogenes* the limits vary according to whether the product has been formulated to prevent its growth:

- In products in which growth can occur the limits mean that when five samples, each of 25 g (total 125 g) are tested this pathogen should not be detected
- In products in which growth will not occur, five samples are tested, and every sample must have not more than100/g

You should read FSANZ's Guidance on the application of microbiological criteria for *Listeria monocytogenes* in RTE food – download it at:

http://www.foodstandards.gov.au/code/microbiollimits/Pages/Criteria-for-Listeria-monocytogenes-in-ready-to-eat-foods.aspx

FSANZ states that: "Where insufficient, inadequate or no information exists to demonstrate that growth of *L. monocytogenes* will not occur in a RTE food, the food is considered to support growth and therefore a limit of 'not detected' would apply." This means you need to obtain information to satisfy your regulator that your product will not support growth of *L. monocytogenes*. In Appendix 6 we list the information you will need to assemble.

4.1.3 GMP and SSOP controls

Good Manufacturing Practices for the manufacture of roast meats include:

Injection of brine

Cuts are injected with brine containing various seasonings, salt and other additives. If a needle becomes blocked or breaks during processing the correct injection rate will not be obtained. Improving consistency of brining is covered in detail in Part 6.8.

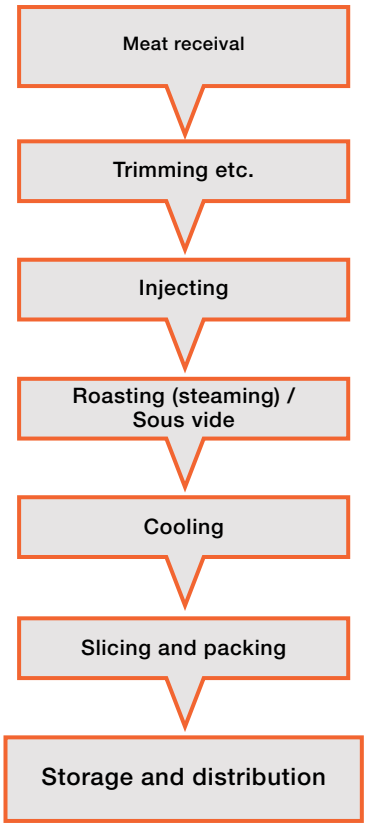
Post processing handling (slicing and packing)

Roasts are susceptible to recontamination with *L. monocytogenes* after processing, especially during slicing and packing. More information can be found in Part 6.17.

Storage and distribution

There is a regulatory requirement to store RTE meats under refrigeration no warmer than 5°C. This prevents growth of most pathogenic bacteria except for *L. monocytogenes.*

Figure 4.1 Process flow diagram for roast meats



4.1.4 HACCP controls

The roasting of meat products has CCPs for cooking and cooling.

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 (AS 4696: 2007) there is little likelihood that any surviving spores of *C. botulinum* can germinate, grow and produce toxin.

Monitoring the cooking process

The cooking process should deliver 65°C for 10 minutes or an equivalent process (see Table 6.4). To monitor the cooking process, the temperature probe needs to be inserted at the slowest heating point of product placed at the slowest heating part of the cooker. More information can be found in Part 6.15.

Figure 4.2 Checking the temperature at the slowest heating point using a hand held temperature probe

Monitoring the cooling process

Cooling minimises the growth of pathogen spores which have survived the cooking process. Roast beef cooling must follow the Australian Standard (AS 4696: 2007) for 'Uncured cooling requirements'. It is necessary to monitor cooling by inserting the temperature probe in the slowest cooling point of the product. More information can be found in Part 6.16.

4.2 Cured and cooked products

Products which are cured and then cooked include muscle meats and emulsified meat packed in an edible casing. The cooking process must be adequate to kill pathogens present at the slowest cooking point. Cooling is important to prevent any surviving bacteria from growing, as is temperature control during storage and distribution.

A valid process is one in which:

- Curing agents are present at a level which preserves the product (this is defined in AS 4696:2007 as "minimum of 2.5% salt on water phase and 100 ppm nitrite in-going"). 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 (see Table 6.4)
- Cooling conforms with the 2-stage process in the Australian Standard (AS 4696: 2007) or with an alternative arrangement approved by the controlling authority
- Storage, distribution and retail temperatures no warmer than 5°C

4.2.1 Basic types

This category contains muscle meats such as ham and corned silverside, and emulsified meat packed in an edible casing, such as frankfurters and Strasburg.

4.2.2 Microbiological limits

For cured or cooked whole muscle products to achieve a satisfactory food safety status they must conform with the microbiological limits in the Food Standards Code (see Table 4.2). These limits will be applied if there is testing undertaken by the regulator. They may not necessarily be part of a regular testing program, but if the production process is not designed to meet them, the product should not be made.

You can validate whether your product supports the growth of *Listeria monocytogenes* following the advice in Part 8.5. It is possible to reformulate your product so that is does not support the growth of *L. monocytogenes* following the advice in Appendix 6.

Table 4.2 Microbiological limits for cured/cooked meat

	Number of samples (n)	Number of samples (c) allowed to be >m but <M	Limit (m)	Maximum (M)
Coagulase-positive *staphylococci*	5	1	100*	1,000*
Products in which growth of *L. monocytogenes* will not occur	5	0	100	
Products in which growth of L. monocytogenes can occur	5	0	0**	
Salmonella	5	0	0**	

* Count per gram of product
** Not detected in 25g samples

What do the limits mean?

When five samples are tested for *S. aureus*, four must have a count not more than 100/g while one can have a count between 100 and 1,000/g; no sample can have more than 1,000/g.

For *Salmonella* the limits mean that when five samples, each of 25 g (total 125 g) are tested this pathogen should not be detected.

There should be no problem passing the *Salmonella* test because the cooking requirements can kill high *Salmonella* loadings.

For *L. monocytogenes* the limits vary according to whether the product has been formulated to prevent its growth:

- In products in which growth can occur the limits mean that when five samples, each of 25 g (total 125 g) are tested this pathogen should not be detected
- In products in which growth will not occur, five samples are tested, and every sample must have not more than100/g

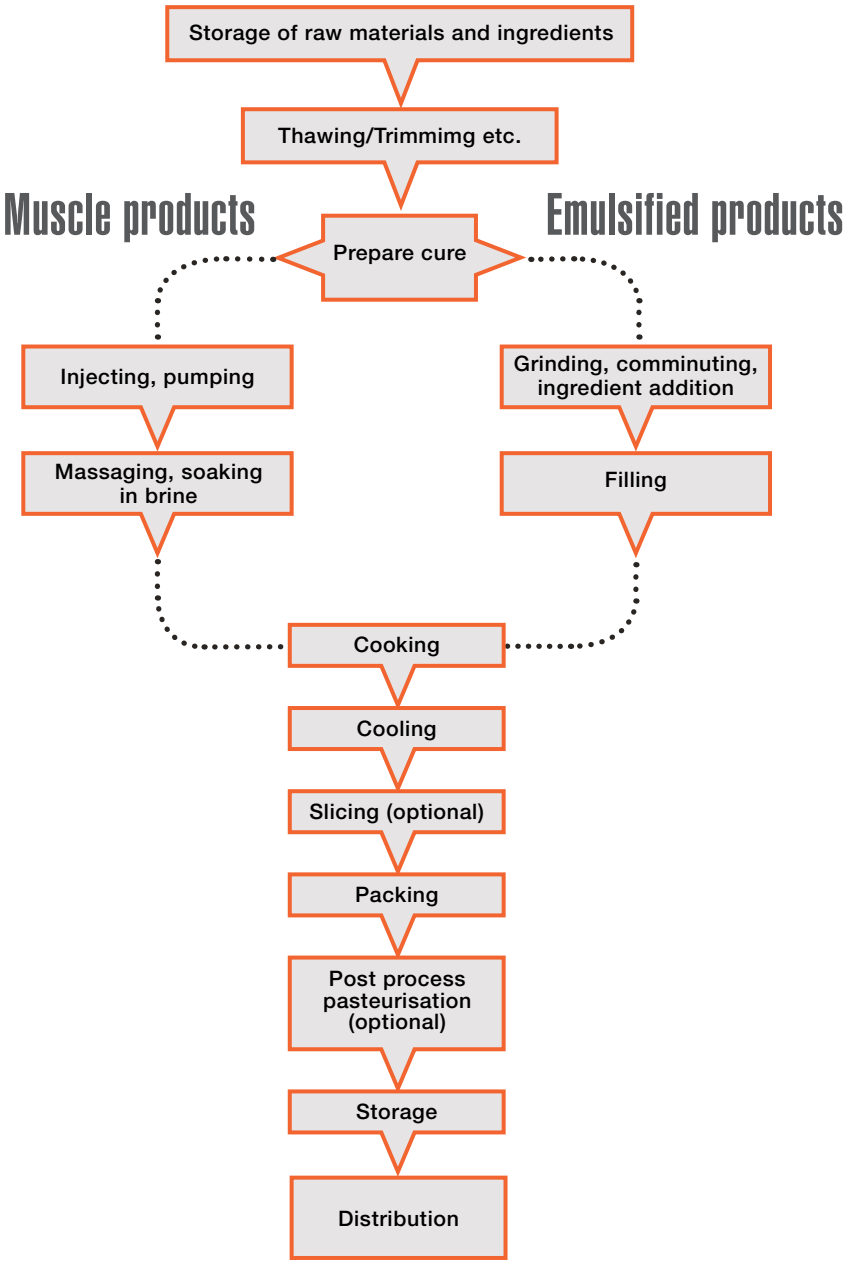
You can read more in FSANZ's Guidance on the application of microbiological criteria for *Listeria monocytogenes* in RTE food – download it at:

http://www.foodstandards.gov.au/code/microbiollimits/Pages/Criteria-for-Listeria-monocytogenes-in-ready-to-eat-foods.aspx

FSANZ states that: "Where insufficient, inadequate or no information exists to demonstrate that growth of *L. monocytogenes* will not occur in a RTE food, the food is considered to support growth and therefore a limit of 'not detected' would apply." This means you need to obtain information to satisfy your regulator that your product will not support growth of L. monocytogenes. In Appendix 6 we list the information you will need to assemble.

For *L. monocytogenes* however, the problem is that it survives very well in factory environments, especially in cool, moist areas such as chilled packing areas and storage rooms. It is important that everything possible is done to prevent it recontaminating cooked product. The sections on Post-process contamination (Part 6.17) and cleaning (Part 5) of these guidelines contains important information regarding the actions that must be taken to control this dangerous bacterium.

Figure 4.3 Outline process flow diagram for curing and cooking of meat products



4.2.3 GMP and SSOP controls

Good Manufacturing Practices for the manufacture of cured, cooked meats include:

Injection and massaging

Muscle pieces are cured by injecting (pumping) with brine, followed by soaking or massaging (tumbling). Emulsified products receive curing agents during bowl chopping.

Salt at a concentration of 3-4% in the water phase lowers the water activity which acts in tandem with chill storage to prevent the growth of *Salmonella* and *E. coli*. Nitrite is added at 125 mg/kg (125 ppm) to control the growth of *Clostridium botulinum* in the cooked product by preventing spores from growing.

Massaging spreads the brine salts (sodium chloride and nitrite) more uniformly through the muscles and salt helps to bind the pieces of meat into the ham shape within the netting.

Storage and distribution

There is a regulatory requirement to store ready-to-eat meats under refrigeration no warmer than 5°C. This prevents growth of most pathogenic bacteria except for *L. monocytogenes*.

4.2.4 HACCP controls

The curing and cooking of whole muscle products has CCPs at the brining, cooking, cooling, storage and distribution stages.

Brining

Nitrite is present up to of 125 mg/kg (125 ppm) in finished product to control the growth of *Clostridium botulinum* and *C. perfringens*. Exceeding this concentration can be toxic to consumers. The injection rate is monitored at the beginning of the process and at intervals by weighing individual units. More detail on achieving consistency of brining is included in Part 6.8.

Monitoring the cooking process

A valid process is one which delivers at least 65°C for at least 10 minutes or an equivalent process as set out in Table 6.4 in Part 6.15. Cooking in an oven means that there will be hot and cold spots, even with forced air circulation and you'll need to include a data logger in the product centre and at the slowest heating point in the cooker to ensure that all product receives sufficient temperature and time.

If you cook in a water bath – for example Franks or Strasburg, ensure product is at least 10 cm beneath the surface to obtain uniform cooking.

Monitoring the cooling process

The Australian Standard (AS 4696: 2007) contains a 2-stage cooling process where the key is the time it takes for the slowest cooling point of product to cool from 52°C to 12°C and then to 5°C. The temperatures and times in the Standard are aimed at preventing growth of the target bacterium, *C. perfringens*, if it is present, to an unsafe level.

Some plants start cooling by spraying cooked product, by immersing in an ice slurry or by hanging product in a cool spot. Large products are difficult to cool within the time limits of the Australian Standard and you may need to develop an alternative arrangement for approval by your regulator. In Appendix 5 we provide a model alternative arrangement based on a predictive model and limiting the predicted growth of *C. perfringens* to 1 log unit.

Metal detection

Metal can enter smallgoods during a number of operations such as grinding, bowl chopping and injecting. We provide more information on detecting metal contamination and disposing of suspect product (see Parts 6.11 and 7.6).

In-pack pasteurisation

Post-process pasteurisation – heating product after it's been packed - kills pathogens (especially *L. monocytogenes*) picked up after cooking. This is an optional step in the process; further information can be found in Part 6.19.

Storage and distribution

Maintaining finished product colder than 5°C is a regulatory requirement which is also monitored as a CCP. This prevents growth of pathogenic bacteria except for *L. monocytogenes*.

4.3 Pâté

Pâtés, liverwursts and terrines are an emulsion of cooked, cooled and packaged meat or offal. Gelatin or a garnish, such as cracked pepper, may be added to the surface. Nitrite is added to some pâtés to give a red colour.

A valid process for pâté manufacture is one which:

- Cooks all ingredients to at least 65°C for 10 minutes or an equivalent temperature/time regime (see Table 6.4)
- Cools according to the 2-stage Australian Standard
- Storage, distribution and retail temperatures no warmer than 5°C
- Has hygiene controls and GMPs for post-process handling and packing

4.3.1 Basic types

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 1 kg, which is sliced to order in delicatessens, to small retail vacuum-packs.

4.3.2 Microbiological limits

The Food Standards Code sets microbiological limits for pâté (see Table 4.3.1). These limits will be applied if there is testing undertaken by the regulator. They may not necessarily be part of a regular testing program, but if the production process is not designed to meet them, the product should not be being made.

You can validate whether your product supports the growth of *Listeria monocytogenes* following the advice in Part 8.5. It is possible to reformulate your product so that is does not support the growth of *L. monocytogenes* following the advice in Appendix 6.

Table 4.3 Microbiological specifications for pâté

	Number of samples (n)	Number of samples (c) allowed to be >m but <M	Limit (m)	Maximum (M)
Products in which growth of *L. monocytogenes* will not occur	5	0	100	
Products in which growth of L. monocytogenes can occur	5	0**	0*	
Salmonella	5	0**	0*	

* Not detected in 25g samples
** This limit only applies to product that is packaged

What do the limits mean?

For *L. monocytogenes* in products in which growth can occur, and for *Salmonella* the limits mean that when five samples, each of 25 g (total 125 g) are tested these pathogens should not be detected in any sample. There should be no problem passing the *Salmonella* test because the cooking regime can kill high *Salmonella* loadings.

For *L. monocytogenes* in products in which growth will not occur, five samples are tested, and every sample must have not more than 100/g.

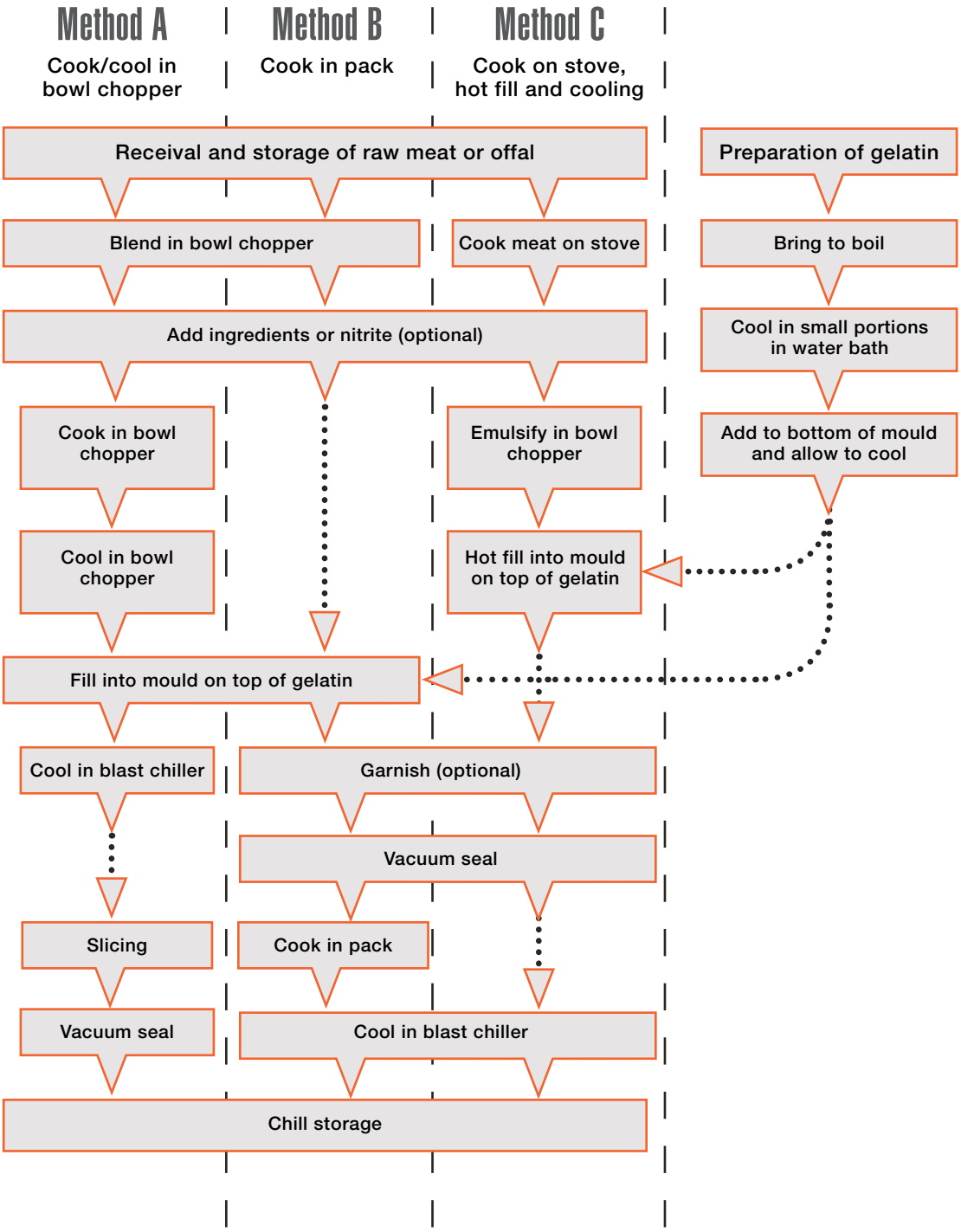
For *L. monocytogenes* however, the problem is that it survives very well in factory environments, especially in cool, moist areas such as chilled packing areas and storage rooms. It is important that everything possible is done to prevent it recontaminating cooked product. The section on Post-process contamination (6.17) in Part 6 of these guidelines contains important information regarding the actions that must be taken to control this dangerous bacterium.

You should also read FSANZ's Guidance on the application of microbiological criteria for *Listeria monocytogenes* in RTE food – download it at:

http://www.foodstandards.gov.au/code/microbiollimits/Pages/Criteria-for-Listeria-monocytogenes-in-ready-to-eat-foods.aspx

FSANZ states that: "Where insufficient, inadequate or no information exists to demonstrate that growth of *L. monocytogenes* will not occur in a RTE food, the food is considered to support growth and therefore a limit of 'not detected' would apply." This means you need to obtain information to satisfy your regulator that your product will not support growth of L. monocytogenes. In Appendix 6 we list the information you will need to assemble.

Figure 4.4 Process flow diagram for pâté



4.3.3 GMP and SSOP controls

For general information on Sanitation and Good Management Practices that apply to all products read Parts 5 and 6 of these Guidelines. Specific Good Manufacturing Practices for the manufacture of pâté include:

Cooling of cooked product

If the product is cooled in a jacketed bowl chopper, heat is quickly reduced from 85° to around 35°C by the circulation of cold water. Second stage cooling is carried out in a chiller after the product has been filled into the moulds. This cooling method will easily comply with the Australian Standard (AS 4696: 2007).

For larger pack sizes (1-2 kg) processed in a non-jacketed chopper, chilling may be slow at the centre of the product.

