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Guidance Document

Production of Uncooked Fermented Salami (UCFM)

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Title

Guidance Document: Production of Uncooked Fermented Salami (UCFM)

About this document

This guidance document has been developed to help processors of uncooked comminuted fermented meat (UCFM) products to comply with the Food (Uncooked Comminuted Fermented Meat) Standard 2008 (UCFM Standard). It covers the processing requirements and Good Operating Practices for the production of safe UCFM products.

Related Requirements

The requirements to which this guidance document relates to are:

- Animal Products Act 1999
- Food Act 2014
- Food (Uncooked Comminuted Fermented Meat) Standard 2008
- Australia New Zealand Food Standards Code. Applicable parts include:
  - Part 1.2 Labelling and other requirements
  - Standard 1.3.1 Food additives
  - Standard 1.6.1 Microbiological limits in food
  - Standard 2.2.1 Meat and meat products

Document history

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July 2014	September 2017	All	Full document review and reformat. References have been updated.

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1 Purpose

The guide is intended to help processors of UCFM products to meet requirements specified under the Food (Uncooked Comminuted Fermented Meat) Standard 2008 (UCFM Standard). The UCFM Standard comprises the legal requirements and takes precedence over any guidance material.

This guidance document covers the processing requirements and Good Operating Practices (GOP) for the production of safe UCFM products. It describes:

- regulatory and best practice microbiological and product limits; and
- GOP in the production of UCFM products; and
- product and process validation; and
- product and process verification; and
- corrective actions for non-compliant UCFM products.

MPI has also published a resource (Making Uncooked Salami (Uncooked Comminuted Fermented Meat or UCFM), which is focused on the making of UCFM products, and aims to help small to medium sized producers who may benefit from extra practical assistance to help them comply with the UCFM Standard.

This guidance document on how to comply with the applicable requirements is not the only way to achieve compliance. You are encouraged to discuss alternatives from the approaches outlined in this guidance document with MPI.

The term "must" is not typically used in guidance. In this particular document the term "must" is only used in the context of the requirements set out in the UCFM Standard, Australia New Zealand Food Standards Code, or any other applicable legal instrument.

Note – this guide generally applies to UCFM products regardless of whether they are intended to be shelf-stable or refrigerated.

2 Background

UCFM means an uncooked comminuted fermented meat which has not been heated during production to a core temperature of 65°C for at least 10 minutes, or an equivalent combination of time and higher temperature. Examples of UCFM products commonly produced in New Zealand include Salami, Chorizo, Saucisson and Pepperoni.

The UCFM Standard applies to all processors of UCFM products and focuses mainly on processing requirements for the control of pathogenic bacteria, particularly shiga-like toxin producing *Escherichia coli* (STEC). Other pathogenic bacteria of relevance include *Salmonella, Staphylococcus aureus* and *Listeria monocytogenes.*

The UCFM Standard expects processors to have GOP in place. MPI's Processed Meats Code of Practice provides guidance on the development and implementation of GOP.

3 Definitions

Back slopping refers to using the partially fermented batter from a previous batch to initiate fermentation in a subsequent batch. It is prohibited by the UCFM Standard

Batter mix means all the ingredients in a recipe that have been combined prior to filling a casing

cfu means colony forming unit, and is a way of measuring the number of viable bacteria in a discrete sample

Fermentation means the anaerobic breakdown of sugar into lactic acid (by microorganisms in the starter culture) within the batter, which lowers the pH of the batter

Food Standards Code (the Code) means Australia New Zealand Food Standards Code which is developed and administered by Food Standards Australia New Zealand, see www.foodstandards.govt.nz

Good Operating Practice (GOP) means the documented procedures relating to practices that are required to ensure products are fit for their intended purpose

Maturation means the process of ageing meat products to promote drying at a specified temperature and time, which occurs after the fermentation stage; also commonly referred to as "**drying**"

MPN means Most Probable Number, and is a method used to determine bacterial numbers based on probability

National Microbiological Database Programme (NMD) is a programme administered by MPI. Under this programme, slaughter plants test meat for *E. coli* at least weekly, and their data is recorded in a national database. Go to www.mpi.govt.nz and search for 'NMD'

Process lethality means the total kill of *E. coli* resulting from the fermentation and maturation process. It can be determined by predictive modelling or challenge studies

pH means a measure of acidity or alkalinity. A pH of 7 is neutral (pure water), below 7 is acidic (e.g. lactic acid or vinegar), and above 7 is alkaline (e.g. caustic soda or soap)

Ready-to-eat (RTE) Products means product that is ordinarily consumed in the same state as that in which it is sold or distributed and will not be subject to a Listericidal process before consumption

Starter culture means a commercial preparation of microorganisms for fermenting the batter

Shelf stable means food that has been processed so that it can be safely stored at room temperature for a period of time.