Cooling can be improved by:

- Taking the heat out of the product for 30-60 minutes outside the chiller – in front of a fan
- Placing the moulds in an ice bath
- Placing the moulds in front of the blowers in the chiller
- Making sure there is plenty of air circulation around each mould

Post process contamination

Pâtés are susceptible to recontamination with *L. monocytogenes* after processing, especially during packing or slicing. More information on contamination during packing and slicing can be found in Part 6.17.

Vacuum sealing

Small retail packs which are vacuum-sealed are probably anaerobic except at the surface. The vacuum sealing should withdraw any remaining oxygen.

Pâté manufacture requires a high standard of hygiene in the final packing and vacuum sealing stages to prevent recontamination with *L. monocytogenes*. The product has a relatively long refrigerated shelf life and *L. monocytogenes* may reach levels that are dangerous for vulnerable consumers.

4.3.4 HACCP controls

Pâté manufacture has two CCPs:

1. Cooking temperature and time (see Part 7.4)
2. Cooling rate (see Part 7.5)

Monitoring the cooking process

It is usual to heat raw materials to more than 90°C during cooking, so the process will be more than equivalent to 65°C for 10 minutes. It is important to ensure that all product receives sufficient temperature for sufficient time. This will happen automatically in a jacketed bowl chopper but, if the product is cooked on a stove, the ingredients must be mixed thoroughly so that all product gets sufficient heat to kill pathogenic bacteria. When cooking after filling into a mould or pack the standard cooking requirements (65°C for 10 minutes or equivalent) apply.

Monitoring the cooling process

The Australian Standard contains a 2-stage cooling process where the important points are the time it takes for the product to cool to 12°C and 5°C. The temperatures and times in the Standard are aimed at preventing growth of the target bacterium, *C. perfringens*, if it is present, to an unsafe level.

Good Manufacturing Practices which will ensure conformance with the Standard are described in Part 4.3.3.

4.4 Dried meats

Dried meats are low moisture, air- or oven-dried products.

A valid process is one which controls pathogenic bacteria by:

- A high salt level during the early stages
- Drying to a very low moisture level <0.85 a_w

4.4.1 Basic types

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.

Figure 4.5 Biltong is a dried, cured meat that originated in Southern Africa

4.4.2 Microbiological limits

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. These are excluded in the document "Guidance on the application of microbiological criteria for *Listeria monocytogenes* in RTE food" (see Figure 2 in FSANZ's Guidelines – there is a decision tree which excludes shelf stable products from testing under Standard 1.6.1).

4.4.3 GMP and SSOP controls

For general information on Sanitation and Good Management Practices that apply to all products read Parts 5 and 6 of these Guidelines. Specific GMPs in the manufacture of dried meats are slicing, salting, drying, and packing.

Slicing

Slicing reduces the thickness of raw meat to allow uniform take-up of salt. Slicing also allows rapid drying of the product to help prevent bacterial growth.

Salting

Salting lowers the water activity (a_w) in meat, which also inhibits the growth of many pathogens.

Drying

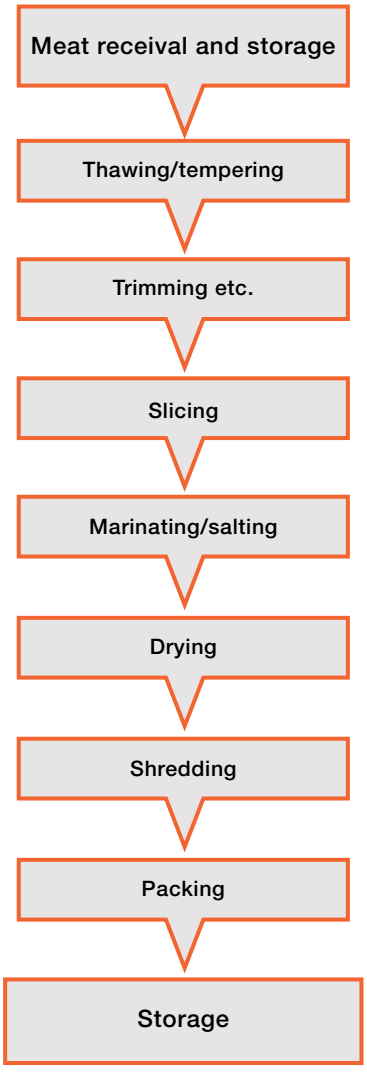
Control of the drying process and the water activity (a_w) is very important to product quality and safety. See Part 6.13 for further information.

Packing

To maintain product quality and safety, it is important to use 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

Figure 4.6 Process flow diagram for dried meats



4.5 Slow cured meats

Slow cured meats are dry-salted, then dried at low temperature and low relative humidity.

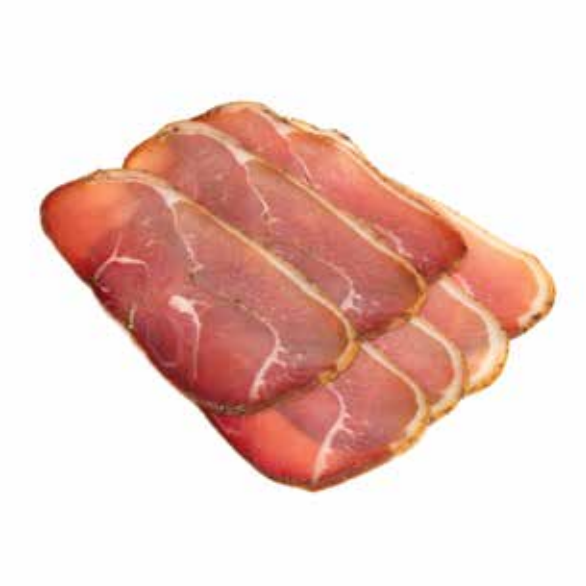
A valid process for safe manufacture of slow-cured meats is one in which:

- Salt level and refrigeration temperature are used to control growth of pathogens early in the process
- Drying occurs at low temperature and relative humidity to inactivate some pathogens and inhibit the growth of others

4.5.1 Basic types

In Australia, slow cured meats, such as Prosciutto, are usually prepared from boneless legs with a requirement that the pH is not >6.0 before salting. Other slow cured products such as Speck and Lachschinken are processed from meat portions. Meat undergoes a dry salting process followed by drying at low temperatures (around 10–15°C) and low relative humidity (around 70–85%).

Figure 4.7 Slices of Prosciutto



4.5.2 Microbiological limits

The Food Standards Code sets microbiological limits for ready-to-eat products (see Table 4.4). These limits will be applied if there is testing undertaken by the regulator. They may not necessarily be part of a regular testing program, but if the production process is not designed to meet them, the product should not be being made.

Slow cured meat products will not support the growth of *Listeria monocytogenes* providing the water activity is <0.92.

Table 4.4 Microbiological specifications for slow cured meats

	Number of samples (n)	Number of samples (c) allowed to be >m but <M	Limit (m)	Maximum (M)
Coagulase-positive staphylococci	5	1	100*	1,000*
L. monocytogenes	5	0	100*	
Salmonella	5	0	0**	

* Count per gram of product
** Not detected in 25g samples

What do the limits mean?

When five samples are tested for *S. aureus*, four must have a count not more than 100/g while one can have a count between 100 and 1,000/g; no sample can have more than 1,000/g.

For *Salmonella* the limits mean that when five samples, each of 25 g (total 125 g) are tested this pathogen should not be detected.

If the product does not support the growth for *L. monocytogenes*, five samples are tested, and no sample may have more than 100/g.

FSANZ states that: "Where insufficient, inadequate or no information exists to demonstrate that growth of *L. monocytogenes* will not occur in a RTE food, the food is considered to support growth and therefore a limit of 'not detected' would apply." This means you need to obtain information to satisfy your regulator that your product will not support growth of *L. monocytogenes*. In Appendix 6 we list the information you will need to assemble.

You should read FSANZ's Guidance on the application of microbiological criteria for *Listeria monocytogenes* in RTE food – download it at:

http://www.foodstandards.gov.au/code/microbiollimits/Pages/Criteria-for-Listeria-monocytogenes-in-ready-to-eat-foods.aspx

4.5.3 GMP and SSOP controls

For general information on Sanitation and Good Management Practices and Process Control that apply to all products read Parts 5 and 6 of these Guidelines. Specific GMPs for the slow curing process include:

Curing

In a typical process in the slow curing of pork, the legs are cured in a chill room for 12–24 days depending on the mass of meat which typically ranges from 12 to 25 kg). Salt diffuses from the outside surfaces of the pork leg to the inside, inhibiting the growth of many pathogens at the low curing temperature.

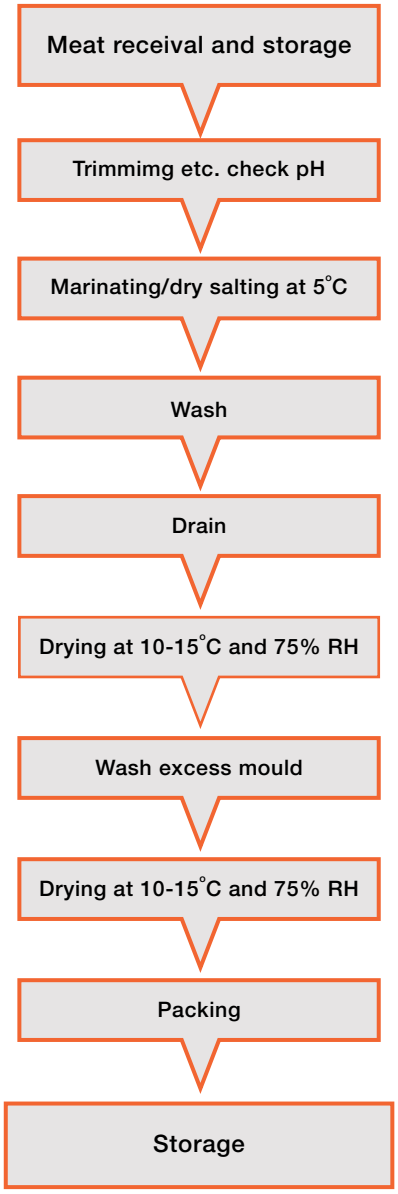
Drying

Cured legs are dried for many months under controlled temperature and relative humidity (e.g. 10–15°C and 75% RH) conditions. The final product has a low water activity and can be stored at an ambient temperature because the water activity is <0.92 and pathogens will not grow. Mould can grow and is removed after about six months drying (about half way through the process). See Part 6.13 for further information.

Vacuum packaging

Vacuum-packed legs are stored under refrigeration. Vacuum packing is a GMP which protects an expensive product from contamination or physical damage.

Figure 4.8 Process flow diagram for slow cured meats



4.6 Uncooked comminuted fermented meats (UCFM)

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 sausages.

Irrespective of the type of UCFM, the process is valid only if it conforms with the requirements of the *Australia New Zealand Food Standards Code*, Standard 4.2.3 (Production and Processing Standard for Meat) so that:

- The batter is fermented using a starter culture to produce a controlled reduction in pH of the meat
- The number of *E. coli* in the final product complies with Standard 1.6.1 (Microbiological limits in food)
- The process can inactivate the highest *E. coli* counts of in-going raw materials to levels that comply with Standard 1.6.1
- Records are kept of each batch of UCFM manufactured for 12 months after the use-by or best-before date of the product

4.6.1 Basic types

Fermented meats have been made for centuries in many European and Asian countries. European salamis originated in the Mediterranean region and are seasoned with spices; they are not smoked and usually have Italian or Spanish names. In cooler parts of Europe semi-dry sausages emerged which are less spiced, smoked at cool temperatures and typically have Germanic names.

Typical 'European' UCFM made in Australia range from dry sausages with a 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.

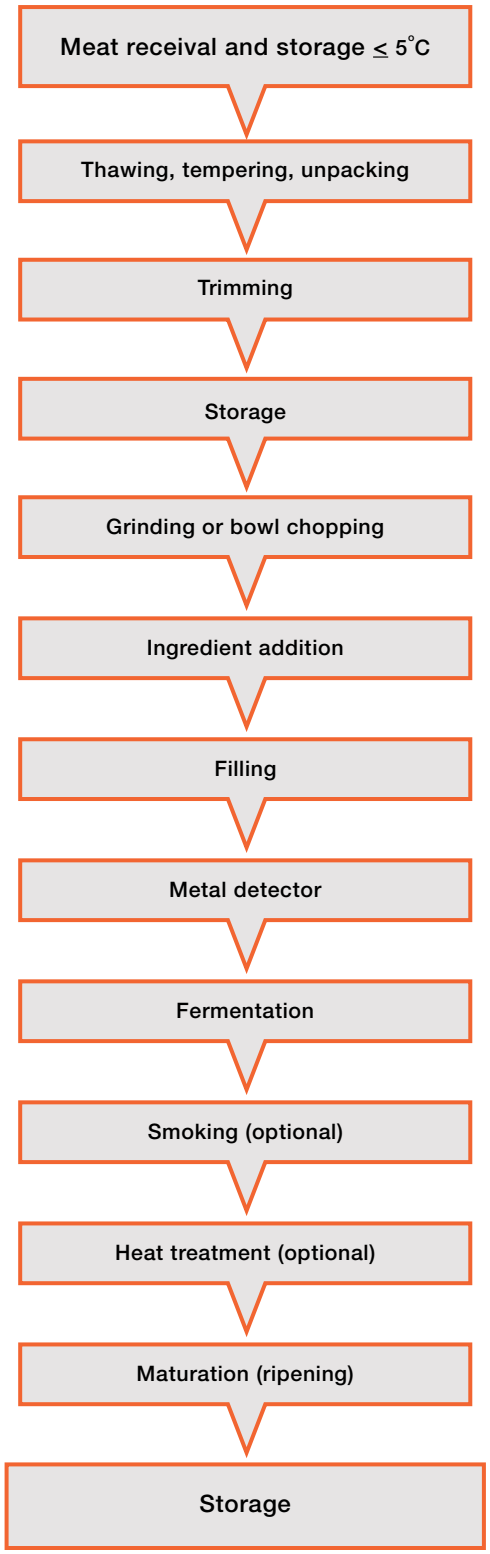
Fermented sausages are also made in Middle Eastern and Asian countries and these are covered in Part 4.8.

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 of the final UCFM:

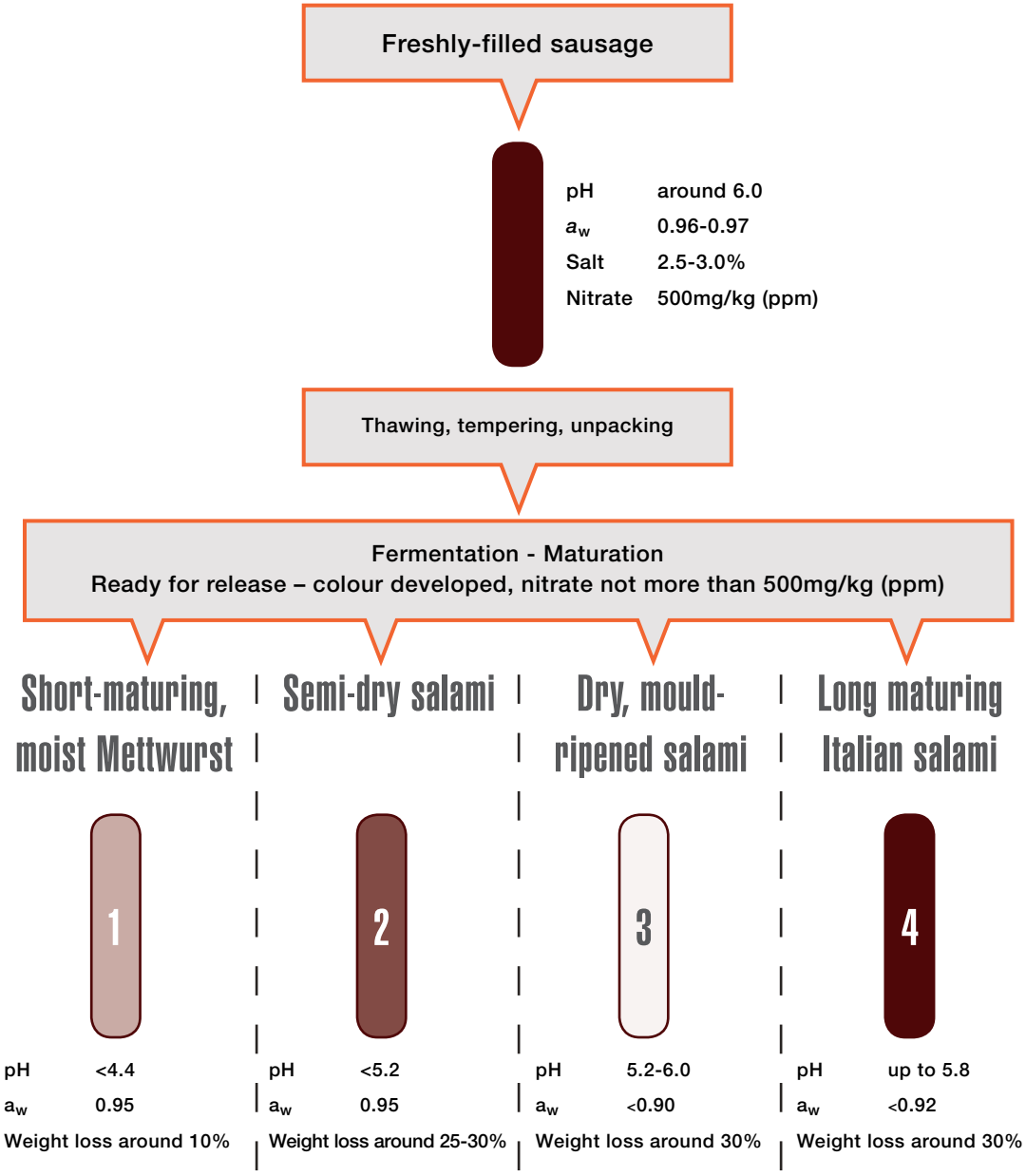
- Curing mix composition/concentration of nitrite/nitrate, salt concentration and spices
- Types of starter cultures
- Fermenting temperature, which can vary from <20°C for dry, Italian sausages to >30°C for soft, spreadable sausages, with semi-dry types being fermented in 20-30°C range
- Maturing time and temperature
- Sausage diameter
- Final pH and water activity

Figure 4.9 Process flow diagram for UCFM



Within this great diversity of UCFM there are four basic categories:

Figure 4.10 UCFM manufacture – changes which occur after filling in the main product categories



All these variables make UCFM manufacture one of the most complicated processes in the food industry. On the positive side, the process can be designed to give interesting products that are acceptable to both traditional and 'Australian' consumers. On the negative side, there is great scope for introducing process changes that may lead to a potentially dangerous product.

The process stages or unit operations are similar for the manufacture of most UCFM products and the process flow diagram applies to most processes.

Moist sausages.

These products typically have short fermentation and maturing times and rely on low pH (<4.4) for shelf-stability.

Semi-dry sausages.

Longer maturation periods (depending on diameter) result in a product which is shelf stable when its pH is <5.2 and water activity is <0.95.

Dry salami.

After fermentation salamis can be smoked or mould ripened at low temperature (10°C–12°C) for up to two months to give a water activity <0.90 and pH 5.2-6.0.

Very dry, high pH Italian salamis.

These sausages are matured for long periods (>2 months) at low temperatures (around 12°C) which provides shelf-stability due to low water activity (<0.92).

Typical chemical compositions of ingoing batter and different types of UCFM are shown in Figure 4.1. The range of water activity (a_w) and pH in different product types illustrates the wide spectrum of UCFM. Note that the *Australia New Zealand Food Standards Code*, Standard 1.3.1– *Food Additives*, allows up to 500 mg/kg (ppm) 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.

4.6.2 Microbiological limits

The Food Standards Code 1.6.1 (Microbiological limits for foods) sets microbiological specifications for UCFM (Table 4.5).

These limits will be applied if there is testing undertaken by the regulator. They may not necessarily be part of a regular testing program, but if the production process is not designed to meet them, the product should not be being made. Your local regulator can confirmed the testing program and requirements such as L. monocytogenes if your product supports growth.

Table 4.5 Microbiological specifications for UCFM

	Number of samples (n)	Number of samples (c) allowed to be >m but <M	Limit (m)	Maximum (M)
Coagulase-positive staphylococci	5	1	1,000*	10,000*
Salmonella	5	0	0**	
E.coli	5	1	3.6	9.2

* Count per gram of product
** Not detected in 25g samples

What do the limits mean?

For *S. aureus* the limit means that when five samples are taken, four must have counts of coagulase positive staphylococci of not more than 1,000/g, while one count can be between 1,000 and 10,000/g. No count can be greater than 10,000/g.

For *Salmonella* the limit means that when five samples, each of 25 g (total 125 g) are tested *Salmonella* must not be detected.

For *E. coli* the limit means that when five samples of UCFM are sent for testing by the MPN method, no sample can have more than 9.2 *E. coli*/g. One sample is allowed to have between 3.6 and 9.2/g *E. coli*.

4.6.3 Important GMPs and SSOPs

For more in-depth information on GMPs and SSOPs, refer to Parts 5 and 6 of these guidelines. The following GMPs are especially important in the manufacture of UCFM:

- Tempering: prevents fat softening and smearing
- Starters and sugar: starters drop the pH and overwhelm other bacteria, especially staphs by their high count; sugars are their energy source
- Salt: lowers the water activity of the batter, which inhibits pathogens
- Nitrite: enhances colour and inhibits growth of clostridia
- Ascorbate: together with erythorbate, enhances colour
- Vacuum filling: reduces the oxygen level, which inhibits spoilage bacteria and promotes fermentation
- pH: early lowering of pH is vital for food safety and it must be measured properly
- Moisture loss: vital for food safety and needs to be monitored correctly

Appendix 2 (Background on safe manufacture of UCFM) contains more information on these GMPs, plus other useful information on starters and colour formation.

4.6.4 HACCP controls

CCPs for UCFM manufacture are:

- Meat receival and tempering: CCP is carcase meat no warmer than 7°C and pieces of meat no warmer than 5°C (see Part 7.1)
- Allergen control: CCP is no undeclared allergens (see Part 7.2)
- Nitrite addition: premixes contain sodium and potassium nitrate and nitrite for a CCP of no more than 500 mg/kg in the finished batter to prevent growth of *C. botulinum* (and to enhance colour) (see Part 7.3)
- Fermentation: controlled pH drop within the first 48 hours inhibits pathogenic bacteria (see Part 7.7)
- Maturing: weight loss must proceed until the valid process is obtained. That is, a moisture content in final product so *E. coli* is inactivated to meet the requirements of Standard 1.6.1 (see Part 7.8)
- Metal detection: all product passes metal detection as verified by test pieces (see Part 7.6)

The final product is verified to conform with the *E. coli* requirements of *Australia New Zealand Food Standards Code*, Standard 1.6.1 – *Microbiological limits for food.*

4.6.5 Meeting the Standard for *E. coli*

The Australia New Zealand Food Standards Code, Standard 4.2.3 – *Production and Primary Processing Standards for Meat* requires a process which reduces the population of *E. coli* in the batter so that the final product conforms with Food Standard 1.6.1 – Microbiological limits for food.

This can be done in either of two ways:

- Commissioning a laboratory to carry out challenge testing on products

or

- Providing key process details so that the controlling authority can make a judgement on whether the process is adequate to cope with high-level contamination of *E. coli*

The first option, challenge testing, is expensive and is usually done only by large manufacturers. The test involves seeding a typical batter with non-pathogenic *E. coli* and monitoring their numbers throughout the fermentation and maturation stages.

The second option can be done by smaller operations, in two stages.

In Stage 1 an *E. coli* Predictor tool is used to establish how much *E. coli* your process inactivates. The following information is required to insert into the Predictor:

- Temperature of the batter
- Temperature of fermentation
- Duration of fermentation (hours)
- Temperature at each stage of maturing
- Length of each stage (hours)

Further information on how to use the Predictor is in Part 8.4. At the end of the calculation, you'll see how many *E. coli* your process can inactivate.

In Stage 2 the predicted inactivation for your process is compared with the likely high-end contamination found on beef, pork and lamb produced by your suppliers. If your process can cope with high-level contamination it will be safe.

4.6.6 Shelf stability and food safety

At the end of ripening, for a product to be released as shelf stable, it must achieve specified levels of pH and a_w.

Requirements for shelf life stability of UCFM varies according to the category:

- Moist UCFM relies on a pH <4.4
- Semi-dry UCFM is shelf stable when pH is <5.2 and a_w is <0.95
- Dry, mould ripened UCFM require pH 5.2-6.0 and a_w <0.90
- Very dry high pH Italian UCFM is shelf-stable at a_w <0.92

These levels are important and it is vital that pH and water activity (a_w) are measured accurately. These levels apply only to UCFM and the specific conditions of pH, a_w, nitrite, salt and starter bacteria – not to other smallgoods.

4.6.7 Heat treatment

As shown in the process flow diagram, some manufacturers heat-treat UCFM with a process in which the core temperature is maintained at 55°C for a period of at least 20 minutes, or an equivalent combination of time and higher temperature.

Standard 4.2.3 distinguishes between cooked fermented sausages (CFM) and heat-treated and does not consider the heat-treating regimes as equivalent to a cooking process. For this reason Standard 4.2.3 states: *"To avoid doubt, a UCFM includes comminuted fermented meat which has been heat treated."*

4.7 Cooked comminuted fermented meats

In the 1990s, following outbreaks of food poisoning from consumption of UCFM, manufacturers developed fermented sausages which receive a cooking step.

A valid process for cooked fermented sausage is that the fermented product receives 65°C/10 minutes or an equivalent heating process and is cooled according to the AS 4696: 2007

4.7.1 Basic types

Many manufacturers use a cooking step where fermented sausages receive 65°C/10 min or a temperature/time which gives an equivalent killing effect. This process, together with other parameters in the UCFM process, will provide a satisfactory reduction in *E. coli*.

If the product is made from manufactured meat (i.e. it has at least 660 g/kg meat) is cooked it is labelled as '*Fermented manufactured meat – cooked*'.

If it 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 (see process flow diagram in Part 4.6), except that a cooking or heating step is introduced following fermentation or after maturation.

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

4.7.2 Microbiological limits

There are no microbiological limits set in Standard 1.6.1 for cooked fermented meats. These are excluded in the document "*Guidance on the application of microbiological criteria for Listeria monocytogenes in RTE food*" (see Figure 2 in FSANZ's Guidelines – there is a decision tree which excludes shelf stable products from testing under Standard 1.6.1 because they receive a listeriocidal process after sealing in the casing).

4.7.3 GMP and SSOP controls

For more in-depth information on GMPs and SSOPs, refer to Parts 5 and 6 of these guidelines. The GMPs are very similar to UCFM (see Part 4.6.3).

It's important to control any pathogens present in the batter during the early stages of fermentation. If the pathogens grow out of control early on, the cooking process may not kill them all.

Appendix 2 (Background on safe manufacture of UCFM) contains more information on these GMPs, plus other useful information on starters and colour formation.

4.7.4 HACCP controls

The manufacture of CFM has CCPs similar to those set out in Part 4.6.4.

Monitoring the cooking or heating process

The cooking process must deliver 65°C for 10 minutes or an equivalent process. To monitor the cooking process, the temperature probe needs to be inserted in the slowest heating point of the product, usually at the centre of the biggest product. More information can be found in Part 6.15

Monitoring the cooling process

Cooling correctly minimises the growth of spores of pathogens which are capable of surviving the cooking process. CFM follows the "*Cured cooling requirements*" set by the Australian Standard (AS 4696: 2007). Monitor cooling by inserting a temperature probe in the slowest cooling point of products located in known 'dead spots' (slow cooling areas) of the chiller. More information can be found in Part 6.16.

4.8 Unusual sausages: uncooked and unfermented

There are a number of sausages produced in European, African and Asian countries which don't conform with UCFM. They may be intermediate-moisture sausages such as the Middle-eastern sücük, or soft spreadable sausages like the German Teewurst.

A valid process requires the product to have a CCP for pathogenic bacteria

4.8.1 Basic types

There are a number of sausages that are not UCFM but may be confused with salamis:

- Middle-eastern sausages such as sücük, soudjuk
- Asian sausages such as Lap cheong
- Soft, spreadable sausages such as Teewurst, Braunschweiger, N'duja
- South African Droewors
- Cyprus Smoked Sausages – Kypriaka Loukanika

All traditional smallgoods reflect regional influences in the methods used for low temperature preservation. Manufacturers use traditional recipes with regional ingredients and processes passed down over generations. The manufacture of these products brings together the combination of environmental and technological factors.

The Asian sausage Lap cheong is a speciality of humid tropical regions of Asia and uses high sugar, high temperatures and moderate airflow to preserve a narrow diameter product. The number of days required to dry products is dependent on replicating the local ambient weather conditions.

The South African sausage uses vinegar as a component to inhibit bacterial growth while matching the airflow with the drier regional conditions and more moderate ambient temperatures. It also requires a number of days to extract the moisture to a level where moulds won't spoil the product.

4.8.2 GMPs and SSOPs

For more in-depth information on GMPs and SSOPs, refer to Parts 5 and 6 of these guidelines. Because of the wide range of products, their processes and their compositions, refer to Appendix 3 (Background information on unusual sausages) where more details on each category are provided.

4.8.3 HACCP controls

Some products, such as soft spreadable sausages, have no CCP for target pathogens such as STEC and *Salmonella*. It should be noted that products like Teewurst are consumed widely in Europe and have been implicated in outbreaks for food poisoning. In Germany Ammon et al. (1999) and Werber et al. (2006) found a significant linkage between STEC illness and consumption of soft spreadable sausages. More recently, Kuhn *et al.* (2013) implicated Teewurst consumption with a long-lasting outbreak of salmonellosis in Denmark.

Other 'unusual' sausages, like sücük and Lap cheong are often eaten after light cooking which may not eliminate all pathogens. However, as will be seen from Appendix 3, the maturing temperature and time used for some products e.g. Lap cheong generates high levels of inactivation when the parameters are entered into the *E. coli* Inactivation in Fermented Meats Model predictor tool (see Part 8.4 for more information on the predictor).

Ultimately, it is necessary for the manufacturer to provide the regulator with a validated process. Appendix 3 provides information on the process parameters required.

4.9 Sliced smallgoods

The development of modern slicing and packaging machines has seen a great extension in supermarket display cases to accommodate the range of vacuum- and modified atmosphere packed RTE meats.

A valid process for slicing and packing relies on GMPs and SSOPs to maintain separation of raw and cooked areas, plus a high standard of in-process and end-of-day cleaning.

As can be seen from Table 4.6, sliced, ready-to-eat (RTE) meats have caused illness and death. Routine testing has also led to the recall of sliced RTE meats. Over the period 2001-2013, there have been 37 recalls of which 21 (58%) were from large manufacturers and 16 (42%) from smaller manufacturers, all because of the presence of *L. monocytogenes*.

Table 4.6 Outbreaks of illness in Australia from consumption of sliced RTE meats

Year	Product	Hazard	Cases (deaths)
1997	Cured, cooked meat	*S.* Muenchen	24 (2)
1997	Cured, cooked meat	*S.* Anatum	25
2005	silverside-corned beef	*L. monocytogenes*	5 (3)

4.9.1 Basic types

Smallgoods which are sliced and/or packed in aerobic packs have a short shelf life while those packed under vacuum or modified atmosphere (MA) have shelf lives of several weeks.

4.9.2 Microbiological limits

The limits are identical to those for the particular product being sliced e.g. cured and cooked, or fermented meats, and are described earlier in this section. Note that the FSANZ "Guidance on the application of microbiological criteria for *Listeria monocytogenes* in RTE food" state that the limit for *L. monocytogenes* in products that have a refrigerated shelf life of 5 days or less, will always be the limit for products that do not support the growth of *L. monocytogenes* regardless of whether the unsliced product was able to support the growth of the bacterium (see part 8.5).

4.9.3 GMP and SSOP controls

For more in-depth information on GMPs and SSOPs, refer to Parts 5 and 6 of these guidelines. If your business includes slicing and packing ready-to-eat smallgoods, the following GMP will apply:

Post process contamination

Ready-to-eat products are susceptible to recontamination after processing, especially during slicing and packing. Slicing requires a high standard of hygiene in the final packing and vacuum sealing stages to prevent recontamination with *L. monocytogenes*.

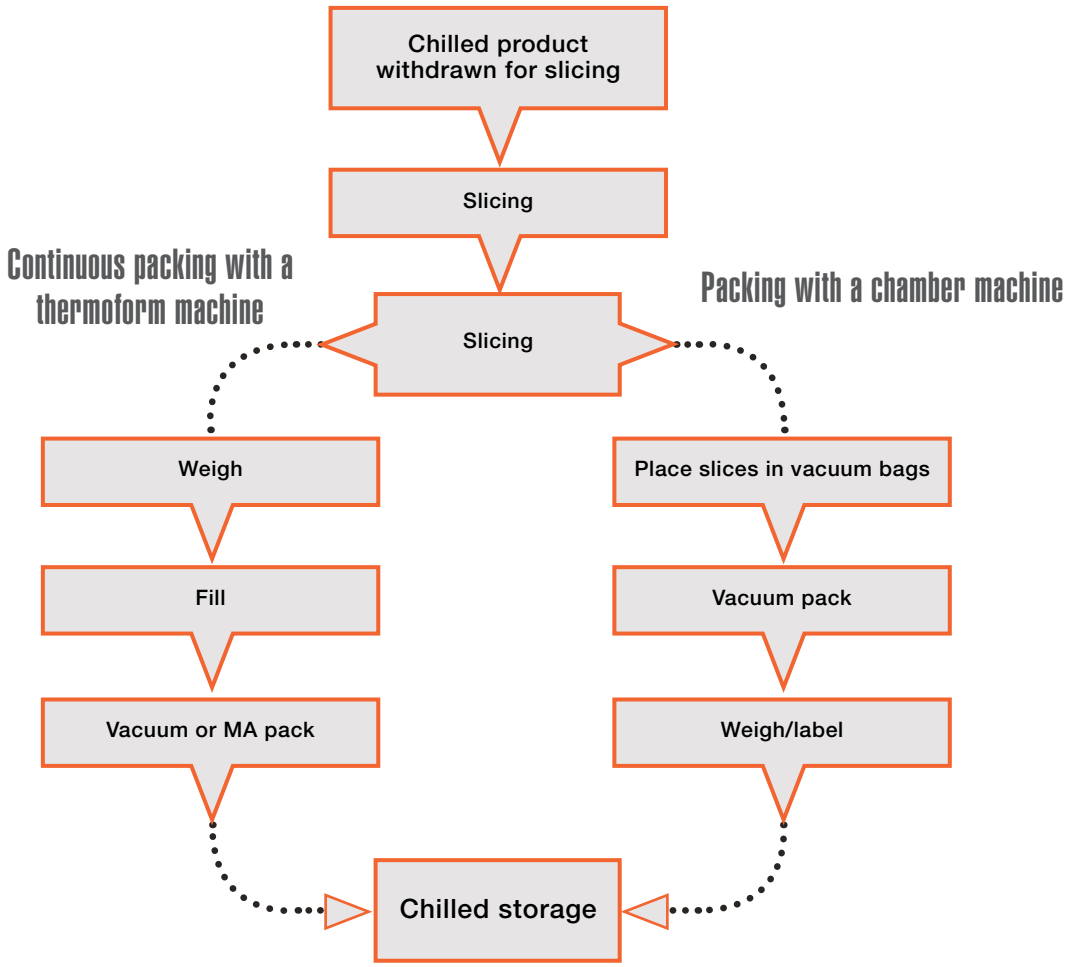
The risk of recontamination can be reduced by slicing and packing first thing in the morning when no raw product is present.

More information on post process contamination and Listeria growth can be found in Parts 6.17 and 6.20, respectively.

4.9.4 HACCP controls

There are no CCPs for slicing and storage of smallgoods, meaning that effective GMP and SSOP programs are critical to maintain safety. The cold chain does not prevent growth of L. monocytogenes. It does prevent pathogens such as *Salmonella* and pathogenic *E. coli* from growing, but if they are already there they will be consumed by the customer.

Figure 4.11 Process flow diagram for slicing and packing



Part 5: Construction and Cleaning

5.1 Construction of smallgoods plants

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

It doesn't matter whether you operate 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.

There is an Australian Standard, which details how premises should be designed and built. It is the *Australian Standard for the Hygienic Production and Transportation of Meat and Meat Products for Human Consumption* (AS 4696: 2007). Some states also have individual standards that apply to manufacturers of smallgoods.

In general, standards are either prescriptive or outcomes based. Prescriptive standards specify every last detail that must be met e.g. the arc needed for coving between wall and floor. Outcomes based standards specify only that you need to achieve a safe product. With outcomes based standards, the details of how you achieve a safe product must be included in your food safety plan. Your local controlling authority will have copies of these standards.

There are some basic fundamentals that must be addressed in a well-designed and constructed premises. These include:

- Having a safe water supply and one which supplies sufficient for all your plant needs
- Maintaining food contact surfaces in good, clean condition
- Preventing cross-contamination from insanitary objects
- 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

These elements prevent the contamination of materials and final products with microorganisms (germs) from people, equipment and the workplace environment or with chemicals used in food plants. Pre-requisite programs need to be in place to manage these elements.

The requirements in the *Australia New Zealand Food Standards Code Standard 3.2.3 – Food Premises and Equipment* will also need to be complied with. It is easy to read and follow and can be downloaded from the Food Standards Australia New Zealand (FSANZ) website, www.foodstandards.gov.au.

5.2 Cleaning the plant

When the processing day ends the food plant needs a major clean down and, 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 on 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 on 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' Sanitation Standard Operating Procedures (SSOPs). Some of the essentials of hygiene and sanitation are covered in the following section.

5.2.1 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 purchased.

5.2.2 Cleaning

The removal of soils like waste, dirt, grease, food scraps and blood from equipment and premises is termed cleaning. A 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.

5.2.3 Detergents

All detergents are formulated to remove fat and protein from the food plant. They typically contain 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.

Detergents are also built 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.

5.2.4 Sanitisers

As well as being soil-free, the cleaned surfaces of food plants must also have extremely low bacterial levels (<5/cm^2). The role of the sanitiser is to destroy any bacteria remaining on the surface. Traditionally, hypochlorite has been the most widely used sanitiser, but it's corrosive and other forms of chlorine, such as chlorine dioxide, are becoming available. Quaternary ammonium compounds (QUATS) 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.

5.2.5 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 for around 15 minutes (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 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.

5.2.6 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 & Safety (WH&S) (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 microbiological monitoring
- Working out a cleaning budget

5.2.7 Costs of cleaning

The major costs for cleaning food factories are labour, cleaning chemicals and 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 on labour.

5.2.8 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. Cleaning will need to be done while keeping the equipment dry because Listeria thrives if there is moisture around.

Table 5.1 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.

5.2.9 Work instructions

A protocol must be documented for each area to be cleaned. A typical protocol 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
- Rinse the detergent with water, then allow to drain
- Apply sanitiser and leave for required contact time
- Rinse if required
- 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 Workplace Health and Safety (WHS) instructions, where needed, and give the cleaner an idea of the time needed to clean the equipment.

5.2.10 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 - colour-coded is good e.g. red means only use for floor waste, green is used for product only
- Do sanitise brushes and store them correctly between use
- Do use low pressure cleaning systems to minimise splashing and aerosols
- Do store hoses 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 (FIFO – first in, first out) and having everything on shelves.
- Do maintain door seals in good condition – they can harbour Listeria
- Always do a 'pre-op' inspection 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.

5.3 Breaking the Listeria cycle

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

- Be vigilant with plant hygiene
- Introduce routine strategies to kill any Listeria which have entered parts of the premises and equipment which are difficult to clean

This is called 'Breaking the Listeria cycle' and there are several strategies available.

5.3.1 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.

5.3.2 Heating chillers to eliminate Listeria

Meat and Livestock Australia (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%).

Work by Eglezos *et al*. (2010) and Eglezos and Dykes (2011) indicates 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.

5.3.3 Heating equipment which can be moved into cookers

The idea of heating pieces of equipment in smokehouses began about 10 years ago and is now routinely practiced in North American plants. At weekends, equipment which can be moved is taken to the smokehouse and 'cooked' to 70-80°C for one to two hours.

5.3.4 '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 in setting up but, once done, it takes only two to three hours to free the slicer of Listeria in those parts which cannot be accessed by routine cleaning.