Tempering is slowly raising the temperature of frozen meat until it is at a temperature just below freezing

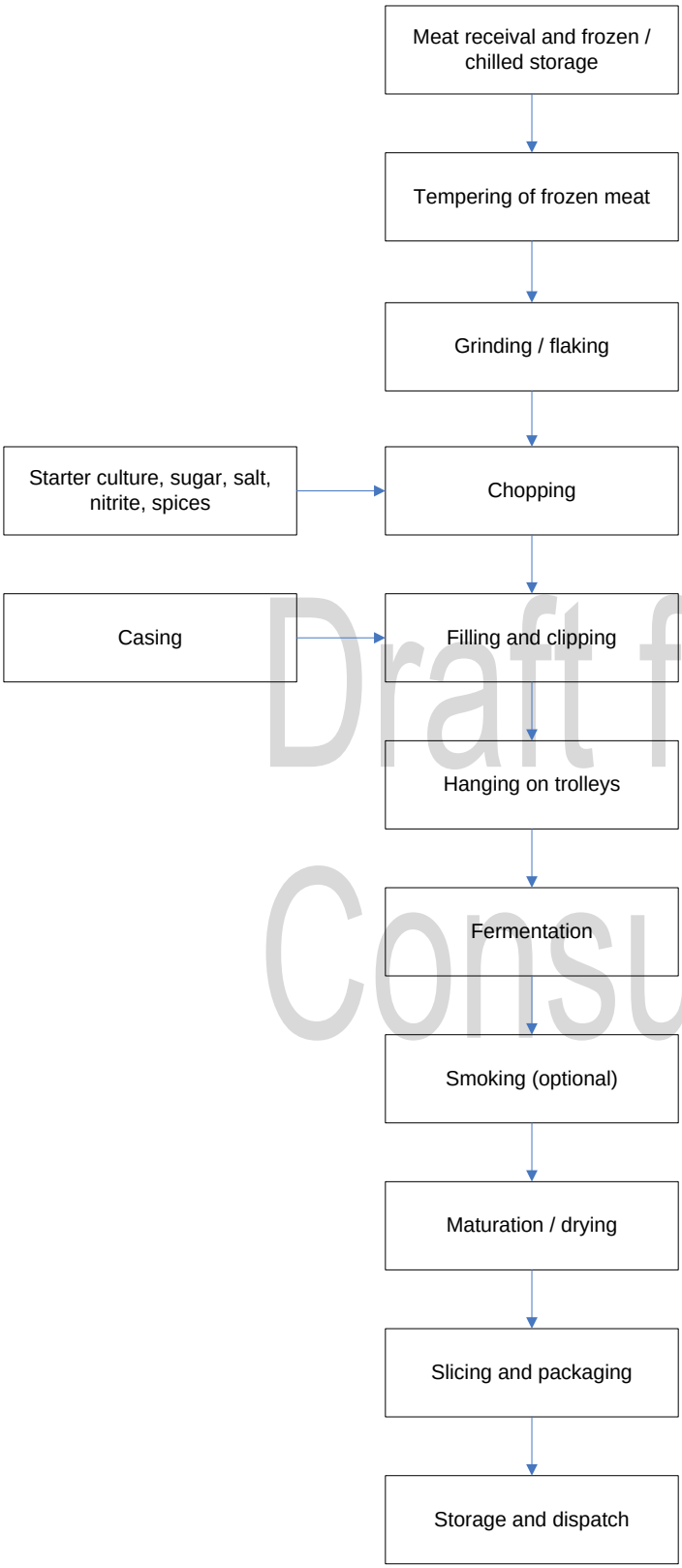
UCFM means **u**ncooked **c**omminuted **f**ermented **m**eat, for example salami/sausage

Validation means collecting and analysing evidence to confirm that the UCFM product and manufacturing process meets the requirements of the UCFM Standard. This must be carried out by the UCFM producer (UCFM Standard 4(2))

Water activity (a_w) means a measure of the water in the food which is available for bacterial growth. A more detailed description of water activity can be found in the MPI Processed Meats Code of Practice

4 Process overview

Figure 1: steps for a typical UCFM manufacturing process



5 UCFM requirements

All UCFM must be produced in accordance with the UCFM standard, and comply with any relevant standards in the Australian New Zealand Food Standards Code (the Code).

As there is not a cooking step to control the growth of any pathogenic bacteria, other hurdles are crucial in making a safe product. These hurdles include (but are not limited to):

- reduction of water activity through drying; and
- pH reduction by acid production during fermentation; and
- growth of competitive flora during fermentation; and
- addition of nitrite

The acid production during fermentation produces a rapid pH drop, while the drying process results in a lowered water activity (a_w). These characteristics work together to aid the inactivation and control the growth of any pathogenic bacteria.

The UCFM process should be capable of consistently achieving the outcomes given in this section. The manufacturer must be able to provide evidence (such as records) that these outcomes can be met.

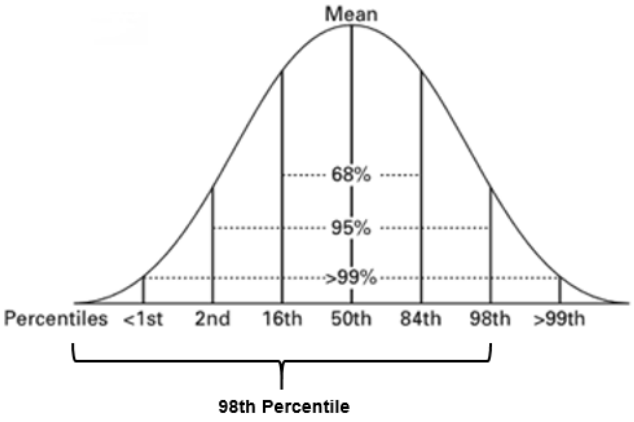
5.1 Microbiological limits

5.1.1 Requirements for *E. coli* count for in-going meat

The number of *E. coli* present in the in-going raw meat must be known to the 98th percentile (see Appendix 1 for more information). It is important to know this number, so you can develop processes which will inactivate any pathogenic bacteria in the batter.

The 98th percentile (as shown in Figure 2) is established over time, by testing the number of *E. coli* on or in meat.

Figure 2: A normal distribution curve with the location of percentiles



For example, data from the national NMD profile for beef shows the *E. coli* count at 98th percentile is 1.18-log cfu/g. This means that the UCFM process must be able to reduce the number of *E. coli* by at least 1.18-log or using the rounded value, a 2-log reduction (See section 6.1.2 for further detail).

The 98th percentile for an *E. coli* count can be determined by using the following:

a) for meat produced in New Zealand:

i) the National Microbiological Database (NMD); or
ii) data provided by the company supplying the raw meat ingredients; or
iii) data that you, the processor of the UCFM product, have collected

b) for meat imported into New Zealand:

i) an overseas data source equivalent to the NMD; or
ii) data provided by the company supplying the raw meat ingredients; or
iii) data that you, the processor of the UCFM product, have collected

Under the NMD rules, slaughter premises processing cattle, calves, lamb/sheep, deer, goats, poultry, ostriches and emus regularly test meat for *E. coli*, and their data is recorded in the NMD. UCFM manufacturers can use this data for in-going levels of *E. coli* using the species national profiles.

Access to the NMD can be requested through registering for the NMD programme at http://www.foodsafety.govt.nz/industry/general/nmd/documents.htm.

The published national profiles (password protected) for each species can then also be found at the above link, under 'Reports & strategy'.

5.1.2 Requirements for end product

All UCFM products must comply with the applicable microbiological limits specified in Standard 1.6.1 of the Code and corresponding Schedule 27 as shown in Table 1 and 2.

Table 1: Microbiological limits for UCFM products specified in Standard 1.6.1 and corresponding Schedule 27

Microorganism	n	c	m	M
Coagulase positive *staphylococci* / g	5	1	1000	10 000
E. coli / g	5	1	3.6	9.2
Salmonella / 25 g	5	0	0	-

Where:
n = number of samples examined from a batch of food
c = maximum number of samples allowed to have results greater than m but less than M
m = acceptable microbiological level in a sample
M = maximum level which when exceeded in one or more samples would cause the lot to be rejected

Under the Code, different limits apply for *Listeria monocytogenes,* depending on the final product characteristics. You can demonstrate whether or not *Listeria* will grow in a product, and use the relevant limit as shown in Table 2. You can determine this based on factors such as the pH and a_w of the product. There is more information about this in part 1 of the MPI *Listeria* guide.

Table 2: *Listeria monocytogenes* limits for ready-to-eat (RTE) foods specified in Standard 1.6.1 and corresponding Schedule 27

Food	n	c	m	M
RTE food in which growth of *Listeria monocytogenes* will not occur	5	0	100 cfu/g	
RTE food in which the growth of *Listeria monocytogenes* can occur	5	0	Not detected in 25g	

You are not required to routinely test all batches of UCFM products against these criteria. It is recommended that samples of products are occasionally tested as part of your verification programme.

It is up to you to decide how frequently these tests should be carried out, based on the number of batches you produce per week or month. We recommend testing the first 3 batches of any new product. This frequency can be reduced if all results are within operator-defined or regulatory limits. If you make significant changes to any recipe, then we recommend testing the first 3 batches of products made under the new recipe.

5.2 pH and water activity

You must:

- establish pH and a_w limits for your UCFM product(s); and
- monitor and record the pH and a_w during processing.

A UCFM product that is intended to be shelf stable needs to have a pH and/or a_w which will prevent the growth of pathogenic bacteria at ambient temperatures.

It is generally accepted that UCFM products with a combination of pH<5.2 **and** a_w<0.95 are shelf stable (Meat & Livestock Australia, 2015). You can use other combinations of pH and a_w, but they will need to demonstrate that the final product will be safe at the intended storage temperature.

For further guidance, see section 7 Validation.

A product should not be released for sale until it has reached its target pH and a_w (e.g. combination of pH<5.2 **and** a_w<0.95). UCFM products which do not meet the established pH and aw parameters for shelf stability must be refrigerated and stored at ≤5°C. It may be possible to cook such a product to make it safe.

5.3 Additive levels

The amount of additives in the final product must comply with the maximum permitted levels specified in Standard 1.3.1 and corresponding Schedule 15 of the Code (refer to section 6.7.3).

5.4 *E. coli* reduction

If you use farmed beef, pork and venison of New Zealand origin, your process must be designed to deliver a minimum 2-log reduction of *E. coli.* For further information refer to section 6.1.2.

6 Control measures

This section provides guidance on control measures that you should implement to ensure that GOP is applied and the requirements of the UCFM Standard are met. It is expected that you will have documented procedures covering these control measures, which are specific to your operation. You need to follow these strictly for every batch of UCFM you make, because any deviation from established procedures may result in an unsafe product.

6.1 Raw materials and ingredients

All UCFM ingredients and packaging should come from reputable suppliers and be safe to use.

6.1.1 Type and quality of raw meat

Only use meat of good microbiological quality for making UCFM products because:

- the UCFM process doesn't involve a kill step, such as cooking, that would reliably eliminate all pathogenic bacteria; and
- there are limitations to the numbers of pathogenic bacteria that can be destroyed during fermentation and maturation.

It is not advisable to use:

- mechanically separated meat or trimmings; or
- veal from young calves; or
- meat from poultry; or
- any other meat that may have high levels of pathogenic bacteria.

These types of meat may have a higher prevalence of *Salmonella* and STEC compared to whole muscle cuts or fat from farmed animals like cattle, deer, sheep, pigs and goats.