Table 5.1 Cleaning and sanitising priority 1, 2 and 3 sites

	Pre-operation	Inprocess cleaning	End-of-day cleaning
Priority 1 sites			
Slicers, dicers, deskinners etc **Hoppers which feed them** **Conveyors for cooked product** **Tables, benches on which product is portioned or packed**	When: During pre-op How: Re-clean if necessary and dry with paper towels. Spray with no-rinse sanitiser and allow contact time. Wipe dry with paper towel before start-up.	When: Each work break or product change How: Remove scraps of meat. Spray non-rinse sanitiser and allow contact time. Wipe dry with clean paper towel before start-up.	When: After shutdown How: See work instruction
Priority 2 sites			
Chiller doors **Switches** **Hand forklift controls**	When: During pre-op How: Re-clean if necessary and dry with paper towels. Spray with no-rinse sanitiser and allow contact time. Wipe dry with paper towel before start-up	When: As necessary if gross contamination occurs How: Wash with bucket and brush. Mop up moisture. Spray non-rinse sanitiser and allow contact time. Wipe dry with clean paper towel	When: After shutdown How: See work instruction
Air vents, blower units and drip trays in cooked product areas			When: Weekly on weekend How: According to work instruction. Fog through air conveying system with sanitiser
Priority 3 sites			
Equipment for handling packed products (Lazy Susan, roller conveyors) **Motor housings**	When: During pre-op How: Re-clean if necessary and dry with paper towels. Spray with no-rinse sanitiser and allow contact time. Wipe dry with paper towel before start-up	When: As necessary if gross contamination occurs How: Wash with bucket and brush. Mop up moisture. Spray non-rinse sanitiser and allow contact time. Wipe dry with clean paper towel	When: After shutdown How: See work instruction
Floors, drains, walls	When: During pre-op How: Re-clean if necessary and dry with squeegee.	When: As necessary if gross contamination occurs How: Wash with bucket and brush. Use squeegee to prevent puddles of water	When: After shutdown How: See work instruction

Part 6: Good Manufacturing Practices (GMPs)

Good Manufacturing Practices (GMPs) are basic to the way a business is set up to supply safe products.

6.1 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

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

6.1.1 Thermometers

Thermometers need to be calibrated at least once a week at a temperature close to the range where the thermometer is routinely being used (e.g. refrigeration or cooking). User manuals contain useful information on the thermometer and it is a good idea to keep them for reference. The CSIRO Meat Research Newsletter, Number 91/2 “Thermometers” also contains useful information on calibration. It can be found at http://www.meatupdate.csiro.au/data/MEAT_RESEARCH_NEWS_LETTER_91-2.pdf.

Oven and cool room probes can’t be easily removed so calibrate them in-place, using a calibrated thermometer at least once a month.

Most medium and large-size premises have a reference thermometer calibrated by a National Association of Testing Authorities (NATA) accredited laboratory. This is used only for calibrating working thermometers. The reference thermometer is calibrated annually by a service company accredited by NATA to perform the calibration.

6.1.2 Scales

Scales are calibrated according to the manufacturer’s requirements and checked at intervals by an approved agency.

6.1.3 General equipment

A number of instruments like pH meters and metal detectors are calibrated according to the manufacturer’s requirements.

6.2 Receiving and storing 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 raw materials and ingredients are received they need to be inspected for wholesomeness, and specifications such as temperature must be checked (no warmer than 5°C for cartoned meats and 7°C for carcases).

Records must be kept so that any lot which causes a problem can be worked back to. It's all part of having traceability.

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

Receival and storage temperatures are regulated under the Australian Standard (AS 4696: 2007) and there is no tolerance for temperatures warmer than those stipulated, except under an approved program.

Once accepted, raw materials should be:

- Moved to storage or directed to processing as soon as possible
- Maintained at appropriate 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 first-in-first-out (FIFO) basis

6.3 Receiving and storing packaging material

Packaging materials and packaging practice used for smallgoods should comply with the Australian Standard: AS 2070: 1999, *Plastics Materials for Food Contact Use*.

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 to ensure affected product can be traced if a problem occurs – all part of traceability.

6.4 Formulation and assembly

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. This is easy if a premix is purchased and the entire bag is added to a batch. Problems start when ingredients are weighed out one by one. A trained person is less likely to make a mistake, especially if they are not distracted, and some companies have staff who specialise in batching-up ingredients. Training on how to weigh out ingredients is essential.

Consistency is an important part of process control. Some elements that need to be considered when making batches of ingredients are listed in Table 6.1.

Table 6.1 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 incorporated? Use in strict rotation within use by	If nitrite is in the blend with the spices, it can degrade rapidly - shelf life can be as short as 3 months. Old blends means the final product will be low in nitrite. Nitrite blended with salt/sugars alone is much more stable.

* More information on reducing variability in Appendix 4

Figure 6.1 Adding ingredients into a batch

6.5 Allergens

The Allergen Bureau (www.allergenbureau.net) estimates 4-8% of children and 1-2% of adults have a food allergy.

When people eat food containing an allergen to which they are sensitive, symptoms range from mild to severe and affect the:

- Respiratory tract (wheezing, asthma)
- Gut (nausea, vomiting, diarrhea)
- Skin (hives, eczema, itching)

By far the most serious condition is anaphylaxis – blood pressure drops, breathing is restricted and the victim goes into shock; some people die of anaphylactic shock.

There has been an increasing awareness of the effect of a variety of common foods and ingredients to which a small percentage of the community have an allergic reaction. The most common allergic reactions are to the protein components of foods like wheat (gluten), soy and peanuts. So oils and fibre from these foods have a very limited risk of initiating a reaction but may contain traces of protein depending on the process used. There are other elements in foods to which consumers can have intolerances, such as lactose and sulphites; these are treated in the same fashion as the allergens.

There is a group of allergens called the Big 8 (see Table 6.2), which cause 90% of all allergic reactions. These foods are: wheat, peanuts, soybeans, milk, eggs, tree nuts, crustaceans and fish.

Keeping a register of all allergens kept on the premises, such as the simple list below, can help answer any questions from concerned customers. Suppliers of premixes can help with this.

Table 6.2 Checklist for allergens

Allergen	Present
Milk and dairy products	Yes/No
Eggs and egg products	Yes/No
Peanuts and peanut products	Yes/No
Tree nuts and their products	Yes/No
Soy and soy products	Yes/No
Crustaceans	Yes/No
Fish	Yes/No
Wheat	Yes/No

Other ingredients that need to be listed include products which contain cereals with glutens, sulphite, sesame seeds or bee products (Royal jelly).

Regulators require (Clause 4 of *Australia New Zealand Food Standards Code* Standard 1.2.3 – *Mandatory Warning and Advisory Statements and Declarations*) that manufacturers must list allergenic ingredients on their labelling with appropriate warnings for at-risk consumers. Manufacturers need to include the segregation of these foods and ingredients in their GMPs and assess the risks in their HACCP plan. Package labels must be checked regularly to detect any ingredient changes in raw materials and ingredients. Manufacturers need to require suppliers to inform them 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 in such a way that they don't inadvertently contaminate products that haven't 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

Labelling is a key part of controlling allergens and customers rely on you to tell them whether products are safe for their special needs.

Further information

More information on allergens is available on the FSANZ website: http://www.foodstandards.gov.au/consumer/foodallergies/Pages/default.aspx

The Allergen Bureau website (http://www.allergenbureau.net/) also provides great resources. The VITAL (Voluntary Incidental Trace Allergen Labelling) tool, which is used to calculate potential cross contamination, can be found there.

More information on labelling requirements can be found on the NSW Food Authority websites:

http://www.foodauthority.nsw.gov.au/industry/labelling/#.U9Wrjk3lqUk www.foodauthority.nsw.gov.au/consumers/food-labels/label-facts

Other state regulators may also have useful information on their websites.

6.6 Tempering and thawing

Standard AS 4696: 2007 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. All product should be fully immersed.

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.

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.

6.7 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.

6.8 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 combines 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).

Fresh brine solutions should be used for every batch. Curing solutions used for injection should be monitored for saline and nitrite concentration and should not be recycled after the first day of use or between batches.

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.

Massaging helps the brine salts (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.

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 6.3.

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 is anaerobic and can only grow in the complete absence of oxygen. 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.

Table 6.3 Reducing variability in curing

Stage	Check	Because
Brine make up	Brine temperature	Brine must be cold before injection to maintain product temperature and to minimise loss of nitrite
	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?	Volumetric 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?
	Are the dry goods fully dissolved in the brine before use?	Undissolved dry goods equals variability in salt and nitrite

* More information on reducing variability in Appendix 4

6.9 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 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.

Figure 6.2 Grinder producing minced meat

6.10 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.

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

Figure 6.3 A pack of sliced bacon being put through a metal detector

6.12 Fermenting

Manufacturers' instructions on the use of starter cultures must be followed, particularly:

- Rate of addition
- Whether the culture is suitable
- Storage and shelf life of the culture
- Reconstitution methods – direct into the bowl chopper or dissolving in water for 30 minutes
- Quantity and type of fermentable sugar added to assist fermentation
- Expected final pH and time this should be achieved
- Temperature and relative humidity during fermentation

Refer to the section on starters in Appendix 2 of these guidelines for more information.

6.13 Drying and maturing

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.

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. At low 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

Figure 6.4 Maturing room: Salamis being dried and matured

6.13.1 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, *Staphylococcus aureus*, can tolerate low water activity (down to 0.85) and its growth is usually controlled by lowering the temperature.

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
- Tying up the water so it is not available to the bacteria. This is done by adding curing agents such as salt to form brine. 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 monitored by using a water activity meter. Other methods include measuring weight loss and moisture content which can then be related to a_w.

6.13.2 Salamis

The relative humidity needs to be controlled during fermentation and maturation (ripening).

At the beginning of drying there should not be any water on the product surface, and condensation on the surface can be minimised by commencing with a relatively low humidity.

The gradient between the relative humidity of the air and water activity of the product should not be more than 5% so that case hardening won't occur.

6.13.3 Slow cured meats

Slow cured products should be dry-cured while reducing the relative humidity.

Dry curing is done by:

- (Traditionally) rubbing the surface with salt, nitrate and nitrite and holding at 5°C or lower for about 10 days or, more usually, tumbling meat at very slow speed under vacuum
- Holding at this temperature for a sufficient time (25–45 days) for the salt concentration at the centre to reach about 1%
- Drying the product at increasing temperatures for up to 100 days
- Ageing in a cool dry environment

The relative humidity is decreased gradually throughout the process from about 95% to 60%.

6.13.4 Dried meats

Products such as jerky are commonly made by curing then heating in a fan-forced oven at 60–70°C, with a relative humidity of about 15–18%, for 5–12 hours. The aim is to produce a product with:

- Water activity of about 0.75–0.85
- Moisture content of about 20%
- Salt content of about 5%

The high drying temperatures will reduce the nitrite level. It is important that the drying oven is calibrated for temperature and air velocity variations at various points.

6.14 Smoking

Product in the smokehouse should be evenly spaced to help air circulation and enhance even smoking. Smoking is important for flavour. Smoke also generates chemicals which inhibit the growth of bacteria and moulds and is important in preventing mould growth. Mould-ripened salamis are not usually smoked.

Figure 6.5 A smoke house and cooking oven

6.15 Cooking

For each cooked product, a suitable heat-processing step must be applied to kill target pathogenic vegetative cells. 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
- If product is cooked in an open hot water bath then the product should be held at least 10 cm below the water surface with equipment such as a metal screen
- Smallgoods should receive a '*Listeria monocytogenes* 6D cook' by using the time/temperature parameters in Table 6.4

Inserting a probe at the slowest heating point of the product will verify that your equipment can deliver the process.

Table 6.4 Holding times at product core temperatures required to deliver 6 log reductions in *Listeria monoctyogenes* counts

Temperature (°C)	Time (min)
55	200
56	146
57	108
58	79
59	58
60	44
61	33
62	24
63	18
64	13
65	10
66	7
67	6
68	4
69	3
70-72	2
73-76	1
76 or warmer	<1

Note: A 6D process is a process which reduces the bacterial count 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 6.5.

Table 6.5 Reducing variability in cooking

Stage	Check	Because
Filling/hanging	Brine temperature	Brine must be cold before injection to maintain product temperature and to minimise loss of nitrite
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? How is time controlled? Manual or part of a program?	Smoking is often the driest part of the cook cycle. Product surface has to be dry before smoking – or smoke won't adhere. 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.

* More information on reducing variability in Appendix 4

6.16 Cooling

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

Cooling under the Australian Standard (AS 4696: 2007) is a two-stage process (Table 6.6).

Table 6.6 Temperature:time parameters for cooling meats (AS 4696: 2007)

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

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 with full scientific backing.

In Appendix 5 we include a model alternative process for cooling large RTE meats.

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 product are listed in Table 6.7.

Table 6.7 Reducing variability in cooling

Stage	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.

6.17 Slicing and packaging

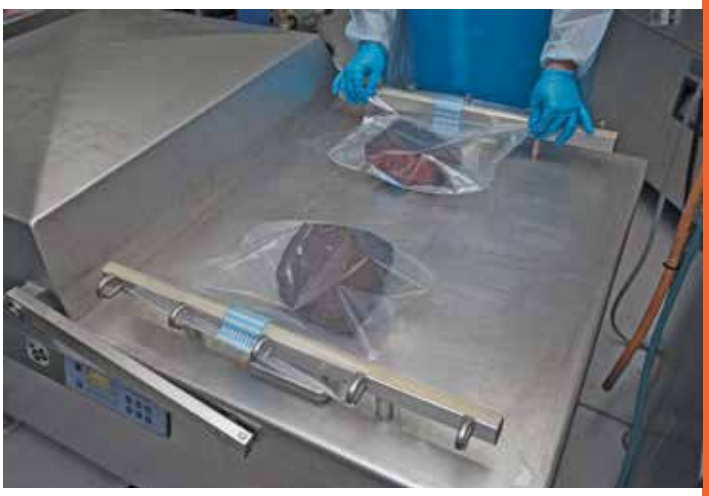
These operations rely on GMPs and SSOPs to prevent or minimise recontamination of the cooked product with spoilage and pathogenic microorganisms. See Part 5 for advice about cleaning and control of Listeria in the plant.

Ready-to-eat 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 conveyer belts and rollers, drains, floors and equipment. There are a number of ways in which contamination with *L. monocytogenes* can be minimised.

Figure 6.6 Manual vacuum sealer



In large plants this can be done 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
- Having filtered air and positive air pressure in slicing and packing rooms
- Linking slicing/packing rooms with the dispatch area through a tiny hatch
- Spraying antimicrobials to decontaminate the surfaces of products immediately prior to slicing and packing (see section 6.18)
- Pasteurising products in-pack (see section 6.19)
- Taking steps to break the Listeria cycle by heating movable pieces of equipment in the cookers
- Heating chillers to kill Listeria which are colonising them

Figure 6.7 Conveyer belts are difficult to clean

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 on how and when they must wash their hands and change gloves

Further information on the control of *Listeria monocytogenes* can be found in Appendix 6.

6.18 Surface decontamination of RTE meats

The weak point in processing RTE meats is the stage between when products emerge from 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 of operators

Contamination by Listeria at this stage is confined to the surface and antimicrobials can be used in two ways:

- As surface sprays or dips
- Incorporated into packaging material

The most commonly used antimicrobials used in sprays are lactic acid and acetic acid at a concentration of 2.5%. One product contains a mixture of organic acids plus phenols, with smoke flavouring an option as a surface spray. All surfaces are sprayed immediately before placing product in the vacuum bag and sealing. Under vacuum the antimicrobial is spread in a thin layer over the entire meat surface.

Packaging film impregnated with nisin has proved effective in controlling Listeria in RTE meats, though cost is a consideration.

In summary, surface sprays for whole muscle pieces are an effective way of controlling Listeria growth over the shelf life. As with using antimicrobials in the formulation, surface sprays should not be used to extend the shelf life since this compromises the food safety basis of the spray.

6.19 Pasteurising products 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 and a leaking pack alone offers opportunity for contamination. To obtain a similar level of confidence, both cold and hot pasteurisation, in the final pack are becoming increasingly used in the industry.

Cold pasteurisation is achieved by High Pressure Processing (HPP) which can achieve a 5-log reduction in Listeria in RTE meats. Drawbacks are that modified atmosphere packs will not withstand the high pressures (350 MPa).

In hot pasteurising, sufficient heat must be applied to the slowest heating point in a pack to produce a 2-log reduction in Listeria. It is achieved by various means:

- Immersion in hot water, maintained by steam
- Microwave heating
- Integrated steam pasteurising and packing

Small and medium size plants pasteurise by immersing final packs of product in a hot water bath with steam injected to quickly rise the water temperature to 90-95°C. Depending on the product and packaging format, a thermal process 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 MA packs 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.

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.

6.20 Growth of Listeria in the cold chain

Chilling is not a CCP for Listeria, because it can grow at chill temperatures, and this pathogen must be controlled by SSOPs and GMPs. Unfortunately, the cold chain provides the opportunity for *L. monocytogenes* to reach dangerous levels because long shelf-lives of vacuum-packed smallgoods at retail (6-7 weeks) allow the pathogen to grow in the packed product.

At 5°C in RTE meat, Listeria can double its numbers every two days. Over a week's storage it will increase its population around ten-fold. After two weeks storage the numbers will increase 100-fold and so on. So, a month after the product is packed, if there was one Listeria present at packing, it will have multiplied to 10,000. If a vulnerable person eats a sandwich with 100 g of luncheon meat, they will take in 1,000,000 Listeria – which may be enough to infect them.

It's important that hygiene around the slicing and packing operation is at a very high level and that there is control over SSOPs. Reformulating product so that it will not support the growth of *Listeria monocytogenes* is an option (see Part 8.5).

Part 7: Critical Control Points

To run a successful business, control points are needed throughout the process for regulatory, food safety, sensory and profitability reasons. The various controls include Control Points (CPs), Quality Control Points (QCPs) and Critical Control Points (CCPs) (Table 7.1).

Table 7.1 Control points to meet manufacturer and consumer requirements

Requirement	Element controlled	Control mechanism
Meat	Meat receival, product storage temperatures and pathogens	Critical Control Points (CCPs)
	Foreign matter	Critical Control Points (CCPs)
Product quality	Sensory attributes	Quality Control Points (QCPs)
Profitability	Weight control	Control Points (CPs)

Some companies include all of the above types of control points in their HACCP plan to align with customer requirements. It must be emphasised, however, that the HACCP plan is intended strictly for food safety, where the focus is on hazards which will injure consumers.

This part only deals with Critical Control Points because they are the ones essential to achieve safety for your product. Critical Control Points were discussed in Part 2 – so you may need to look back there. The CCPs in this section were identified through hazard analysis and through looking at the processes defined in Part 4 on the various products.

7.1 CCP: Receival temperatures

The Australian Standard 4696: 2007 specifies that raw meats must be held at no warmer than 7°C (carcases) 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 *Staphylococcus aureus*) cannot grow at temperatures colder than 7°C (see Appendix 1 for more information on these target bacteria). For pieces of meat the Standard was set in order to align with the Food Standards Code which required retail storage no warmer than 5°C (see Part 6.2 for advice about receiving and storing raw materials).

These temperatures are regulatory requirements and are sometimes referred to as Regulatory Control Points (RCPs).

In many HACCP plans receival temperature are used as CCPs with 7°C (carcases) and 5°C (pieces of meat) as CLs.

These plans have corrective actions for managing meat when it arrives ‘warm’.

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 option to reject it and you'll probably consider how much warmer the meat is than the CL and how long it's been there. 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

Remember that there are requirements for temperature reduction of meat after slaughter via the Refrigeration Index (RI), and the boning room should also track the RI until it reaches 5°C or lower before despatch.

If you accept warm meat you are taking over the responsibility for ensuring that the meat reaches the correct temperature in the allowed time.

If the 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.

7.2 CCP: Ingredient control – allergens

There are several points in the process where allergens may be added:

- In dry formulations. Be specific with the supplier if ingredients need to be allergen-free
- Processing. If allergen-free products are made first, a contaminated processing line should not be a factor

For further information about allergens see Part 6.5.

Labelling needs to be clear to identify any allergens present

An allergen in 'normal' use is sulphite, which has been used as a preservative for about two thousand years. In countries where sausages are made from surface trim, sulphite is essential to provide sufficient shelf life.

Sulphite can be used in raw sausages and sausage meat at a concentration up to 500 ppm (500 mg/kg) – the Critical Limit (CL), but it cannot be used in minced meat because:

- Some people are allergic to sulphite and it can cause asthmatic and other respiratory conditions in these consumers
- It's illegal and regulators may take you to court even if only a small amount is detected

Don't fiddle with ingredients – use them strictly according to the manufacturer's instructions

Procedures to prevent inadvertent transfer of even a small amount of sulphite include:

- Using a dedicated grinder for sausage manufacture
- In smaller operations, making batches of mince first thing, when the grinder is clean and free of sulphite

7.3 CCP: Ingredient control – nitrite addition

Sodium nitrite is used for colour development and to control some of the microorganisms that can make consumers ill, especially *C. botulinum*.

However, nitrite is toxic to consumers at a level above 1500 mg/kg (ppm) and its addition to the mix must be controlled (see advice in Section 6.4).

In operations where nitrite is added as part of a pre-weighed curing mixture with salt (sodium chloride), it's unlikely that it can be over-added to the batter. In operations where nitrite is weighed out separately extreme care is needed and the nitrite register should be filled in accurately.

7.4 CCP: Cooking

Cooking is a CCP which eliminates pathogens such as *Salmonella*, pathogenic *E. coli* and *L. monocytogenes*. Bringing the 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 6.4 kills target pathogenic bacteria (see Part 6.15).

To monitor the process, ensure the temperature probe is calibrated and located at the slowest heating point of the product.