6.1.2 Farmed beef, pork and venison

If you use New Zealand beef, pork or venison, you can use the national profiles (98th percentile data) for *E. coli* from the NMD programme. MPI is able to provide a national profile for these meats which is likely to reflect most meat produced in New Zealand.

Table 3 provides *E. coli* values for beef, pork and venison from the national profiles as of 31 October 2016.

Table 3 also shows the required inactivation that the process will need to meet based on the 98th percentile. A value rounded to the nearest whole log count has also been provided for simplicity. This rounded inactivation number of 2-log will include a safety margin to try to take account of any process variation.

Therefore, the validated UCFM process should be capable of achieving a 2-log reduction in the population of *E. coli* when New Zealand beef, pork or venison is used as the raw material.

If you use meat other than farmed New Zealand beef, pork or venison you will need to establish the levels of *E. coli* as described in section 5.1.1.

Table 3: *E. coli* Count (98th percentile) from the national NMD profile and Required Inactivation as of October 2016

Species	*E. coli* (log cfu/g)	Rounded inactivation number (log)
Beef	1.18	2.00
Venison*	0.80	2.00
Pork*	0.91	2.00

* - calculated from carcass counts.

Using your suppliers' NMD data may provide more flexibility for your UCFM process. For example, individual suppliers may have an *E. coli* profile with a 98th percentile lower than that of the national profile. Therefore you may be able to apply a process with a lower lethality (i.e. <2-log inactivation).

If you use imported beef and pork, you will need to obtain *E. coli* data from their meat supplier, or do your own tests on incoming raw meat. Testing should be based on a statistically valid sampling plan which will provide regular test results over a 12 month period, so that you and MPI can have confidence that the validated process can consistently achieve the required microbial inactivation for *E. coli*. The 98th percentile of that data should be used to calculate inactivation requirements.

6.1.3 Wild meat

Meat that is killed by certified hunters and then inspected and dressed in premises with Risk Management Programmes is not subject to the NMD testing programme, so the *E. coli* count may not be known.

As described in section 5.1, you could determine the *E. coli* count on the in-going meat by testing the meat yourself, or consult with your supplier who may have this data available.

6.2 Starter culture

You need to select a starter culture that is suitable for the fermentation of meat at the temperature range used to manufacture UCFM products. It should contain a preparation of microorganisms which:

- successfully competes with other microorganisms for the nutrients in the batter mix; and
- produces microbial inhibitors; and
- is microbiologically safe; and
- produces a rapid, controlled reduction of the pH of the batter mix as a result of the fermentation process; and
- is stable under the processing conditions

Selection of cultures that perform under your processing conditions is critical, as individual culture strains may work best at different temperatures and tolerances. Instructions from your supplier regarding the storage and shelf life of the culture should be strictly followed, as should the procedures for the use of the culture in your product.

6.3 Herbs, spices and additives

Herbs and spices may be contaminated with pathogenic bacteria such as *Salmonella*. You should purchase these ingredients from reputable suppliers who are able to meet agreed specifications consistently. Whenever possible:

- request certificates of analysis from your suppliers; and/or
- verify (check) compliance to agreed specifications (e.g. microbiological levels). This may be done by taking samples and sending them to a laboratory to have them microbiologically tested

To avoid potential problems with high levels of microbiological contamination, sterilised spices or extracts of herbs and spices could be used instead.

Only food additives permitted by the Food Standards Code can be used in the manufacture of UCFM products.

6.4 Storage of raw meat

Raw meat and batter mix used for making UCFM products must be stored at ≤5°C.

This will prevent the growth of pathogenic bacteria such as *E. coli* O157:H7 (one of the STECs), *Salmonella* and *Staphylococcus aureus*.

When removing meat from the packaging, procedures should be established to ensure that no plastic packaging is caught in the meat, which could end up in your product.

6.5 Tempering

Temperature control during tempering is important for quality and food safety reasons. It should be done in a manner and under conditions that minimise the growth of pathogenic bacteria. For example you could temper the meat in a chiller or fridge which is set at ≤ 5°C.

Frozen meat is usually tempered to about -5°C to -2°C to prevent fat from softening and 'smearing' during grinding or chopping.

If you need to thaw meat in a water bath, make sure that the water is potable and the time/temperature of thawing do not create conditions that will allow the growth of pathogenic microorganisms.

There is more information about how to temper meat safely in part 3 of the MPI Processed Meats Code of Practice.

6.6 Grinding or flaking

Meat for UCFM production is usually ground or flaked in the tempered state and the latent heat of melting limits any temperature increase. If the meat is not frozen or tempered (for example it is completely thawed) the resulting batter may be above 5°C .If this happens, the ground or flaked meat should be:

- used immediately; or
- stored in a chiller which is set at ≤5°C.

Grinders and flakers should be checked and maintained regularly to prevent metal contamination from the equipment.

6.7 Chopping and ingredient addition

The batter is formed by cutting and mixing the ground or flaked meat with the other ingredients (often in a bowl chopper). The batter should be filled immediately into casings or, be held in a chiller at ≤ 5°C if being filled later.

6.7.1 Use of starter culture

Fermentation of UCFM products must be initiated by a starter culture. You should follow the instructions provided by the starter culture supplier regarding the preparation and addition of the starter culture. These should include the:

- reconstitution method (e.g. some freeze-dried cultures have to be dissolved in distilled water for about 30 minutes before adding into the batter mix); and
- amount of starter culture to be added to any given amount of batter; and
- type and amount of fermentable sugars to be added; and
- fermentation temperature.

6.7.2 Prohibition of back slopping

You must not use back slopping in processing UCFM products. Back slopping is where you use the fermented meat from one product batch as the starter culture for the next batch.