7.5 CCP: Cooling

The Australian Standard (AS 4696: 2007) contains a two-stage cooling process where the important points are the time it takes for product to cool from 52°C to 12°C and to 5°C within 24 hours of the completion of cooking (see Part 6.16). The slowest cooling point is important because, if *C. perfringens* is found at that point, it has the best chance to grow to a dangerous level.

The Australian Standard allows you to utilise an alternative cooling procedure for approval by your controlling authority. In Appendix 5 we provide a model alternative process based on predicted increase of *C. perfringens* during cooling.

7.6 CCP: Foreign matter control

As indicated in Part 1.2, a significant proportion of recalls were for presence of foreign matter (metal, rubber and plastic) hazards which, if ingested, could cause injury to the mouth or alimentary tract, or even death by choking.

There are several stages in the process where foreign matter can enter:

- Polyentrapment when manufacturing meat is unwrapped
- During storage of dry goods (e.g. insects, rodent droppings)
- Bone fragments during trimming
- Opening bags of ingredients (string, plastic, paper fragments)
- Operators (hair, bandaids, jewellery etc)

Refer to Part 6.11 for further information on metal detection in large and small operations.

The CLs for metal are set by the sensitivity of the detector, which is monitored regularly and as necessary.

For other foreign matter (e.g. rubber, plastic, hair, droppings) zero tolerance is required.

7.7 CCP: Fermenting UCFM

The Australia New Zealand Food Standards Code, Standard 4.2.3 – *Production and Processing standard for meat* requires the use of a starter culture to ferment the meat (for further information see Appendix 2). The starters must service a number of aspects to control the growth of pathogens:

- Compete successfully for the nutrients in the meat medium
- Produce microbial inhibitors
- Be safe microbiologically
- Produce a controlled reduction of the pH of the meat mix

A pH of 5.2 or lower within 48 hours is recognised as adequate protection against the growth of pathogens. Some manufacturers regard it as a CL, thereby making fermentation a CCP.

It is important is that you monitor:

- pH of a fermenting UCFM
- Temperature and time of fermentation of UCFM

7.8 CCP: Maturing UCFM

Maturation reduces the water activity and, together with the pH fall in fermentation, inactivates the target bacteria, *Salmonella* and pathogenic *E. coli*. Maturation is covered in more detail in Part 6.13.

Fermented sausages are matured or ripened by holding in rooms with low relative humidity and low air movement. 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. For spreadable sausage such as Mettwurst the moisture loss over two to five days ripening may be only 10-15% and the CCP to control pathogens is a low pH. For dry salamis the weight loss over several weeks of ripening may reach 35%.

As with fermentation, some manufacturers consider maturing to be a CCP. The CL is weight loss within an acceptable range and is monitored by weighing a sample of units (sausages). See Appendix 2.9 for advice on how to weigh a representative sample of units.

It is important is that you monitor:

- Temperature and time of maturation/drying of UCFM
- Temperature and time of smoking of UCFM
- Weight loss or water activity

7.9 Verifying finished batches of UCFM

Some manufacturers adopt a 'test-and-hold' approach to releasing batches of UCFM by testing for *E. coli* as set out in Standard 1.6.1. The Standard is designed primarily for investigations by food authorities in the case of a regulatory activity (recall or food poisoning incident).

Some manufacturers use an *E. coli* test as part of a CCP for release of product to the market, with The *Australia New Zealand Food Standards Code* (Standard 1.6.1 – *Microbiological limits for foods*) as the CL.

It is important that you determine the *E. coli* count in:

- Raw meat ingredients used to make a UCFM
- Product after fermentation plus any subsequent process such as smoking and maturing

This testing will give you confidence when you validate your process using the *E. coli* Inactivation in Fermented Meats Model Predictor (see Part 8.4) or verify that a batch conforms with Standard 1.6.1.

Part 8: Validating your Processes

The Australian Standard (AS 4696: 2007) defines validation as obtaining evidence to demonstrate the effectiveness of a system of controls.

It should be emphasised that a number of unit operations, such as meat receival temperature, cooking, cooling, nitrite and sulphite upper limits are all regulatory requirements. Their values are set by regulation and have all been validated. What you need to do is ensure that your processes conform with the regulatory requirements.

Validation is usually only done once, but must be repeated when you change a process.

8.1 Validating temperature/time

Temperatures and times are the basis of:

- Cooking temperature:time regimes to achieve a Listeria cook
- Cooling temperature:time to meet AS 4696: 2007

The task of establishing temperature-based CCPs has become more straightforward with the development of thermocouple probes attached to data loggers and supported by software which can integrate temperatures:times with growth rates of important bacteria.

8.2 Validating sulphite use

For sausage meat you can validate that 500 ppm sulphite is present by:

- Making a batch size designed to use the whole pack of premix and which has been formulated to give a final product with not more than 500 ppm sulphite

or

- Working out how much metabisulphite is needed for a specific batch and weighing the correct amount of premix

or

- Having sulphite levels in finished products tested at a laboratory

Your calculation is the validation and your controlling authority will check it.

You need to verify that each batch of fresh sausage contains no more than 500 ppm sulphite by noting on the batch sheet that the correct addition has been made and keeping a register. Your controlling authority may require calculations for sulphite backed up by laboratory testing.

8.3 Validating nitrite use

Nitrite prevents spores of *C. botulinum* from germinating. At concentrations up to 500 mg/kg of a combination of nitrate and nitrite, which is the maximum limit for use in UCFM, nitrite does not cause an immediate toxic reaction in consumers, so weighing out and adding nitrite is a CCP for two hazards.

Most processes use a curing premix where the salt and nitrite have been pre-weighed. Salt lowers the water activity of the meat and slows down the growth of some pathogenic and spoilage bacteria. It is important to monitor that the premix has been added in the correct amount. Where chemicals are weighed individually there is scope for error if the person using the scales is distracted. Keep a nitrite register as a check that the correct amount has been used. You can also test nitrite levels in the laboratory.

8.4 Validating UCFM processes

The *Australia New Zealand Food Standards Code* Standard 4.2.3 – *Production and Processing Standard for Meat* requires you to verify your process in two ways:

1. Ensure that the number of *E. coli* organisms in your final UCFM comply with the microbiological limits in Standard 1.6.1 in the Code
2. Demonstrate that your production process handles the variations of *E. coli* contamination in the ingoing raw meat ingredients

The *E. coli* in fermented meats predictor developed by UTas (you can download it from http://www.foodsafetycentre.com.au/fermenter.php) is used by industry and regulators to provide an estimate of how much *E. coli* is inactivated under conditions which occur as UCFM matures.

To use the Predictor you need to know the following:

- Temperature of the batter
- Temperature of fermentation
- Duration of fermentation (hours)
- Temperature at each stage of maturing
- Length of each stage (hours)

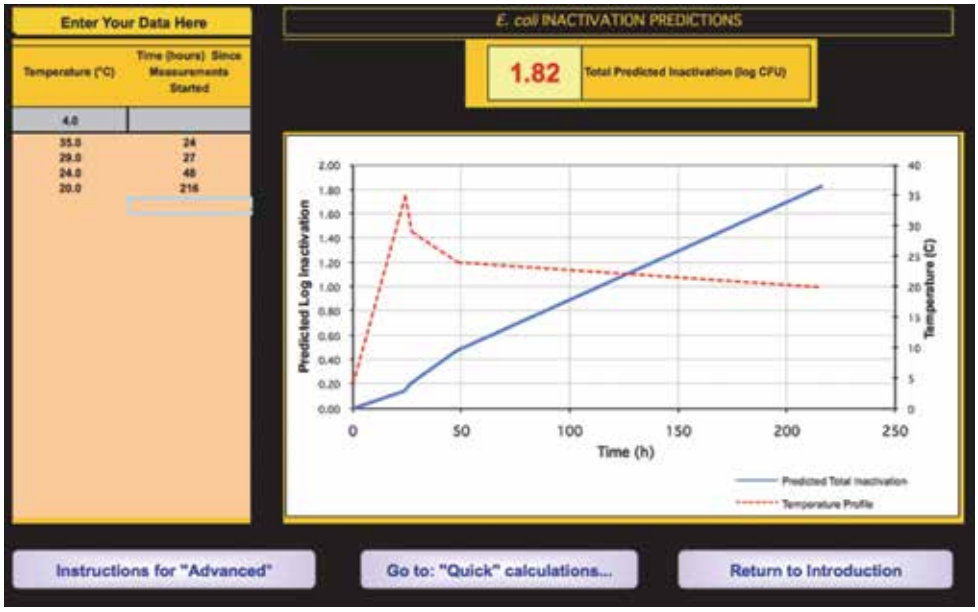
When you insert the temperatures and times at each stage of fermentation and maturation in the Predictor you'll see a value for *E. coli* inactivation.

In our example (Table 8.1) a typical process is presented.

Table 8.1 Typical process temperatures and times for manufacture of UCFM and predicted inactivation of *E. coli*

Process	Temp (ºC)	Time (h)	Cumulative time (h)	Cumulative *E.coli* kill (log)
Fermentation	35	24	24	0.14
Smoking	29	3	27	0.20
Fermentation	24	21	48	0.47
Maturation	20	168	216	1.82

Figure 8.1 Screen shot of the *E. coli* Inactivation in Fermented Meats Model, predicting the inactivation of *E. coli*



In Figure 8.1 the process can be expected to lead to a reduction of 1.82 log *E. coli*. That means if 1.82 log (which is 66 cfu/g) *E. coli* were present in every gram of batter, there would be less than one surviving in each gram of the final, matured product.

Your next task to comply with Standard 4.2.3 is to establish that your process can cope with the highest levels of *E. coli* you will ever encounter in the batter. How can you do this?

Large companies will know the microbiological profile of their incoming raw meat because they test frequently, over time and build up hundreds of *E. coli* counts for their raw meat ingredients. Their database will tell them if their process can cope with extreme counts.

In the event that *E. coli* counts > log 1.82 cfu/g occur, the company will need to amend their process. This can be done by increasing the temperature and/or time of the fermentation and/or maturation process. The Predictor is a useful tool to answer 'what if?' questions like *"What if we change to a starter that works well at a higher temperature – how much more E. coli inactivation will we get?"*

For smaller companies if you don't have data on *E. coli* in your meat raw materials you can't fulfil the requirements of Standard 4.2.3. However, your auditors may find it acceptable if you validate your process against ESAM data gathered for *E. coli* in carton meats (Table 8.2).

Table 8.2 Prevalence (%) and high-end counts (log) of *E. coli* in meats used for UCFM (ESAM data)

Species	Prevalence (%)	90th %	Maximum
Beef	6.5	1.92	2.6
Pork	3.0	1.76	2.4
Sheep/lamb	6.7	1	1

When we look into the data in this profile we see that:

For most of the time your ingoing meats will often have no *E. coli* because the prevalence is low

When *E. coli* is present, the high counts (90% and maximum counts) will be diluted by the meat which has no *E. coli*

You can see that if you have beef or pork in your product the high counts of *E. coli* sometimes exceed 2 log units – when that happens your process must be able to reduce to a level so that your product complies with Standard 1.6.1 (see Table 4.6.1).

8.5 Validating that cooked products will not support the growth of *L. monocytogenes*

The international food safety body, the Codex Alimentarius Commission, assembled a team of experts and reviewed the risk of contracting listeriosis. Codex made a distinction between foods that support the growth of *L. monocytogenes* and those that do not. Most smallgoods (especially products like hams and luncheon meats) will support the growth of *L. monocytogenes* but some, like salami and prosciutto, will not.

The Codex decisions give two options:

Option 1: If your product allows the growth of *L. monocytogenes* then the recall limit is 'not detected in a 25g sample'.

Option 2: If *L. monocytogenes* can't grow over the product's shelf life, the recall level is at 100/g – that's 2,500 times more leeway from the manufacturer's viewpoint and reflects the reduced risk from products that don't allow growth of *L. monocytogenes*.

In mid-2014, Australia's standards-setting body, FSANZ, adopted the Codex options and manufacturers can now decide whether to change formulations for RTE meats to prevent growth occurring if *L. monocytogenes* contaminates the final product during slicing and packing.

In the Australia New Zealand Food Standards Code (Standard 1.6.1- Microbiological Limits for Foods), FSANZ say that growth of *Listeria monocytogenes* will not occur in a ready-to-eat food if:

(a) The food has a pH less than 4.4 regardless of water activity; or

(b) The food has a water activity less than 0.92 regardless of pH; or

(c) The food has a pH less than 5.0 in combination with a water activity of less than 0.94; or

(d) The food has a refrigerated shelf life no greater than 5 days; or

(e) The food is frozen (including foods consumed frozen and those intended to be thawed immediately before consumption); or

(f) It can be validated that the level of *Listeria monocytogenes* will not increase by greater than 0.5 log cfu/g over the food's stated shelf life.

Food Standards Australia New Zealand has issued a document 'Guidance on the application of microbiological criteria for *Listeria monocytogenes* in RTE food' which should be consulted for further information.

http://www.foodstandards.gov.au/code/proposals/Documents/P1017-MicroAppR-SD1.pdf

You will need to prove to your regulator that your product is 'bullet proof' to the growth of *L. monocytogenes*. You can do this by collecting data (initially pH and water activity, but see the list below) from each batch and inserting them into a predictive microbiology tool. Called the *L. monocytogenes* Growth Model, this tool was developed by scientists in Denmark and Australia, and is an alternative to challenge testing. It's a piece of software into which you enter a number of key parameters about your product and it predicts for how long it can stop the growth of *L. monocytogenes*. You should also check with your local regulator for other validation requirement such as testing for *L. monocytogenes*.

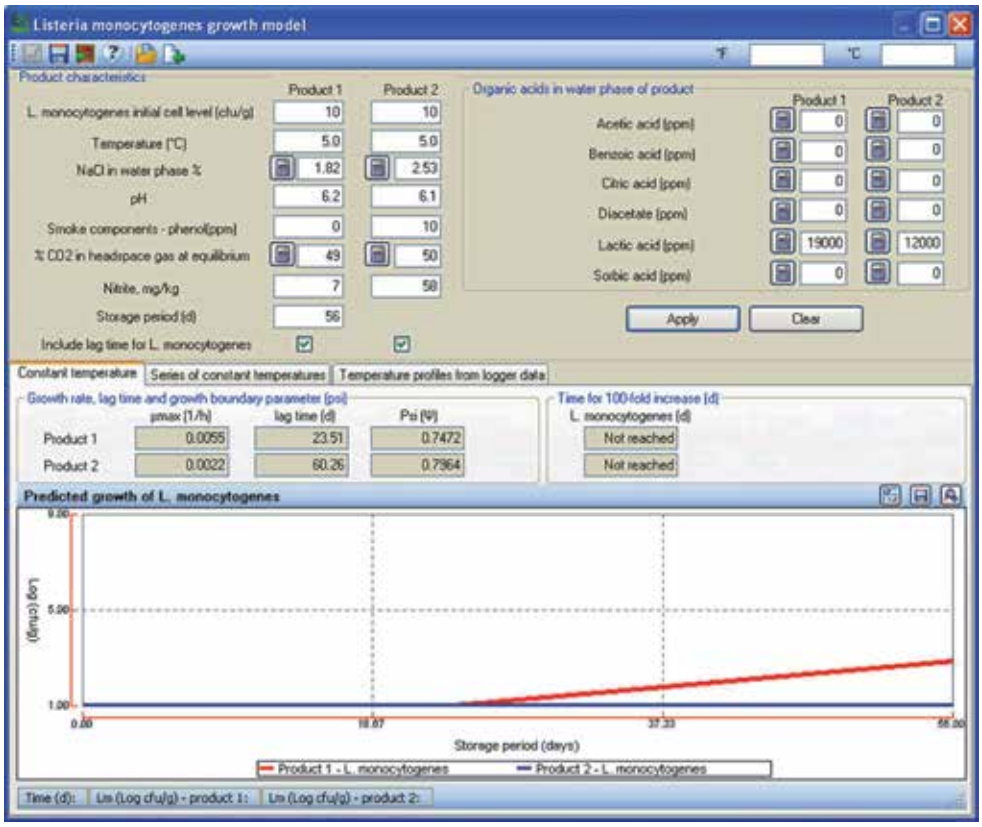
This model (Mejlholm & Dalgaard, 2009) is part of the Food Spoilage and Safety Predictor (FSSP) software package and has been peer reviewed and validated by international experts (Mejlholm *et al*., 2010). MLA has road tested the FSSP in Australian smallgoods and verified that it is an effective *L. monocytogenes* management tool.

In Appendix 6 we provide detail on how you can use the tool and the screen shot below shows you what you need to know 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
8. Phenol content (if you use smoke)

In Figure 8.2 you'll see some actual data entered into the tool from two batches of sliced ham packed in modified atmosphere (MAP). You'll see batch differences in salt, lactate, pH and especially nitrite. These have a big effect on *L. monocytogenes*, and the tool tells you that growth starts after 24 days in Product 1 (a risky batch) while no growth occurs in Product 2 over the whole shelf life.

Figure 8.2 Screen shot of *L. monocytogenes* Growth Model



Appendix 1: Pathogenic bacteria

A1.1 Target bacteria and how to control them

Bacteria are important in smallgoods manufacture for both the right and the wrong reasons.

'Good' bacteria are starter cultures used in fermented smallgoods or added as probiotics to improve the healthiness of some foods. To be most effective, such bacteria are added in large numbers (more than one million per gram) and grow to even larger numbers, around 100 million per gram of product. As they grow, starter bacteria convert sugar to lactic acid in fermented foods. They cause the drop in pH which occurs during the first 24–72 hours. In doing so, they also restrict or inhibit growth of 'bad' bacteria. First, the huge numbers make it difficult for competing bacteria to grow. Second, they release various chemicals including some called bacteriocins, which limit the growth of some of the bad bacteria.

'Bad' bacteria are those which cause illness among consumers of smallgoods. They do this in two ways. Some bacteria produce chemicals called toxins that are poisonous to humans, and which they release into the food as they grow. The toxin causes food poisoning, particularly vomiting, usually between two to six hours after eating the product. For example, the *S. aureus* toxin is heat resistant and cannot be destroyed by cooking and can induce vomiting within three to six hours of eating a contaminated food. Other bacteria cause illness by growing within the gut. It usually takes between 24 and 48 hours for these bacteria to grow to numbers high enough to cause illness.

Disease-causing bacteria are called pathogenic bacteria or pathogens. The pathogens which can cause problems in smallgoods are:

- *Salmonella*
- Pathogenic *Escherichia coli*
- *Staphylococcus aureus*
- *Listeria monocytogenes*
- *Clostridium botulinum*
- *Clostridium perfringens*

Some bacteria can exist in two forms – vegetative cells and spores. Vegetative cells are active and grow. Spores are not active but are much more resistant to damage from heat or chemicals, including those used to kill vegetative cells in foods or on food contact surfaces. Spores are produced to protect the cell from harsh conditions and for dispersal. When conditions become more favourable, or when the spores find themselves in a better environment they break out ('germinate') and become active and start to grow again. Not all bacteria can form spores but *Clostridium botulinum* and *Clostridium perfringens* do.

> When we talk about bacteria 'growing' we mean that they are increasing in numbers, not in size. Bacteria are simple living things made up of one cell only. They reproduce by producing a second set of everything they need and then dividing into two complete, new cells. For them to have a noticeable effect on us, or other environments, they usually have to be present in very high concentrations e.g. 1 to 10 million cells per gram in food, or mL, or square centimeter on a surface.

All of the bacteria listed above can be found on raw meat from time to time, though infrequently and usually in very low numbers. This has been demonstrated by baseline studies of Australian meat such as those shown in Table A1.1.

Table A1.1 Prevalence of target pathogens in raw meats used for smallgoods manufacture

	Pigs	Beef		Sheep	
	Carcases	Carcases	Boneless	Carcases	Boneless
Salmonella	1.0%	0.2%	0.1%	0.1%	1.3%
E. coli **O157:H7**	ND*	0.1%	ND*	0.7%	1.3%-
S. aureus	14.9%	24.3%	17.5%	24.15	38.6%
L. monocytogenes	ND*	21%	-	-	-

* ND means that these bacteria were not detected ('found') in these particular surveys. In fact, they are found only very rarely on raw meat (and other foods).

Pathogens are present in some of the raw materials you receive. In this section we will build up a fact file on the likes and dislikes of each of these important pathogens. We will also identify how you can control each type in different smallgoods, including cured, cooked, dried and fermented products.

The problem

Bacteria are microscopic – if you lined them up in a queue you'd get about one million of them in a metre. This allows them to get into small crevices on working surfaces and on meat (Figure A1.1).

Figure A1.1 Electronmicrographs of *Salmonella* on a working surface (left) and a typical mixed population on meat (right) .

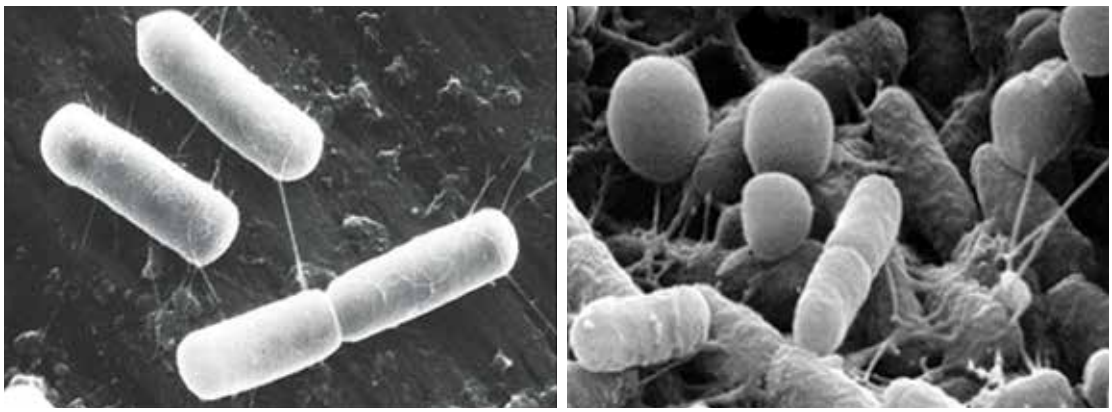
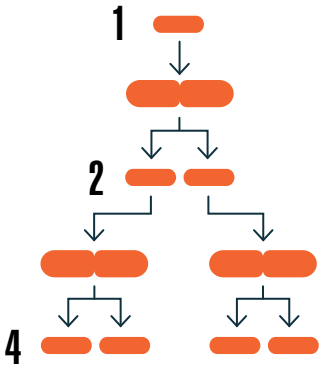
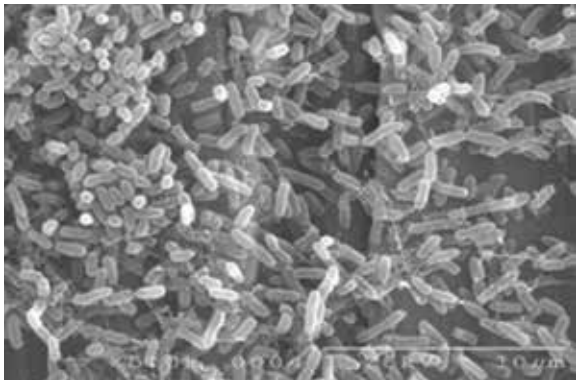


Figure A1.2 Simple division is a streamlined way of doubling the population. If conditions are good one bacterium will grow to more than one million in about seven hours



This doubles the population and, given good conditions, one bacterium will multiply to 1,000,000 in less than seven hours. As you can see in Fig A1.3, they completely overgrow the surface of the meat, generating off odours and making the meat slimy.

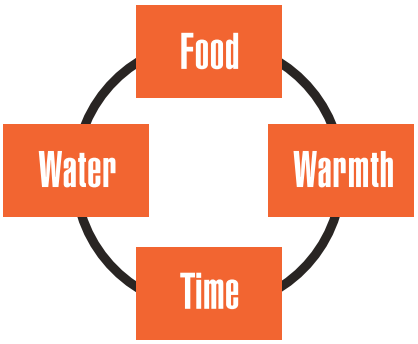
Figure A1.3 The result of bacterial growth – the meat surface is overgrown and the population will be more than 10 million/cm^2 of the meat's surface



What do bacteria need?

If bacteria have the four factors they need (food, water, warmth and time) they'll grow quickly to large populations (Figure A1.4).

Figure A1.4 The four components needed by bacteria in order to grow



Meat contains protein, vitamins and other growth factors and is more than 70% moisture, so it's an excellent food for bacteria. Temperature is a major control factor. In the meat industry, two main categories of bacteria are important, depending on the temperatures at which they can grow (Table A1.2).

Table A1.2 Growth ranges and optimum growth temperatures for bacteria which grow on meat

	Gowth rate	Fastest gowth	Target bacteria
Psychrotophs	–5 to 20ºC	12 to 15ºC	*Listeria*
Mesophiles	7 to 45ºC	25 to 3ºC	*Salmonella, E. coli, Staphylococcus, Clostridium*

Depending on the temperature of the meat, the time required to double the population varies. For example, if the temperature is around 30°C, *Salmonella* will double in about 20 minutes; at 10°C it will take eight hours to double and at 7°C it won't grow.

Controlling bacteria in your operation

The basis of most controls is simple - just take away whatever bacteria need in order to grow. You're in the meat business, so you can't deny them their food. However, the other factors are within your control and are used widely in your everyday operations.

Temperature

In your business you probably use four temperature zones to control target bacteria:

Freezing stops all growth because most of the water is removed as ice crystals

Chilling cooler than 7°C stops target bacteria which are mesophiles, but not Listeria which can grow steadily at chill temperatures

Cooking at 65°C for 10 minutes kills all target vegetative bacteria, but not spores of Clostridium

Cooling cooked meats rapidly through the Danger Zone (35-45°C) prevents spores from germinating and the resulting bacteria increasing in population

Water

Curing involves adding salt or sugar to make a brine. In brine, the water is 'tied-up' by the salt and is not available to the bacteria. There is a technical term called water activity (a_w) which describes how much water is tied up. Pure water has an $a_w = 1.0$ while cured meats like ham and bacon have an $a_w < 0.975$.

This is important because $a_w = 0.95$ is the cut-off point for growth of target bacteria such as *Salmonella* and *E. coli*.

Ingredients

Other controls which you use involve addition of chemicals which prevent bacterial growth. Adding sulphite to sausage meat slows down the growth of spoilage bacteria and gives you and your customers sufficient shelf life

Nitrite in ham and bacon prevents Clostridium spores from germinating.

If you use liquid smoke or smoke generated from wood you're also using chemicals which help to stop target bacteria from growing.

Vacuum packing

When you remove air from a pack by drawing a vacuum you're taking away the oxygen which spoilage bacteria need in order to grow. So vacuum packing improves shelf life, but it has no effect on *L. monocytogenes* , which can grow in vacuum packs at chill temperatures.

Time

Ageing carcases and vacuum packed primals in the chiller can improve their eating quality but *L. monocytogenes* grows steadily in the chiller. In fact, your chiller may be a permanent source of Listeria – growing in the door handle, door seals, refrigeration drip tray and other locations.

A1.2 *Salmonella*

The *Salmonella* bacterium is named after Dr Daniel Salmon who was in charge of a research program that first discovered them around 1880. We now know that there are several thousand types of *Salmonella*, most of which 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 *S.* typhi. *Salmonella* is normally found in the gut of animals and birds and is therefore sometimes found on meat.

Impact

Salmonella in smallgoods have caused several outbreaks of illness in Australia. Some examples are given in the Table A1.3.

Table A1.3 Selected outbreaks of food poisoning from smallgoods

Year	State	Product	Number of cases
1981	Victoria	Salami	>300
1993	South Australia	Salami	>100
1997	Victoria	Cooked meats	>900 (3 dead)

As well as these illnesses, there have been numerous recalls of product because of *Salmonella* contamination.

Infectious dose

How much *Salmonella* is needed to cause illness? Early studies indicated at least 100,000 were needed to cause gastroenteritis (i.e. infection in the gut causing abdominal pain and often diarrhoea) in healthy adults. More recently, as few as 100 organisms caused illness 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 in the stomach.

Growth of *Salmonella*

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 A1.4.

Table A1.4 Conditions under which *Salmonella* grows

Conditions	Minimum	Optimum	Maximum
Temperature (ºC)	7	35 - 43	46
pH	3.8	7 - 7.5	9.5
a_w	0.94	0.99	>0.99

Killing *Salmonella*

Under conditions which stop them growing, bacteria start to die. For example, the combination of low pH and water activity that develops during the fermentation and maturation of salamis eventually prevents growth which means that any *Salmonella* in the batter gradually die.

Salmonella cells are also affected by heat and, at 65°C, they die very quickly. For example, 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 one minute, less than one *Salmonella*/gram would remain alive. This shows the effectiveness of the cooking process as a CCP. However, *Salmonella* are good survivors and can survive for a long time on dry surfaces, or in low moisture foods.

Relevance for smallgoods manufacture

Salmonella is a target organism for all smallgoods processes because it can be a contaminant on raw meat. The UCFM process has the most problems in making sure the pathogens are killed. There are several stages in the UCFM process which are critical. These include adding salt to minimise *Salmonella* growth, and adding sugar and starter cultures to ensure that fermentation proceeds quickly so that the pH and water activity decline and prevent growth.

Risk rating for HACCP plans

Salmonella is only found rarely on Australian meat, as can be seen from recent baseline surveys of chilled carcases, frozen boneless beef and retail meats (Table A1.5).

Table A1.5 Prevalence of *Salmonella* on red meats

Product	Positive samples/total samples (% positive)
Beef carcases	0/1155
Boneles beef	1/1082 (0.1%)
Lamb carcases	0/1117
Boneless sheepmeat	3/557 (0.5%)
Ground beef	4/360 (1.1%)
Diced lamb	2/360 (0.6%)

The risk rating varies between red meat and poultry because of the high prevalence in the latter (Table A1.6).

Table A1.6 Qualitative risk rating for *Salmonella* on meat and poultry

Product	Severity	Likelihood	Risk rating
Raw meat	Moderate	Low	Low
Raw poultry	Moderate	High	Moderate

A1.3 Pathogenic *Escherichia coli*

Escherichia coli is named after Dr Theodor Escherich who first discovered it in 1885. *E. coli* grows in the gut of all warm blooded animals and large numbers are excreted in the faeces. Most forms of *E. coli* are harmless and, in fact, even contribute to our health. These harmless *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.

Importantly, though, there are also pathogenic types of *E. coli* and they have caused severe food poisoning outbreaks, including causing deaths. Animal meat used in smallgoods manufacture can carry pathogenic types of *E. coli*. This meat can come from cattle, pigs, sheep and other mammals.

Impact

There are three types of illnesses caused by pathogenic *E. coli* where the bacterium:

- Invades the gut and causes bloody diarrhea (this is Hemorrhagic Colitis or HC)
- Makes toxins which cause kidney failure (this is called Haemolytic Uraemic Syndrome or HUS)
- Causes blood clots which may lead to brain damage (this is called Thromobocytic Thromobocytopaenic Purpura or TTP).

Pathogenic *E. coli* in Mettwurst caused a major incident in South Australia in 1995 when around 150 people became ill. For 22 children the illness was very severe and one child died. Some of those who survived have life-long complications from the infection, including permanent kidney damage requiring ongoing treatment or a kidney transplant.

Infectious dose

The infectious dose of pathogenic *E. coli* for healthy adults is probably thousands to tens of thousands of cells. The symptoms are gastroenteritis which clears up in a few days. However, for those who are at risk, like the very young and very old, the infectious dose is lower and less than 100 cells can lead to severe illness. The bacterium invades the colon and causes ulcers which may require surgery. This ulceration is called Haemorrhagic Colitis (HC). The bacterium may also make toxins which cause kidney failure. This is called Haemolytic Uraemic Syndrome, or HUS. Those pathogenic *E. coli* which cause serious illness are called Enterohaemorrhagic *E. coli* (EHEC). EHECs are now the main target organism for ensuring safe processes for fermented smallgoods.

Growth of EHEC

EHEC grow under similar conditions as *Salmonella*.

Killing *E. coli*

Like *Salmonella*, once conditions exist 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* is vulnerable to heat and, at 65°C, they die very quickly. In emulsified sausages a centre temperature of 65°C for 10 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. Among smallgoods, EHEC survival in fermented meats is the greatest risk.

Relevance for smallgoods manufacture

Because it is a contaminant on raw meat, EHEC is a target organism for all smallgoods processes. The UCFM process has the most problems in making sure the pathogen is made inactive.

Like *Salmonella*, there are several critical stages in the UCFM process. These are adding salt to minimise *E. coli* growth before fermentation, and inactivation, which occurs during maturation. Under certain conditions *E. coli* can survive for long times in dry environments.

Unlike *Salmonella* EHEC have resistance to acidity, so ensuring a successful fermentation and maintaining an adequate maturation period for salami is vital for making sure that the bacterium, if present, is destroyed. As well, 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. Their acid tolerance and the seriousness of EHEC infections is why UCFM manufacturers are closely scrutinised and checked by their controlling authority.

Risk rating for HACCP plans

The pathogenic types of *E. coli* can cause severe food poisoning. Fortunately, it is found only rarely on Australia meat, as can be seen from recent baseline surveys of chilled carcases, frozen boneless beef and retail meats (Table A1.7), leading to a moderate risk rating (Table A1.8).

Table A1.7 Prevalence of pathogenic *E. coli* on red meats

Product	Positive samples/total samples (% positive)
Beef carcases	1/1155 (0.1%)
Boneles beef	0/1082
Lamb carcases	6/1117 (0.6%)
Boneless sheepmeat	1/557 (0.2%)
Ground beef	1/357 (0.3%)

Table A1.8 Risk rating for pathogenic *E. coli* on meat and poultry

Product	Severity	Likelihood	Risk rating
Raw meat	High	Low	Moderate
Raw poultry	High	Low	Low

A1.4 *Listeria monocytogenes*

L. monocytogenes has been known for over 70 years as a pathogen of small animals. It was named after Lord Lister who pioneered antiseptic surgery – methods for preventing wounds becoming infected during surgical operations. During the 1980s *L. monocytogenes* became known as a food-borne 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*.

Impact

L. monocytogenes has caused a number of serious outbreaks of food poisoning from smallgoods in several countries around the world, some of which are illustrated in Table A1.9.

Table A1.9 Global outbreaks of food poisoning caused by *L. monocytogenes* in smallgoods

Year	Place	Product	Number of cases
1987-89	UK	Pâté	>350 (>90 deaths)
1990	Perth, WA	Pâté	11 (6 deaths)
1992	France	Pork tongues in aspic	279 (63 dead)
1998-99	USA	Hot dogs, deli meats	101 (15 deaths)
2000	NZ	Corned beef	2
2000-01	USA	Frankfurters	>29 (>4 deaths)
2003	Adelaide, SA	Corned beef	>5 (3 deaths)
2009	NSW/Qld	Chicken wraps	>36 (3 foetal deaths)

Infectious dose

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 cases the illness progresses sometimes with flu-like symptoms to meningitis (infection in the brain) or septicaemia (blood poisoning). In 20-30% of cases the patient will die. These consumers are the elderly, the pregnant and their foetus or new-born baby, 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. As shown in Table A.1.10 the risk is much higher for these individuals.

Table A1.10 Risk rating for HACCP plans

Product	Severity	Likelihood	Risk rating 'normal' customers	Risk rating 'vulnerable' customers
Cooked meat	High	Low	Low	High

Regulators have set a 'zero-tolerance' for *L. monocytogenes* in ready-to-eat foods because of the potential for it to grow in some foods to levels high enough to cause infection in susceptible consumers. Unfortunately zero tolerance is very difficult to achieve in practice because *L. monocytogenes* is a robust organism which lives in food factories and also grows steadily in many long shelf life refrigerated foods.

International regulations (such as in the EU or those issued by Codex Alimentarius) now recognise that it is very difficult to completely eliminate *L. monocytogenes* from foods and, for foods that do not permit the growth of *L. monocytogenes* (e.g. fermented meats), a level of up to 100 cells per gram is permitted.

Growth of *L. monocytogenes*

L. monocytogenes grows over a wide range of environmental conditions commonly found in meat and smallgoods products and processing plants and operations (Table A1.11).

Table A1.11 Conditions under which *L. monocytogenes* grows

Conditions	Minimum	Optimum	Maximum
Temperature (ºC)	0	37	45
pH	4.39	7	9.5
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 under refrigeration. 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 huge 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.

Killing *L. monocytogenes*

L. monocytogenes is not unusually heat resistant. Temperatures of 65°C for 10 minutes or 75°C for 30 seconds will reduce population levels in food by a million-fold in every gram of product.

Relevance for smallgoods manufacture

In the list of outbreaks above, all the products went through a heat process which was enough to eliminate even huge populations of *L. monocytogenes* in the product (>100,000/g).

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.

You can read more about controlling *L. monocytogenes* in ready-to-eat smallgoods in Part 6.18 and Appendix 6 and 7 of these guidelines

A1.5 *Staphylococcus aureus*

Under the microscope *Staphylococcus* looks like clusters of grapes and that's where the name comes fro, in Latin. The most common type *S. aureus*, has a yellow colour which may be seen in boils and pimples caused by the bacterium and in which it grows to high numbers. That's why its common name is 'golden staph'.

Impact

Historically, *Staphylococcus aureus* has caused many outbreaks of food poisoning from salamis because of its unusual tolerance of salty conditions. More recently, however, the organism has been better controlled in cured, cooked meat, because of improved refrigeration and the use of gloves to handle cooked foods. In UCFM manufacture *S. aureus* is controlled through use of starter cultures which outcompete it.

Infectious dose

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 toxic food and cause severe vomiting that can last for hours. High numbers of *S. aureus* are needed before food becomes toxic, at least 1,000,000 per gram.

Growth of *S. aureus*

The bacterium grows at similar temperatures to *Salmonella* and so is controlled by refrigeration. Unlike *Salmonella*, however, it tolerates high levels of salt and can grow in concentrations as high as 20%. It grows relatively slowly and so usually becomes overgrown by other, faster growing bacteria so that foods often spoil before *S. aureus* 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.

Killing *S. aureus*

Staphylococcus 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*. 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 cells, any toxin they have already produced will remain.

Relevance for smallgoods manufacture

Staphylococcus 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 places such as under the arms and in the perineum. Food handlers can transfer the bacterium when they handle food which is why regulations do not allow bare hands to contact foods that are ready-to-eat.

S. aureus may also be present on raw meat. They often come from the hands of operators, but also from diseased animals. Mastitic cows may have large numbers of *S. aureus* in the udder and in abscesses. 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, it will not grow to levels where the toxin has an effect on consumers. Additionally, this accentuates the 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 (Table A1.12).

Table A1.12 Risk rating for HACCP plans

Product	Severity	Likelihood	Risk rating
Cooked meat	Mild	Low	Low
UCFM	Mild	Low	Low

A1.6 *Clostridium perfringens*

This organism has been known for many years as the cause of gas gangrene in wounds, particularly in war wounds. About 60 years ago the organism became recognised as a cause of food poisoning. It produces spores and therefore can survive cooking. It is also the fastest growing organism, with a doubling time of around eight minutes in the range 40–45°C. It was originally called 'canteen disease' because of its association with large outbreaks among workers who ate in the work's canteen from bulk food that had been kept warm, but not warm enough, for many hours.

Impact

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.

Infectious dose

High numbers (more than one million/g) are usually needed to produce enough toxin to cause symptoms of food poisoning.

Growth of *C. perfringens*

Clostridium perfringens grows very rapidly at temperatures between 35-45°C but not under acid conditions, or at low water activity. It is anaerobic and will only grow in foods where there is no oxygen (Table A1.13).

Table A1.13 Conditions under which *C. perfringens* grow

Conditions	Minimum	Optimum	Maximum
Temperature (ºC)	12	43-47	50
pH	5.5	7.2	8.0-9.0
a_w	0.93	0.95-0.96	0.97

Killing *C. perfringens*

Clostridium 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. 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 in cured meats(Table A1.14).

Table A1.14 Risk rating for HACCP plans

Product	Severity	Likelihood	Risk rating
Cooked meat	Low	Low	Low

Relevance for smallgoods manufacture

Clostridium 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 (AS 4696: 2007) are intended to control *C. perfringens* in a two-stage cooling regime. However, cooling of large cuts which have been injected, such as roasts and leg hams, take longer to cool and may not be able to conform with the Standard in these products, and an alternative arrangement may need to be developed for approval by the regulator.

A1.7 *Clostridium botulinum*

This organism 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 food-borne organism because it was almost inevitably fatal, and many food safety regulations, particularly in thermal processing, are aimed specifically at *C. botulinum*. It is also among the biological weapons stockpiled by some nations for germ warfare. Ironically, it is the same toxin that is used in cosmetic treatments ('Botox').

Impact

Symptoms begin with those typical of food poisoning but soon intensify and get worse. The respiratory muscles fail and breathing stops. 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 placed in an iron lung. The effects of the paralysis can last for many months, requiring ongoing respiratory support.

Infectious dose

The toxin is very potent 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 are required to produce enough toxin to cause botulism.

Growth of *C. botulinum*

Some types 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 before *C. botulinum* levels are high enough to lead to significant toxin production.

Killing *C. botulinum*

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 for smallgoods manufacture

The relevance is similar to that for *C. perfringens* with the proviso that, while growth of *C. perfringens* will cause mild diarrhoea, growth of *C. botulinum* will cause serious illness and maybe death. The toxin is destroyed by heating and is a problem only in those products which are eaten without further cooking. The effect of salt, nitrite and rapid cooling through the growth range leads to a low risk of illness (Table A1.15).