Back slopping is not permitted because this can lead to fermentations which are unreliable and difficult to control. Slow or delayed fermentation may permit growth of *Staphylococcus aureus*, *Clostridium botulinum* or other bacterial pathogens. It may also lead to cross-contamination between batches if pathogens have not been inactivated in the originating mix.

6.7.3 Additives

Food additives must be used at levels permitted under the Food Standards Code.

According to the Food Standards Code Standard 1.3.1– 4(6)(e) and the corresponding Schedule 15, the permitted limit for nitrates in UCFM is 500mg/kg, total nitrate and nitrite calculated as sodium nitrite.

Nitrite is used as a curing agent and antimicrobial agent. It is responsible for the cured meat colour and flavour, and also prevents oxidation. The combined effects of nitrite along with organic acids, low pH and low a_w effectively control the growth of *Clostridium botulinum* during the manufacture and storage of UCFM products.

Nitrite can be toxic to consumers at excessive levels and its addition to the batter should be controlled. The use of pre-blended curing mixtures is highly recommended (i.e. nitrite mixed with salt and other ingredients, and which are usually tinted pink) as it prevents the addition of excess nitrite into the batter. When pure nitrite is used, it is possible that the person weighing the ingredients might confuse the quantity required with that of salt and mistakenly add too much nitrite.

You should have procedures in place for correct weighing and identification of additives and ingredients.

6.7.4 Sugar, salt and other ingredients

The correct type and amount of sugars (e.g. glucose and dextrose), as recommended by the supplier of the starter culture, should be used to optimise the conversion of sugars to acid by the bacteria in the starter culture during the fermentation step. This has a direct influence on the rate of pH reduction and the final pH of the product.

Salt is an essential ingredient in all types of UCFM products. Typically, 2.5% to 3.0% of salt is added to the batter. The salt is only taken up by water in the meat (i.e. actual salt concentrations in the meat end up being higher than 3%). At this level, salt serves several functions, including:

- an initial reduction in water activity; and
- providing a characteristic salty taste; and
- contributing to increased solubility of myofibrillar proteins (Toldrá, 2006)

Care should be taken when adding alcohol to the batter as this can inhibit the starter culture and slow the fermentation process.

Glucono-δ-lactone (GdL) may be used as an acidulant (to help lower the pH) in combination with a starter culture.

6.8 Reworked material

Only product that has been through the complete validated fermentation and maturation process (e.g. salami ends and off-cuts) may be reworked back into new product.

You should establish:

- a limit for the amount of rework which can be added to a batch. Rework can affect the functionality and the additive levels (e.g. nitrite) in the finished product; and
- a cut-off period for reworking products from one batch to the next to facilitate traceability and recall procedures. For example, some processors have a weekly cut-off (i.e. material produced in a previous week is not reworked into the current week's production).

6.9 Filling and clipping

The batter should be hygienically filled into food grade casings. If casings are pre-soaked before filling, they should be soaked in potable water and the water changed regularly. The batter should be kept at ≤5°C.

Casings should be filled to the correct diameter, because both under- and over-filling can affect the quality of the end product. Diameter size influences the rate of drying and smoking, and ultimately the flavour and texture of the finished product.

Procedures should be in place to prevent metal contamination if metal clips are used to clip the sausages.

The sausages should be hung evenly spaced to help air circulation and even drying and/or smoking. Procedures should be in place to ensure that products are not contaminated (e.g. splash from wheels) during the transfer of trolleys from one area to another.

6.10 Fermentation

During fermentation, lactic acid bacteria from the starter culture use sugars within the meat and sugar added to the batter to produce acid which lowers the pH of the batter and prevents the growth of pathogenic bacteria. During its growth, the starter culture also produces flavour compounds, enzymes, and other compounds which prevent the growth of other bacteria.

The rate of acid production and pH drop depends on several factors, including:

- the number and type of lactic acid bacteria in the starter culture; and
- the fermentation temperature; and
- the amount and type of fermentable sugar

The fermentation time and temperature throughout the process must be established and validated. This should then be monitored for every batch made. Effective temperature control is critical to the safety of the final product. Deviations in fermentation temperature can significantly affect the lethality of the process and *E. coli* reduction.

In general, higher fermentation temperatures require shorter fermentation times, and faster pH drops preventing pathogenic bacteria growth. For example:

- at the lower temperature range of 21°C to 24°C, fermentation can take as long as 2 to 3 days
- at 28°C to 32°C (range commonly used in New Zealand), fermentation usually takes 16 to 24 hours
- in United States, where faster overall production times are preferred, the fermentation temperature can be as high as 37°C to 40°C for as little as 12 to 18 hours (Hutkins, 2006)

It is important that fermentation produces a rapid drop in pH over the first 48 hours. Slow or delayed fermentation may allow the growth of a range of pathogenic bacteria.

The pH reduction also induces protein coagulation and reduction in the meat's water holding capacity which favours water release and facilitates drying (Toldrá, 2006).

To ensure that the pH decreases within the required rate, pH readings should be taken from each batch during the fermentation period. pH monitoring is further discussed in section 8.3. As part of the validation work you will need to monitor and record the pH drop during the fermentation stage. This would be the rate that the pH would need to drop for every batch made.

You will also need to record the pH, time and temperature of the fermentation process for each batch of UCFM product. For example you could check the pH and temperature in the morning and evening during each day of fermentation.

If the pH does not drop rapidly you will need to reassess your recipe and processing parameters. You may need to discard the batch.

6.11 Smoking and maturation (drying)

Following the fermentation process, UCFM products may be smoked, or go directly to maturation/drying.

Maturation/drying should be carried out in a temperature and humidity controlled room or cabinet, so the rate of drying can be properly controlled. Excessively fast drying should be avoided as this can cause case-hardening, whereas excessively slow drying may result in undesirable microbial growth on the product's surface.

The rate and amount of drying during maturation (and smoking) depends on factors such as:

- Product characteristics
  - product pH; and
  - Product diameter
- Process parameters
  - maturation temperature; and
  - air velocity (rate of airflow over the product); and
  - relative humidity; and
  - product loading/arrangement on the racks; and
  - maturation time

Smoking and maturation temperatures must be controlled and monitored as deviations can significantly affect the lethality of the process and *E. coli* reduction.

The rate and extent of drying must also be monitored by measuring the a_w or weight loss of the finished product.

Semi-dry products are typically dried to remove 20% to 30% of the original water and to give final moisture of about 45% to 50% (Hutkins, 2006). The a_w of semi-dry products ranges from 0.90 to 0.94. Dry fermented sausages will lose about 35% water, giving a final moisture of 35% and a_w between 0.85 and 0.91.

6.12 Slicing and packing

UCFM can be kept whole or sliced before packing into retail packs. Good hygienic practices are essential during the slicing and packing of UCFM products. Controls should be in place to minimise:

- contamination of products from equipment and the environment; and
- cross contamination between raw meat and UCFM products; and
- foreign matter or other substances that could affect the safety and suitability of the product

Ideally, slicing and packing of UCFM products should be done in dedicated areas (i.e. separate room) which are physically separated from areas where raw materials and products are handled. Slicers, conveyors and packing machines should only be used in this area for UCFM and other compatible ready-to-eat (RTE) products.

When physical separation is not possible, the slicing and packing of raw products and processed products such as UCFM should be separated by time. For example, some processors pack RTE products first thing during the day, when there is no raw product in the room and the equipment is clean.

Other controls which should be in place include:

- procedures for controlling the movement of personnel and equipment from raw to RTE areas; and
- effective hygiene routine for personnel before entering RTE areas or handling RTE products; and
- effective cleaning of equipment and the processing environment; and
- training of staff to comply with established procedures

7 Validation

The process of manufacturing UCFM products must be validated to ensure the number of bacteria at the end of a process complies with the microbiological limits specified in Standard 1.6.1 and the corresponding Schedule 27 of the Code.

Validation should be done for each type of product, or group of products with the same characteristics. Validation is usually only done when developing a product or process, and must be repeated if a change is made in the:

- product (e.g. formulation, starter culture, sausage diameter, pH and a_w); or
- process (e.g. fermentation or maturation process time / temperature).

7.1 Validation criteria

You must demonstrate that the validated process is:

a) capable of producing UCFM products that consistently meet:

   i) the microbiological limits specified in Standard 1.6.1 of the Code; and
   ii) the established pH and a_w (for example, a final pH<5.2 **and** a_w<0.95 is generally accepted as safe); and

b) Capable of delivering the required process lethality (e.g. 2-log reduction of *E. coli*).

7.2 Validation methods

There are several methods which can be used for validating the process, and production of safe UCFM products.

7.2.1 Challenge testing

Challenge testing involves inoculating a typical batter with known quantities of non-pathogenic acid resistant *E. coli* and monitoring their levels throughout the fermentation and maturation stages, and particularly at the end of the process.

Challenge testing is considered to be the ideal method for validation because it gives results that are specific to your product and its characteristics (e.g. formulation, sausage diameter) and the process. However, it can be expensive to perform and it requires a high level of technical competency. It is recommended that if you want to do challenge tests, you should consult a research agency or laboratory experienced in carrying out such work.

7.2.2 Predictive modelling

A predictive model can be used to show whether your process is capable of inactivating the levels of *E. coli* in the ingoing meat.

There are several models available. The Meat and Livestock Australia (MLA) model for *E. coli* inactivation (also known as the Tom Ross model) is the one most commonly used in Australia and New Zealand for assessing the inactivation of *E. coli* in a UCFM product during fermentation and maturation.

The report "Predicting *E. coli* inactivation in uncooked comminuted fermented meat products" is also available from the same website. If you intend to use the MLA model you should read the report, as it provides:

- information explaining the scientific basis for the model; and

- an extensive review and analysis of published and unpublished studies regarding the UCFM process and the inactivation of *E. coli* during processing

From these studies it was found that, once fermentation has begun, the combined effects of temperature and time are responsible for most of the observed death of *E. coli*. While salt, drying and low pH are essential for setting up conditions in UCFM products so that *E. coli* are killed, the actual levels do not strongly influence the rate of *E. coli* inactivation.

Two calculators are provided for the model. The instructions for the calculators should be read carefully before they are used. To use either calculators, you need to know the times and temperatures of your fermentation and maturation (and smoking, if this is applied) processes.

The 'Quick' calculator is more appropriate for small operations or for those where the fermentation and the maturation temperatures are static (e.g. the entire fermentation period is at 30°C and maturation is at 15°C).

The 'Advanced' version is more useful if you:

- have variable fermentation and maturation temperatures; and
- are able to obtain data at a regular frequency (e.g. by using a data logger) during the entire fermentation and maturation (and smoking) processes

The 'Advanced' version uses the same model as the 'Quick' calculator, but allows for more times and temperatures to be specified (such as warm-up times before fermentation, cool-down times after fermentation, or heating steps). This allows for more accurate predictions of the *E. coli* inactivation to be made.