Table A1.15 Risk rating for HACCP plans

Product	Severity	Likelihood	Risk rating
Raw meat	High	Low	Low

Appendix 2: Background on safe manufacture of UCFM

There have been several instances where UCFM has been the cause of food poisoning outbreaks in Australia. Some of these instances are summarised in Table A2.1 where it can be seen that pathogenic *E. coli* and *Salmonella* were responsible.

Table A2.1 Outbreaks of illness in Australia caused by UCFM

Year	Product	Hazard	Number of cases
1981	Uncooked fermented meat	*S.* Newport	311
1991	Uncooked fermented meat	*S.* Anatum	>120
1992	Uncooked fermented meat	*S.* Typhimurium	>20
1992	Uncooked fermented meat	*S.* Typhimurium	30
1995	Uncooked fermented meat	*E. coli* O111	>150 (1dead)
2000	Sücük (fermented sausage)	*S.* Typhimurium	6
2002	Uncooked fermented meat	*E. coli* O157	1

In 1981 more than 300 people contracted salmonellosis after eating salami manufactured in Melbourne. The cause was thought to be incomplete fermentation and maturing. The German smallgoods expert Dr Lothar Leistner visited Australia and advised on ways of ensuring sufficient acid production during the early stages of manufacture to control *Salmonella*. He recommended a pH of 5.2 or lower by the end of the first 48 hours of fermentation.

At the time the industry believed this could be achieved by using any or all of:

- Starter cultures
- Gluconodeltalactone (GDL)
- Active cultures from previous batches (backslopping).

These methods were common in the industry over the period 1982-1995. During this time there were sporadic outbreaks of *Salmonella* food poisoning and product recalls for the presence of pathogenic bacteria in salamis.

In early 1995, Mettwurst contaminated with pathogenic *E. coli* caused an outbreak of food poisoning in South Australia. There was speculation that the fermentation had been inadequate. At exactly the same time, news of a similar problem emerged from USA where pathogenic *E. coli* had survived fermentation of salami, leading to a large recall in western USA.

This finding rang alarm bells for UCFM manufacturers and some changed processes to include a cooking step. For those who did not wish to cook salami, UCFM manufacture had become a more difficult task because of the emergence of pathogenic *E. coli*.

Following the 1995 outbreak, regulatory authorities moved swiftly to require manufacturers to validate that their process was capable of inactivating the target bacteria, pathogenic *E. coli* and *Salmonella*. Initially, manufacturers were required to demonstrate that each of their processes could reduce generic *E. coli* in the batter by 1000-fold – it was called 'the 3-log kill'.

Later, Standard 4.2.3 (*Production and Processing Standard for Meat*) amended the 3-log reduction requirement so that before UCFM can be manufactured, the process must be validated in two ways:

- Ensure that the number of *E. coli* organisms in final UCFM comply with the microbiological limits in Standard 1.6.1 in this Code
- Demonstrate that the production process handles the variations of *E. coli* contamination in the ingoing raw meat ingredients

There are a range of CCPs, GMPs and SSOPs needed to manufacture UCFM safely. In this section background information is provided on these, plus information on starter cultures and how to ensure they're able to do their job properly.

A2.1 Raw meat purchase

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

A2.2 Tempering

Tempering is important because the bowl chopping stage of UCFM manufacture requires meat and fat close to 0°C to prevent fat from softening and 'smearing' in the sausage. Thus, tempering of frozen meat in the chiller is a GMP which prevents growth of pathogenic bacteria and leads to correct product texture.

A2.3 Starters and sugar

The role of the starter culture is to make lactic acid in the sausage to reduce its pH to 5.2 or lower within 48 hours from the start of fermentation. The exception is high pH Italian style sausages.

Sugar in the ingredient mix is converted by the starter culture to lactic acid but starter cultures do not really begin to make lactic acid until the sausage warms up to 15°C. At filling, batter temperature is only just above zero. This means that in a wide diameter sausage, it may take 12 hours for the starter cultures to begin to work.

The problem is, any pathogenic *Staphylococcus aureus*, *Salmonella* and pathogenic *E. coli* in the batter will start to grow when the sausage becomes warmer than 7°C. In theory, there's time before fermentation when potentially dangerous bacteria can grow which is why timely acidification is important.

A2.4 Salt

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 the batter 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%.

A2.5 Ascorbate

Sodium ascorbate/ascorbic acid and sodium erythorbate/erythorbic acid (as per Standards 1.2.4 and 1.3.3) are added to improve colour and to act as an antioxidant. Antioxidants remove oxygen from the 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.

A2.6 Spices

Spices are essential for flavour and they also contain manganese which is essential for starter growth. However, spices sometimes have bacterial counts in the millions/g and may contain pathogens such as *Salmonella*. This potential problem can be avoided by using irradiated or other sterilised spices.

A2.7 Gluconodeltalactone (GDL)

GDL is sometimes added to the batter because it generates gluconic acid which quickly lowers the pH of the batter and so controls pathogenic bacteria. However, it will also retard the growth of starter cultures if added at too high a concentration (>1%). Because it's mandatory to use starters, there's no real advantage to adding GDL.

A2.8 Vacuum filling

Pulling a vacuum on the filler means that the newly-filled sausage has a low oxygen level. Even without a vacuum filler, the oxygen in the batter in the casing is quickly consumed. Oxygen is mopped up by antioxidants and natural enzymes in the meat, making the environment unfavourable for spoilage bacteria and preserving the sugar for use by starter cultures.

A2.9 Monitoring weight loss

Checking weight loss is important to assure 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 range of water activity. To monitor weight loss you should use the following principles:

- Make sure your scales are accurate and appropriate – it is no use putting a 150 g unit on a scale which weighs up to 50 kg – the accuracy will not be enough to support your validation.
- Weigh a representative sample – ten units should be sufficient.
- Tie a label on each unit and write the starting weight and the date on it.
- Each time you check-weigh the unit, write the new weight and the date on the label.
- Don't just average the ten weights because that only allows you to say 'on average my product has the correct weight loss'.
- Keep each individual weighing – this will tell you how variable your process is. If it is so variable that some units are too moist to be released you will need to find out why there is uneven drying.

Record and retain the results as part of your verification.

A2.10 Measuring pH correctly

Measuring pH of salamis is not easy because of the high fat content, but pH confirms that fermentation has been normal so the pH meter needs to be used properly. Spear probes have been developed for use on salamis. Ensure the probe is kept clean and calibrated. *Australia New Zealand Food Standards Code* Standard 4.2.3 – *Production and Processing Standard for Meat* contains a section on how to measure pH.

A2.11 When to release your product onto the market

In your process you specify the length of the maturing period and the temperature(s) you use. You must not vary this process. Some problems have occurred when companies have shortened ripening time and released moist product onto the market.

A2.12 Improving your process to inactivate *E. coli*

There are ways to improve the process so that *E. coli* is inactivated, such as:

- Treating the outside of the meat with organic acid such as lactic acid
- Fermenting at a high (35°C) temperature
- Maturing warmer than 30°C e.g. holding at 35°C for three days will give a satisfactory kill when combined with other process parameters
- Extending the maturing time and use a more modest increase in maturing temperature
- Having a brief heating step e.g. bringing the product to 50°C for two minutes

Don't forget – any change to your process means you need to re-validate it

A2.13 Starter cultures

Starter cultures are used commercially to ferment a range of foods. Several industries use commercial starters e.g. cheese and yoghurt manufacture. In the smallgoods industry it is now possible to use starters for a range of products, not just for fermented sausages.

To combat pathogenic bacteria, especially pathogenic *E. coli*, regulations were changed so that backslopping is no longer allowed and use of starter cultures is a 'must'. A range of starter cultures is available, with claims that they will:

- Improve flavour
- Improve the red colour of the salami
- Improve sliceability
- Accelerate fermentation time
- Shorten maturation time
- Give exceptional control over unwanted bacteria

In this section we look at starters in detail, especially what you need them to achieve.

Fermentation requires a starter to make 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 that some fermentations are short (24-36 hours).

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). But you will probably have more sugar than this in your batter. The sugar that the starters do not change to lactic acid will offset the acid flavours.

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

- Choice of starter
- Temperature of fermentation
- Salt content of batter
- Number of starter bacteria

There are four groups of starter cultures used for fermented meats – *Lactobacillus*, *Pediococcus*, *Staphylococcus* and *Micrococcus* (now called *Kocuria*).

- *Lactobacillus* generally produces lactic acid quickly and cleanly
- *Pediococcus* is an acid-producer which also makes flavour and aroma compounds
- *Staphylococcus* and *Micrococcus* produce lactic acid less rapidly than the other starters but convert nitrate to nitrite and also influence flavour and aroma

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 preferred temperature. For most starters this is 30–35°C. If you run your fermentation below 20°C, the starter will make lactic acid only very slowly. Always follow the manufacturers' instructions on the use of starter cultures to ensure optimum conditions for the culture.

Acid production

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.

When you buy a starter culture it should supply a massive population to swamp competing bacteria in the batter such as spoilage bacteria and pathogens. A sachet of culture usually contains about 1,000,000,000,000 bacteria so, in a 100 kg batch, there are at least 10,000,000/g of batter. Once they begin growing, their numbers will increase over the first 48 hours, completely overgrowing other bacteria and pumping lactic acid into the batter. As well as lactic acid, starter cultures also make chemicals called bacteriocins, which reduce the growth of pathogens and spoilers.

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 *Clostridium 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.

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.

GMPs for starters

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

Quality assurance of suppliers

You need starters which have been well treated by your supplier. When they are manufactured, the cultures are grown until they are working in peak condition. They are then freeze-dried, a process which puts their growth on hold with a minimum of damage. If stored well, they will be ready to grow quickly when you put them into a batter with a sugar source.

Quality assurance in your plant

Look after your cultures by keeping them in a freezer until you're ready to use them. That way they will still perform well right up to their use-by date.

Adding starter to the batter

It is not always easy to spread a small amount of starter evenly through a large amount of product. If you dissolve the freeze-dried starter in distilled water for 30 minutes before adding, you not only have a vibrant culture but it is easier to distribute it through the batter. Your supplier will be able to give you more details on the best way of doing this.

There is anecdotal evidence that some manufacturers use brandy or port to provide flavour, and that they dissolve the starter in the alcohol. This is bad practice – starter bacteria are killed by alcohol and you may not get the needed pH fall.

Appendix 3: Background information on unusual sausages

Many sausages in this category are intermediate moisture foods, which may be shelf stable, depending on their pH or a_w.

A3.1 Intermediate moisture foods

For a food to have a useful shelf life without relying on refrigerated storage, it is necessary to control either its acidity level (pH) or the level of water activity (a_w) or a suitable combination of the two. This can effectively increase the product's stability and make it possible to predict its shelf life under known ambient storage conditions.

The microbiological stability of traditional dried Chinese sausage is due mainly to the rapid reduction in water activity (a_w). The a_w is sometimes defined as 'free', 'unbound', or 'available water' in a food, and is the water which can be utilised by microorganisms to support their growth. The a_w of a food can be reduced by eliminating moisture (i.e. drying) or by the addition of chemicals which bind with the water, making it unavailable to microorganisms. Research has shown that the growth and survival of microorganisms is more directly related to a_w than to the moisture of the food (Table A3.1).

Table A3.1 Control of microorganisms by reduced water activity

Water activity (a_w)	Lower limit for
0.90	Growth of most bacteria
0.86	Enterotoxin production by *S. aureus*
0.85	Growth of many yeasts
0.84	Growth of *S. aureus*
0.80	Growth of most moulds
0.70	Growth of most xerophilic moulds

Note that shelf stability and food safety are entirely different concerns. Although the food may be OK for ambient storage there may still be sufficient pathogens in it to cause illness.

A3.2 Food Standards Code

The applicable standard within the Food Standards Code that covers the manufacture of dried meats such as traditional dried Chinese sausage, is Clause 5 of the *Australia and New Zealand Food Standards Code* Standard 1.6.2 – Processing Requirements, which requires that:

"Dried meat means meat that has been dried to a water activity of no more than 0.85 but does not include slow dried cured meat."

Traditional dried Chinese sausage falls under this definition because it is a dried meat product that is dried quickly (not slow cured). The high temperatures used in air drying the product mean that fermentation does not take place, and therefore they do not fall within the regulations for uncooked comminuted fermented meat (UCFM) products.

There are no microbiological limits in the Food Standards Code for dried meats. Due to the low a_w there is little likelihood of any bacterial pathogens being able to grow in the product. However, mould may still grow on the surface if the product is not vacuum packaged.

A3.3 Asian sausages

The Chinese sausage, Lap cheong, is made from pork, fat and spices. It originates from monsoonal regions where high humidity and tropical temperatures dictate the processing method. It is a dried, unfermented sausage intended to be eaten after cooking. However, it may be confused with the Italian style cabanossi and eaten raw. Although salt, rice wine and a high level of sugar is added, there is the possibility for *S. aureus* to grow in the early stages while a_w is still high and if the temperature is in the region 15–40°C for any length of time. Drying, at least in the later stages, is around 50°C for some hours, which is sufficient to kill most pathogens but it does not destroy the toxin produced by *S. aureus*. The product has a low water activity (0.60–0.70). Temperature must be controlled in the early stages to prevent *S. aureus* growth.

The thin calibre of the casing means that air-drying is effective in reducing the moisture level of the product. Lap cheong is typically made by heating in a controlled environment at a minimum of 45–50°C at low relative humidity (65–75%). Moisture is progressively removed, with the rate of moisture loss dependent on ambient conditions, being slower in cooler, wet weather.

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 final a_w about 0.75–0.80, allowing it to be classified as an intermediate moisture food.

The University of Tasmania model for inactivation of *E. coli* in uncooked comminuted fermented meats may be used by regulatory authorities to assess processes. The tool predicts that the Lap cheong process provides a >8-10 log reduction of inactivation of *E. coli*.

These cured sausages and close variants are enjoyed in Asian countries including the Philippines, Thailand and Vietnam, as well as in western countries with large Chinese populations.

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, plus an oxygen/moisture scavenger aids in the maintenance of product quality and preventing mould growth.

The finished product is intended to be warmed before consumption and served hot. It is often sliced and served with steamed rice, noodles or vegetables.

As part of a food safety program, the effectiveness of the drying process 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.

A3.4 Middle-eastern sausages

There are many names for the middle-eastern sausage, of which sücük and soudjuk are just two. The sausage is spicy-hot, semi-dry and made from only ruminant meat (beef, buffalo, mutton). Salt (around 2%), nitrite (150-200 mg/kg) and paprika are added in the mincing stage. Under the ripening conditions (such as seven days at 89°C in a room at 70% relative humidity), 20–25% of the moisture is lost. There may be some natural fermentation but the pH remains between 5.0 and 5.5. The moisture content is low (around 40%) and there is usually no heat treatment or smoking. Traditionally, sücük is eaten cooked as a breakfast sausage, though some people dry and consume it without cooking.

In recent years in Australia, the process has been varied and some manufacturers use starter cultures which necessitate a higher temperature. Other variations are to cook the sausage using the criteria for CFM.

In either event, sücük cannot be considered either a UCFM or, if cooked, a CFM.

A3.5 Soft spreadable sausages

These 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.

Spreadable sausages fall into two categories:

- 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 three to 12 hours) then hung at ambient temperature for one to two days

In both cases the sausages are manufactured for quick marketing in delis, manufacturers' shops etc. They are not intended for long shelf life in supermarkets.

N'duja 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.

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.

Importantly, if you do use a starter culture, you're making a UCFM product which will need to comply with Standard 4.2.3 of the Food Standards Code.

Ultimately, it is necessary for you to provide your regulator with a validated process with a CCP for target bacteria.

A3.6 South African Droewors

This sausage is made traditionally from ruminants (beef, lamb, goat and deer). It is made with a moderate level of fat and has vinegar and possibly soy sauce added. Meat is minced and 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 water activity is between (0.60–0.70). You will need to provide your regulator with a validated process with a CCP for target bacteria.

A3.7 Cyprus Smoked Sausages (Kypriaka Loukanika)

This sausage is traditionally produced in autumn when the pigs are killed. The 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 (a local seed) 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. You will need to provide your regulator with a validated process with a CCP for target bacteria.

Appendix 4: Improving product consistency

Table A4.1 below defines, for various products and processes, the aspects that can vary significantly. Identifying and controlling the most significant sources of variability makes reformulation easier and certainly more effective.

Table A4.1 Checklist for reducing variablity during manufacture of smallgoods

Stage	Product	Check	Because
Ingredient - Meat	bone-in or whole muscle products	Variability in the size of the legs or pieces being used	Cook cycles should be based on the core temperature of the largest piece, which means many smaller pieces will have lower moisture contents
	All	Meat fat specification – variability	Variability in fat content means variability in moisture content in the finished goods, which affects the concentration of the antimicrobials (all expressed or entered per litre of water)
Ingredient - Brine dry goods	All	Are the ingredients weighed in house or pre-blended? Weighing individuals components – how well is it done?	If you're doing it volumetrically, powders can settle
		Scales or scoop?	Scoop or 'up to here' on a bucket can give variability based on the person doing the measuring
		Are the 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?	Some larger scales are ± 200g or more. Floor scales are even less accurate
		How is the nitrite incorporated?	If the nitrite is in the blend with the spices, it can be degraded rapidly
		Are you using in strict rotation? Do you always use within use by?	Most blends with nitrite have a shelf life max of about 3 months. If 'old' nitrite is used the final product will be 'low in nitrite Nitrite blended with salt/sugars alone is much more stable
		Are smoke flavour or extract added?	Try and obtain phenol levels from supplier (you can put this into the Listeria Predictor)
		Substitutions – are ingredients or suppliers alternated? Who works out what the new brine recipe should be?	Potential variability in concentration

Table A4.1 Checklist for reducing variablity during manufacture of smallgoods continued..

Stage	Product	Check	Because
Brine make up	All	Brine temperature	Brine should be cold before injection to maintain product temperature and to minimise degradation of nitrite before cooking
		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?	Volumetric can be inaccurate unless well controlled Variability in the brine concentration leads to variation in antimicrobial concentration
		Are the dry goods used in accordance with suppliers' instructions?	Are the nitrite and salt levels as specified?
		Are the dry goods fully dissolved in the brine before use?	Undissolved dry goods leads to variable concentrations of antimicrobials (e.g. salt)
Injection	All	Does the injection rate you use match the dry goods specification?	If not, concentration of ingredients will not be as intended by dry goods supplier.
		How is the injection rate set on the injector? Do all operators know to set at the same point? What is normal variation and what is the reason for varying the set point?	Identify variability
		Are injection rates checked? Are pieces or tubs of meat weighed before and after injection? Are tare weights used correctly?	Check to see if the weighing really represents injected weight. Sometimes people weigh-out feed tubs with injected meat, but some brine overflow makes its way in there as well. If the whole thing is put in a massager, that's OK. If the meat is taken out without the extra brine, it shouldn't be counted
		Do you always use the same brine for the same product?	If different brines are used (e.g. if there's some left over from another product and don't want to waste it) – variability again.
Massage	All massaged products	Is the injection rate corrected at a massager? Is this calculated correctly?	If this is done, you need to know weight of meat before injection and after injection and what the injected weight should be. Then measure extra brine.

Table A4.1 Checklist for reducing variablity during manufacture of smallgoods continued..

Stage	Product	Check	Because
Curing	Cured in tubs (or similar)	Is cover pickle used?	If they're not in cover pickle, some brine/ liquid will be expressed from the middles while they're curing If they're in large containers (pallet sized), the pieces on the bottom may be pressed badly Could lead to variability in concentrations from ham to ham
		What cover pickle is being used?	Use of a cover pickle means that brine/ liquid/protein is not expressed during curing Some manufacturers use special cover pickles with fewer ingredients at lower concentration (mimicking the concentration of the injected meat rather than the brine itself) If the original brine formulation is used as a cover, the salt etc content of the meat can increase Over time (because of osmosis), the concentrations of the cover pickle and the injected meat even out
		How long are products cured?	Should be about 48 hours to get even brine ingredient distribution Longer than that in a strong brine can increase salt etc levels Some businesses may use this stage as de facto storage. Meat spoilage is delayed.
Filling/hanging	All	What type of casing?	If it's moisture proof, there should be no loss of moisture during cooking
		Is the drip loss known?	Drip loss is generally accepted as being a loss of liquid (and all materials dissolved in the liquid) rather than evaporative
Cooking	Not in moisture-proof casing	What's the cook end point?	Helps to understand variability in cook time
		Is the cooker humidity controlled?	Controlled humidity will help reduce variability in weight loss during cook
		Are the products smoked? Manual or part of a program? How is time controlled? Separate location (or combined function house)? Variability?	Smoking is often the driest part of the cook cycle Product surface has to be dry before smoking – or smoke won't adhere 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
		Is the cook loss or yield known?	Moisture loss during cook is regarded as evaporative, and results in concentration of ingredients added to the product

Table A4.1 Checklist for reducing variablity during manufacture of smallgoods continued..