Both calculators estimate the average log reduction of *E. coli* achieved by the particular process. For the process to be valid, the average log reduction must be greater or equal to the *E. coli* count in the raw meat used.

If you feel that the outcome of the predictive model is not appropriate for your product, a challenge test could be considered. For example, small diameter sausages may become over dried when the times and temperatures required by the model to achieve the calculated lethality is applied.

An example the data you enter may look like this:

Temperature (°C)	Time (hours) since measurements started	This is the process used for these records (Your process will not be the same as this).
4.0		
10.0	6	Process is fermenting at 22°C for 72 hours
17.0	12	
22.0	24	
21.0	36	
21.5	48	
21.0	60	
22.0	72	
26.0	84	Process is smoking at 30°C for a further 36 hours (72 + 36 = 108 hours)
30.0	96	
26.0	108	
22.0	120	Process is drying at approximately 20°C for a further 228 hours or 9.5 days (108 + 228 = 336 hours)
20.0	144	
20.0	336	

Which gives a log reduction of:

	2.48	Total Predicted Inactivation (log CFU)

As time and temperature are mostly responsible for microbial death, the model can be applied to UCFM products with a range of pH and a_w - so long as factors such as pH, drying and salt levels are consistent and within safe guidelines for production of UCFM products.

7.2.3 Use of historical data

If you routinely test your end product, you may have a lot of data that shows your products consistently meet the microbiological standard for UCFM products. This data would be useful for validation but it cannot be used solely to validate the effectiveness of the process to destroy the required level of microorganisms. This is because the levels of microorganisms that were present in the raw material used to make the tested product was not known. *E. coli* may be present sporadically and at varying levels in raw meat, hence the absence of *E. coli* in the final product would not necessarily mean that the process is effective in killing *E. coli* when it is possible that this pathogen was not actually present in that particular batch of raw meat or batter.

7.2.4 Use of previously validated processes

You can produce UCFM products using a process that has been scientifically validated by a reputable agency or research institute, or published in a peer reviewed scientific journal.

This approach can only be applied if you comply with all the product and process parameters that the validated process was based on. For most New Zealand processors, it is more likely that they would still need to do their own validation.

7.3 Actions required when process is determined to be inadequate during validation

For example, you tested the first 3 production batches as part of the validation process. What should you do if something goes wrong (e.g., if the pH of the batter doesn't drop to required level during fermentation)? Options include:

- cease production of any UCFM products using the existing process immediately; and
- any product in stock that has been produced using the existing process must not be released for distribution or sale unless the particular batch is exposed to further treatment that is sufficient to destroy any surviving pathogens (e.g. cooking); and
- make changes in the product or process (e.g. by improving the quality of the raw material and/or the process conditions), and revalidate the process before re-commencing production

If you cannot produce UCFM products that will consistently meet the validation criteria given section 7.1, you may need to recall any batches which are already sold.

There are various ways which may be considered to improve the process so that a bigger reduction in *E. coli* can be achieved, such as:

- fermenting at a higher temperature; or
- maturing at a higher temperature; or
- extending the maturing time; or
- having a brief heating step, e.g. bringing the product to 50°C for 2 minutes (Meat & Livestock Australia, 2015)

You may propose an alternative course of action, but this must first be discussed and agreed to with your evaluator/verifier or MPI before it is implemented.

8 Implementation and monitoring your process

8.1 Implementation of the validated process

UCFM production must be implemented according to your validated process.

You must revalidate your process if you make a change to the product or process which may impact on:

- process lethality (the number of *E. coli* inactivated by the process); or
- the achievement of any of the outcomes discussed in section 5 UCFM requirements

For example, a change in formulation, sausage diameter, pH, a_w, fermentation and maturation times and temperatures may require revalidating your process.

You must establish corrective action procedures for any deviation from your validated process.

8.2 Temperature and time monitoring

You must monitor and record the processing temperature and times at key stages. Process temperature and times must be measured for each batch:

- during fermentation; and
- during smoking(if applicable); and
- during maturation or drying

The temperatures of the fermentation and maturation rooms should be:

- controlled so that they consistently comply with the temperature(s) used when the process was validated; and
- must be monitored for every batch of UCFM product. Some processors may have facilities for continuously monitoring room temperature (e.g. data loggers). In other premises, such monitoring will need to be done manually

Cabinet temperatures should be monitored and recorded for each batch:

- at least twice daily during the fermentation process (e.g. once in the morning and once in the evening); or
- at a frequency necessary to confirm that the scheduled process is being followed

Thermometers used for monitoring should be properly calibrated.

8.3 pH and water activity monitoring

You must monitor and record the pH and a_w of the product at key stages. Weight loss may be used as a proxy for a_w of UCFM product if properly correlated. The rate and extent of drying must be monitored by measuring the a_w or weight loss of the finished product.

The pH must be measured for each batch during processing and after the maturation process (i.e. end product testing).

If it takes longer than 48 hours for the pH to drop below 5.2, or if the pH does not drop far enough, then there is a likelihood that pathogenic bacteria or toxins will still be present. The recommended method for determining pH is given in Appendix 2.

You must establish corrective action procedures for any UCFM product which fails to achieve the required pH within the validated time.

Remember that non-compliant product cannot be reworked into a UCFM product.

Establishing the correlation between weight loss and a_w for each product made can be done by having the a_w of a selection of product samples that have achieved the intended weight loss analysed by a laboratory. Provided that the formulation and processing parameters don't change, the correlation between a_w and weight loss should remain constant. Appendix 3 gives a method for determining weight loss.

A product should not be released for sale until it has reached its target pH and a_w (e.g. combination of pH<5.2 and a_w<0.95).

8.4 Microbiological testing

You must test UCFM products for *E. coli* as part of ongoing verification of the effectiveness of the process to verify compliance to the UCFM Standard. You must also ensure that your product meets microbiological standards for UCFM in the Food Standards Code (see the microbiological outcomes in section 5.1.2).

The number of samples to be tested and the frequency of sampling should be based on a sampling plan which will provide enough data so that you and MPI can have confidence that the validated process is consistently meeting the microbiological limits. Unless you have specialty knowledge around designing microbiological sampling plans, you should work with someone who has this expertise on developing such a plan.

The level of *E. coli* in the finished product can be determined using an MPN method of analysis. Direct plating methods may also be used as long as their lower limit of detection is no greater than 3.6 cfu/g.

9 Corrective action procedures

You must document corrective action procedures for any non-compliance to regulatory requirements (e.g. microbiological limits) or your validated UCFM procedures/parameters. Specific corrective actions must be developed for non-compliances to the product and process criteria.

The corrective actions must address:

- how you will restore control to the process to ensure that further non-compliant product is not made; and
- how affected product will be identified and disposed of; and
- whether you need to recall or dispose of product; and
- prevention of the re-occurrence of the loss of control

You should investigate any incidence of non-compliance or process failure, determine the cause of the failure, and determine the appropriate corrective action.

If a recall is necessary, you can find guidance on recall procedures at www.mpi.govt.nz (search 'food recalls').

10 Records

All records generated from the UCFM production process must be kept for a minimum of 4 years.

11 References

Food Standards Australia New Zealand. (2003). *Amendment No. 68 to the Australia New Zealand Food Standards Code*. Canberra, Australia: Commonwealth of Australia.

Hutkins, R. W. (2006). Meat Fermentation. In R. Hutkins, *Microbiology and Technology of Fermented Foods* (pp. 207–232). Iowa, USA: Blackwell Publishing.

Meat & Livestock Australia. (2015). *Guidelines for the safe manufacture of smallgoods 2nd Edition*. North Sydney, Australia: Meat & Livestock Australia.

Ross, T., & Shadbolt, C. T. (2001). *Predicting Escherichia coli inactivation in uncooked comminuted fermented meat products*. North Sydney, Australia: Meat & Livestock Australia.

Toldrá, F. (2006). Biochemistry of Fermented Meat. In Y. H. Hui, *Food Biochemistry and Food Processing* (pp. 641–658). Iowa, USA: Blackwell Publishing.

Appendix 1: The 98th percentile

The 98th percentile of a normal distribution will account for the majority of the data in the population.

In this case the 98th percentile will account for the majority of *E. coli* count results on a carcass or carton of meat.

With any data like this, there will be 'outliers', which can be unusually high or low results. The highest count in a large data set may be much higher than the rest of the data within the 98th percentile. This may be due to rare contamination events, and give an unusually high bacterial count. Because of this, the highest number which falls within the 98th percentile is used. Note – if you have a very limited number of tests to calculate the 98th percentile from, it may be more appropriate to use the highest count in your data, or the 'worst case' scenario. This is because with small data sets, it will not be clear whether the highest count is an outlier caused by a rare event, or if it is actually indicative of meat with high numbers of bacteria

There are limitations to the number of pathogenic bacteria that can be killed during different processing stages of making UCFM. If high levels of pathogenic *E. coli* are present in the in-going raw ingredients, the cells may survive the process to cause serious illness to consumers, as the UCFM process does not involve a microbial kill step (e.g. cooking).

Appendix 2: Determination of pH

(Based on the *Amendment No. 68* to the Food Standards Code (Food Standards Australia New Zealand, 2003))

Standard method (Food Standards Code Standard 1.6.2)

Mince a representative portion of the sample of the UCFM product and place that portion in a stoppered bottle with twice its weight of water. Shake at 5 minute intervals for 30 minutes and determine the pH value of the liquid electrometrically at 20°C.

Alternative method

pH can also be determined through the use of calibrated, direct-contact pH probes or spear electrodes. They should be standardised against Food Standards Code Standard 1.6.2 to confirm their accuracy and suitability for determining pH of UCFM products.

When testing is done by inserting probes or spear electrodes, it is essential that it is done aseptically so that microorganisms are not introduced into the product.

Indicator strips have generally proved to be unsuitable for measuring the pH of fermenting products, as there may be problems establishing adequate contact between the indicator pad and the product. The fat in the product may coat the indicator pad and prevent liquid from the product reacting with the indicator.

Appendix 3: Monitoring weight loss

(From the MLA Guidelines for the Safe Manufacture of Small goods (Meat & Livestock Australia, 2015))

(1) Make sure your scales are accurate and calibrated. It is no use putting a 150 g sausage on a scale which weighs up to 50 kg – the accuracy will not be enough to support your validation.

(2) Weigh a representative sample – 10 sticks from a batch should be sufficient.

(3) Tie a label on each stick and write the starting weight and the date on it.

(4) Each time you weigh the stick, write the new weight and the date on the label.

(5) Do not just average the 10 weights because that only allows you to say "on average my product has the correct weight loss".

(6) Keep each individual weighing – this will tell you how variable your process is. If it is so variable that some sticks are too moist to be released you will need to find out why there is uneven drying.

(7) Record and retain the results.

(8) During validation of the process, you can check the weights against the a_w to confirm the recipe is producing the necessary reduction.