Stage	Product	Check	Because
Chilling	Not in moisture-proof casing	Is there an intensive chiller as well as a storage chiller?	If they're not in cover pickle, some brine/ liquid will be expressed from the middles while they're curing
		How much time does the product spend in the intensive chiller (if used)? Variability?	Product should spend about the same amount of time as the cook cycle in an intensive chiller More than that increases product evaporative water loss
		How much time does the product spend in the storage chiller before packing? Is product routinely left unpacked over the weekend? Are products packed as soon as possible to minimise losses? Or is a 'stock' of unpacked product to pack from?	Extended time in chiller (if not vacuum packed) leads to loss of moisture

Appendix 5: Alternative arrangement for cooling of large cured, cooked meats

Background

In 2004, an MLA expert panel modified the cooling regimes in AS 4696:2002 for uncured and cured meats from an existing 3-stage, to a 2-stage regime. The panel relied on data supplied from industry for 'large' meat cuts and the data indicated there would be no problem achieving the Australian Standard (AS 4696: 2007). However, in 2014 an industry expert panel reviewing these Guidelines revealed that it was difficult to cool large cured meat cuts within the first stage in the Australian Standard (from 52°C to12°C within 7.5 hours).

However the Australian Standard allows cooked meats to be cooled according to an alternative arrangement and in this Appendix we document how to prepare such an arrangement. It is based on cooling temperature and time which allow up to a 1-log increase in *Clostridium perfringens*, a bacterium that can produce a toxin that causes diarrhea, and is considered the main public health risk to consumers of cooked, processed meats.

To assist you in documenting an alternative arrangement for submission to your controlling authority we present information on:

1. Ingredients which control growth of the bacterium during cooling
2. The elements of your alternative arrangement which your controlling authority may wish to know
3. Inserting your cooling data into the ComBase Perfringens Predictor software
4. Risk of illness from consuming cured, cooked meats which have undergone a one-log increase during your alternative arrangement

You should check with your local regulator for other validation record requirements to support your alternative process.

A5.1 Control of *C. perfringens* during cooling

C. perfringens is a bacterium that can exist in a tough resting state called a 'spore'. When it is active and growing it's called a 'vegetative' cell. Vegetative cells are easily killed during the cooking regimes specified in these Guidelines (see Part 6.15) but if spores are present they'll survive and can germinate, and become active again during cooling. They can grow rapidly, doubling their population every 10 minutes at temperatures in the range 45 - 50°C.

Certain ingredients commonly added to cured meats make it less likely that spores can germinate and grow during cooling.

A5.1.1 Effect of salt, lactate and nitrite

The combination of sodium chloride and sodium nitrite in curing premixes inhibits germination and outgrowth of *C. perfringens* spores. Zaika (2003) 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.

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 (Bates & Bodnaruk, 2003).

A5.1.2 Effect of pH

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.

A5.1.3 Measuring combined effects

While we know that various ingredients and pH affect the likely growth of *C. perfringens* during cooling of cooked meats, its not straightforward to work out how much effect they will have and whether that will be enough to limit growth of *C. perfringens* to safe levels during cooling. Fortunately, the information needed has been put together into software called the *Perfringens* Predictor and, in the following sections, we explain how you can use *Perfringens* Predictor to establish an alternative arrangement based on your products and processes.

A5.2 Information needed for an alternative arrangement

A5.2.1 Product knowledge

Inputs to the ComBase predictor include:

- pH of final product
- Moisture content of cooked product
- Salt and lactate concentration in the aqueous phase of cooked product
- Whether nitrite is added to the product

Information on how to measure these properties is provided in Appendix 7.

A5.2.2 Process information

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 from 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.

A5.2.3 Microbiological testing

Since validation of the temperature:time regime needs to be carried out during actual production it will be necessary to test and hold product from early lots for presence of *C. perfringens*, until you have established that your alternative arrangement is adequate to limit *C. perfringens* to safe levels.

The sampling rate should be explored with your controlling authority. As a guide, many meat microbiologists consider that a process can be monitored by testing 20-25 samples. You could take them all on one day, or you could take five samples on each of five days.

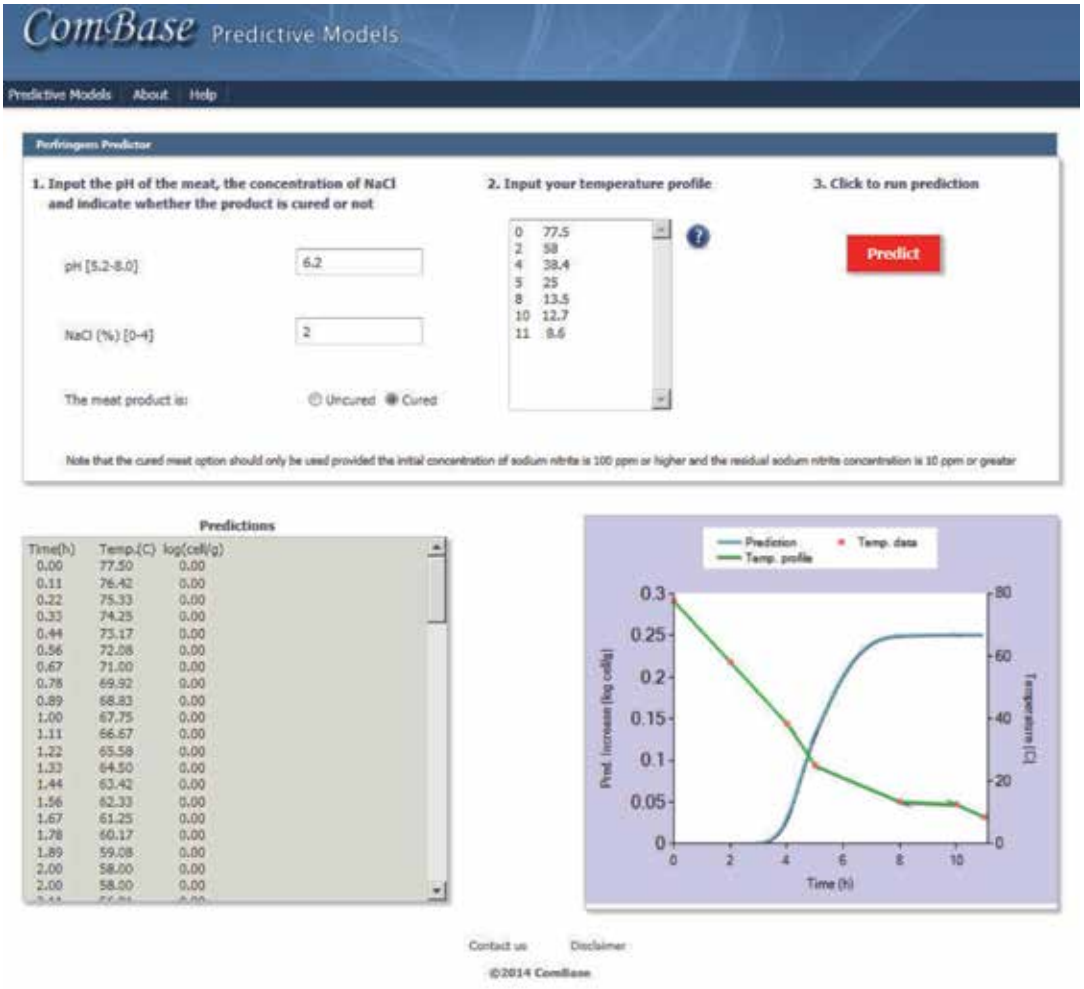
Samples (around 50g) should be taken from near the centre of large cuts of final, cooked product, then placed in a sterile bag, labelled and sent to an approved laboratory for testing of the presence and concentration of *C. perfringens*.

A5.3 Using the ComBase Perfringens Predictor

The *Perfringens* Predictor can be accessed from http://modelling.combase.cc/Default.aspx. You will be required to create an account, which requires you to answer a few questions and provide your email address. 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 and enter data for pH, salt, whether the product is uncured or cured, and temperature:time data; note that your time data must start at 0, as in the example provided by ComBase when you open the Predictor. When you press the PREDICT button the log increase in *C. perfringens* in your product for your process is estimated in the graph.

Figure A5.1 ComBase Perfringens Predictor screen shots



The pH and salt concentration of product have a great influence on growth of *C. perfringens* during cooling. Table A5.1 shows the predicted growth of *C. perfringens* in large cuts of meat (12kg) chilled in full production. Chilling actually required 9.5 hours to traverse the 52-12°C range instead of the 7.5 h allowed in AS 4696: 2007 and the manufacturer was required to clear the lot of production by testing for *C. perfringens*.

In Table A5.1 you can see how pH and salt concentration of final product affects the predicted growth and it's important that you build a database of pH and salt concentration for your large cuts of cooked meats.

Table A5.1 Example of the effects of salt and pH on increases in *C. perfringens* during cooling of meat, estimated by Perfringens Predictor

pH	Salt (wt/wt)	Predicted increase (log)
6.2	2.0	1.82
6.2	2.5	1.12
5.8	2.0	0.59
5.8	2.5	0.27
5.5	2.0	0.11
5.5	2.5	0.05

A5.4 Risk of illness from consuming cured, cooked meats

A5.4.1 Numbers needed for causing illness

C. perfringens illness is usually the mildest forms of food poisoning. Symptoms are usually only diarrhoea which usually subsides within 24 h. It is considered that ingestion of log 8 (100,000,000) cells of *C. perfringens* is needed to cause illness in healthy adults (ICMSF, 1996), equivalent to eating 100g of food each containing log 6 (1,000,000) cells. For people with underlying illness, or the very young or very old, a lower dose may be enough to cause illness. For this reasons, safe levels are generally considered to be lower e.g. in the range log 4-5 (10,000-100,000) cells/g.

A5.4.2 Prevalence and concentration in meat

In an Australian survey the organism was not detected (the limit of detection was 10 cfu/g) in 94 samples of ground beef and in 1/92 samples of diced lamb purchased from supermarkets and butcher shops (Phillips *et al*. 2008).

No data could be found for *C. perfringens* in Australian pork but, In the USA, Kalinowski *et al*. (2003) described prevalence of *C. perfringens* spores in raw meats as shown in Table A5.2.

Table A5.2 *C. perfringens* spore levels in raw meat blends

Number of Samples	Level of *C. perfringens* spores/g*		
197	<3	3-100	>100
	195	2	0

* LOD = limit of detection 3 cfu/g

The prevalence of positives in a range of cooked meats was 2/197 (1%); the two positives for spores were 3.3/g and 66/g and both were isolated from 35 ground pork samples.

A5.4.3 Potentially toxigenic strains

When food with a high level of *C. perfringens* is eaten it can become established in the gut into which it releases a toxin (McClane, 2007). Symptoms include diarrhea and abdominal pain that usually resolves itself as the toxin is excreted in the diarrhea.

There are five types of *C. perfringens* based on toxin type (A, B, C, D, E) and most poisonings are caused by type A strains. Only between 2-6% of all *C. perfringens* carry the gene (the cpe gene) responsible for the production of enterotoxin (Bates & Bodnaruk, 2003).

A5.4.4 log increase is considered a safe process

The United States Code of Federal Regulation (9 CFR 318.17 (a) (2)) allows 1 log (i.e. ten-fold) increase of *C. perfringens* within the product during cooling.

A5.4.5 Effect of refrigeration

Kalinowski *et al*. (2003) measured a 2-3 log reduction in count during 7 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 6 weeks. Similar observations on declines in *C. perfringens*. during chilled storage, although less pronounced, were made by Taormina *et al*. (2003; see below).

A5.4.6 Challenge trials in cured meats

As indicated above, salt and nitrite inhibit 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*. (2003) 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*. (2003). The authors concluded that their results indicated that *"processed meats cured with sodium nitrite are not at risk for growth of C. perfringens during extended chilling and cold storage."*

Marquez-Gonzalez *et al*. (2011) 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.

A5.4.7 Epidemiological data

The safety of these products is support by a statement from the International Commission on Microbiological Specifications for Foods: *"There is no history of C. perfringens diarrhea associated with cured meat products since the bacillus is relatively sensitive to sodium chloride and nitrite"* (ICMSF, 1996).

A5.5 Conclusions

A number of factors make an alternative temperature:time arrangement which allows up to a 1-log increase in *C. perfringens* a safe arrangement.

1. The pathogen is rarely present in meat
2. Only a small proportion of strains are able to produce toxin
3. Salt, lactate and nitrite are inhibitory to spore germination and outgrowth, especially when the pH of meat is below 6.0.

Appendix 6: Predicting the growth of *Listeria monocytogenes* in RTE meats

The Australia New Zealand Food Standards Code (Standard 1.6.1 - Microbiological limits for foods) applies different microbiological requirements for RTE foods depending on whether growth will occur in the food. Food Standards Australia New Zealand has issued a document 'Guidance on the application of microbiological criteria for *Listeria monocytogenes* in RTE food' which should be consulted for further information.

A6.1 Validating your formula

Until very recently the only way you could prove your product was bulletproof against Listeria was 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.

A6.2 The *Listeria monocytogenes* growth model

A quick, cheap alternative to challenge testing has been developed by scientists in Denmark and Australia. 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 stop the growth of *L. monocytogenes*. It's called the *Listeria monocytogenes* Growth Model.

This model is part of the Food Spoilage and Safety Predictor (FSSP) software package and has been peer reviewed by international experts (Mejlholm *et al*. 2010).

MLA has road tested the FSSP in Australian smallgoods and verified that it is an effective *L. monocytogenes* management tool. Later in this appendix you can see how to download the tool – it is free.

To use the tool 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

If you're a small/medium manufacturer you won't have a lab 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 Appendix 7 we list the tests and methods the lab will need to use.

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 (CO_2) in headspace at equilibrium using the method in Appendix 7.

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 *Listeria monocytogenes* Growth Tool

First go to Appendix 6.3 and follow the steps to download the tool.

Now you're ready to enter your product composition data into the tool.

- *Listeria 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:

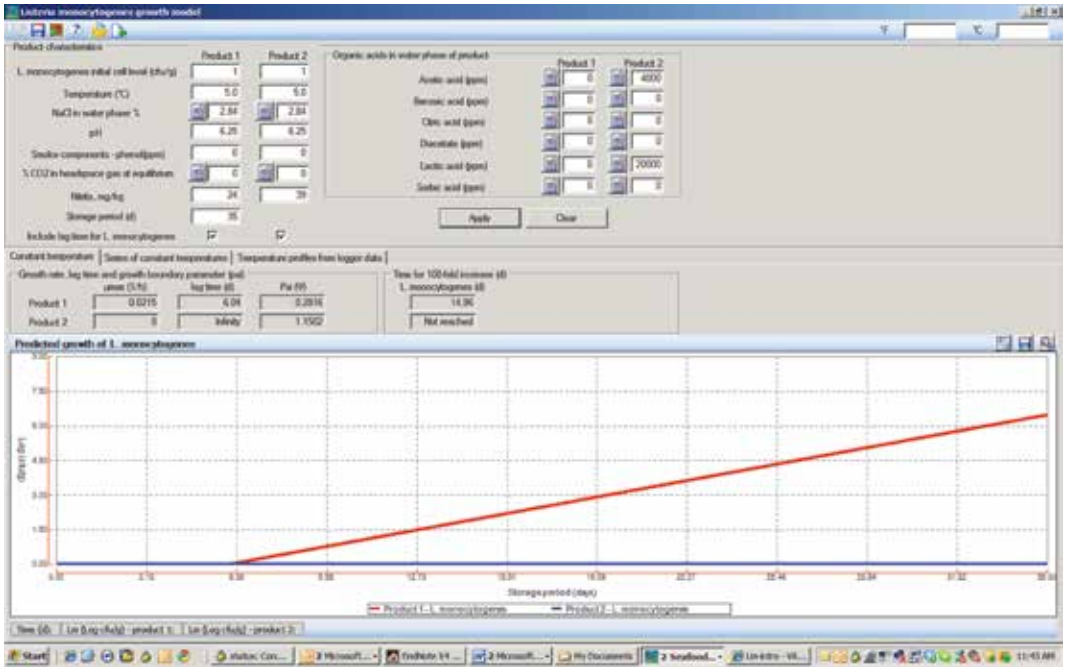
The number of days for a 0.5 log increase in *L. monocytogenes*. The Food Standards Code (Standard 1.6.1 - Microbiological Limits for Foods) allows a 0.5 log increase - If you inserted 1cfu/g as the initial cell level then your graph will start at 0 (the log of 1 cfu/g = 0) and you can easily see when 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 <100 cfu/g *L. monocytogenes* applies, rather than 'zero tolerance'.

Figure 6.1 shows 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 6 days storage. At the end of shelf life (5 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 A6.1 Screen shot of *L. monocytogenes* Growth Model showing 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. Most people use either lactate on its own, or in combination with diacetate – there are proprietary brands on the market. 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 *Listeria 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 CO_2
- 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 A6.1) requires addition of 20,000 ppm of lactate and 4,000 ppm of diacetate to do the job (Table A6.1). And if you decided to use a proprietary brand based on lactate alone, you'd need 31,000 ppm.

Table A6.1 Reformulation with lactate and diacetate to prevent growth of *L. monocytogenes*

	Existing product	New product
Listeria monocytogenes (CFU/g)	1	1
Storage period (days)	35	35
Storage temperature (°C)	5	5
Salt in water phase (%)	2.84	2.84
pH	6.25	6.25
Lactic acid in water phase (ppm)	0	20000
Diacetate in water phase (ppm)	0	4000
Smoke components (phenol ppm)	0	0
CO_2 in headspace (%)	0	0
Nitrite (ppm)	24	39
Day growth begins	6	After 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 Appendix 4 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 food safety plan

In your existing food safety plan you should have nitrite addition as a CCP. In the HACCP plan 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 *Listeria 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 requirements (SQF2000 (Section 4.3) and ISO22000 (End product characteristics)).

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.

A6.3 Obtaining and using the Food Spoilage and Safety Predictor (FSSP)

Setting up the FSSP

The FSSP is downloadable from http://sssp.dtuaqua.dk/

Entering values into the *Listeria monocytogenes* Growth Model

***Listeria 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.

% CO_2 in headspace gas at equilibrium – as measured by the laboratory, or as calculated using the calculator on the *Listeria monocytogenes* Growth Model. To use the calculator you need to know:

Storage temperature, initial gas/product ratio, and initial % CO_2 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. See Appendix 7 for further advice.

Appendix 7: Determination of product composition

If you propose to validate an alternative cooling arrangement and/or a formulation which prevents growth of *L. monocytogenes* over the product's shelf life you'll need to obtain a thorough analysis of your product's composition.

In the section we list the analytical methods needed, either by your company laboratory or an off-site laboratory.

Dry Matter/Moisture

Laboratory analysis of the dry matter percentage is determined by heating at 105˚C for 24 hours (AOAC, 1995b)

NaCl in water phase (%)

- Laboratory analysis of the percentage sodium chloride in the sample by modified Volhard titration method or equivalent (AOAC, 1995a)
- Calculate Dry Matter or lab analysis of Dry Matter (%)
- Laboratory analysis of the percentage Dry Matter by heating at 105˚C for 24 hours (AOAC, 1995b)

pH (Dalgaard and Jorgensen, 1998)

- 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

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-dimethoxyphenol (Tucker, 1942) or the French standard for smoked salmon method (AFNOR, 2004)*

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

$\%CO_2$ in headspace gas at equilibrium

- You can calculate this value using the calculator in the *Listeria monocytogenes* Growth Model (see section A6.3)
- Analyse the $\%CO_2$ in headspace at least two days after production to allow for equilibration

Nitrite (mg/kg)

- Laboratory analysis of the amount of Sodium Nitrite in the composite sample by colorimetric method or equivalent (Dalgaard & Jorgensen, 1998, Anonymous, 1995b)

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 H_2SO_4 eluent. Flow rate was 0.6mL min^{-1}, run time 120 min 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 quantification (Dalgaard & Jorgensen, 1998)

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 FSSP Model

Data required

- Highest product water content (%) - From chemical analysis
- Lowest product salt content (%) - From chemical analysis
- Brine Recipe
  - Ingredient quantity per batch (kg) - including any antimicrobials added at this stage
  - Purity of antimicrobials used (e.g. commercial 60% Sodium Lactate solution)
- Injection rate (standardised or lowest rate achieved)
- Ingredients added at massager
  - Does not include additional brine to correct or standardise injection rate
  - Includes injected meat weight (normal quantity)
  - Ingredient quantity per batch (kg) - including any antimicrobials added at this stage
  - Purity of antimicrobials used (e.g. commercial 60% Sodium Lactate solution)
- Smallest cook / chill loss

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