Food Safety
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33

GUIDANCE NOTE

Good Manufacturing Practices for the Production of Ready-to-eat Raw Fermented Meat Products

Guidance Note No. 33: Good Manufacturing Practices for the Production of Ready-to-eat Raw Fermented Meat Products

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1. GLOSSARY

For the purposes of this guidance document the following definitions will apply:

Back sloping is the use of a natural/previously used wild starter culture in fermentation.

Batch (production batch) is a clearly identified volume or quantity consisting of one or more saleable units sharing a common process, common ingredients, packaging and services.

Casings are edible tubing prepared from natural and artificial materials that are used to contain and hold the meat batter during fermentation and ripening.

Curing is a treatment of meat which uses salt (sodium chloride), sodium or potassium nitrates or nitrites and other ingredients (often referred to as a cure, brine solution or pickle) to draw out water (moisture) from the meat by the process of osmosis. Curing of meats is used for food safety reasons (i.e. slowing or preventing growth of bacterial pathogens) and extension of product shelf life. However, the use of nitrites in the curing solution is also used to develop the characteristic colour, flavour and texture of cured meat products.

Good manufacturing practices (GMPs) are the general operating conditions (i.e. procedures, equipment, facilities, and controls) within the food business manufacturing the food product which help ensure that the appropriate conditions for the production of consistently safe food are maintained.[1–3]

Fermentation is primarily a process by which sugar is broken down to acid by microorganisms (typically added as a starter culture) present in a meat batter. The process of fermentation aids food safety and helps develop product characteristics such as flavour, texture and colour.

Meat batter is the total ingredients (e.g. mixture of lean meat, fat, salt, nitrite, sugars, spices and other ingredients) used in a fermented meat recipe which are combined together before stuffing into casings, fermentation and ripening.

pH is a measure of a product's acidity or alkalinity with a scale that extends from 0 to 14, with the relative strengths of acid and alkaline defined by their pH value on this scale (i.e. pH of 7 is neutral, less than 7 is acidic and greater than 7 is alkaline). The pH scale is logarithmic, meaning that each one point change in pH is 10 times more acidic or less acidic (e.g. pH 6 is 10 times more acidic than pH 7).[4]

Redox potential (Eh) is a measure of the tendency of a chemical species to acquire electrons and thereby be reduced. The Eh of a food determines which type of microorganisms will grow in it, depending on whether they require oxygen for growth (aerobic) or not (anaerobic).[4]

Relative humidity is the concentration of moisture in the atmosphere surrounding a food. Typically, there is an exchange of moisture between a food and its atmosphere which continues until the food is in equilibrium with the surrounding atmosphere. As such, the relative humidity can affect the A_w.[4]

Ripening, ageing or maturation is the process of storing meat products under controlled conditions for a specific time to ensure product safety and develop the required sensory and quality characteristics of the fermented meat product.

Raw fermented meat products are meat products manufactured by a series of process steps which involve stuffing raw cured meat, fat and other ingredients (e.g. salts, nitrite, spices, sugars, microbial starter cultures, etc.) into natural or synthetic casings which are then fermented and dried (matured) under defined conditions. Some raw fermented meat products are also smoked, but none are subjected to heat treatments effective to eliminate or reduce microorganisms of concern to an acceptable level.

Ready-to-eat means a food product intended by the producer or the manufacturer for direct human consumption without the need for cooking or other processing effective to eliminate or reduce microorganisms of concern to an acceptable level.[5]

Shelf life is the period of time over which a food maintains its safety and/or quality under reasonably foreseeable conditions of distribution, storage and use. The shelf life of a food begins from the time the food is produced and/or packed.[4]

Starter culture is a preparation of microorganism(s) used in meat fermentation to break down sugars to acid. The majority of raw fermented meat manufacturers use commercially available starter cultures.[6]

Water activity (A_w) refers to the free or available water within a food that is not bound to food molecules (i.e. water that is available in foods to support microbial growth). A_w has a scale from zero (0% water available) to one (100% water available).[4]

2. SCOPE

This document is applicable to ready-to-eat raw fermented meat products, as defined in the Glossary, which are distributed, sold and consumed raw. The following are outside the scope of this guidance document:

- Raw meat products which do not have fermentation step *(e.g. raw cured and/or dried hams such as Italian Parma or Spanish Serrano/Iberian hams)*
- Fermented meat products which have received a treatment such as heating designed to eliminate or reduce to safe levels any pathogens of concern
- Fermented fish, dairy and vegetable products.

3. INTRODUCTION

Before the widespread application of refrigeration, the shelf stability of many fermented meat products made them popular foods as a source of protein. Many of the traditional European products originated from Southern European, such as Italy and Spain, and were heavily spiced but not smoked. In Northern European countries, many of the products were less spiced but smoked.[7]

In Ireland, there is no established history of producing raw fermented meat products, unlike other European countries.[7–8] However, in recent years, a growing number of raw fermented meat products have appeared on the market. Many of these products are produced in small food businesses by artisans borrowing from techniques derived from Northern and Southern European traditions.

As many fermented meat products are not subjected to any heat treatment during manufacturing, and in most cases are distributed and consumed raw, their safety relies heavily on the ingredients used, the experience of the food business and its understanding of the complex interactions that take place during the production of raw fermented meat products.[9–10]

The manufacture of raw fermented meat products typically involves the mixing of chopped/minced lean meat and fat with salt, curing agents, starter cultures, sugar, spices and other ingredients to form a meat batter. The meat batter is then stuffed into casings and is fermented and dried over a period of time to mature.[6]

Raw fermented meat products develop their characteristic sensory properties of flavour, texture and appearance through the fermentation processes and subsequent ripening (maturing) step. During fermentation, sugars present in the meat batter can be converted to lactic acid by lactic acid bacteria which are naturally present and/or added as starter cultures. The lactic acid (which includes the lactic acid produced in meat *post-mortem*) lowers the pH of the meat batter. At the same time, water migrates to the product surface, evaporates and lowers the water activity (A_w).[9]

Many raw fermented meat products are ambient or shelf-stable, which is a consequence of the combination and control of product characteristics that work together to ensure product safety.[11] These characteristics, which include A_w, pH, redox potential (Eh), humidity, use of preservatives, etc., are referred to as hurdles.[4, 12, 13] Further detail on hurdles is provided in Appendix 1.

However, despite the presence of hurdles, pathogens such as *Listeria monocytogenes, Verotoxigenic Escherichia coli* (VTEC) and *Salmonella spp*. may occur in these products via contaminated ingredients, processing equipment or the processing environment. In addition, some of these pathogens may be introduced as a consequence of post-processing contamination and cause foodborne illness. Thus, the extent to which raw fermented meat products are considered safe is primarily dependent on the application of good manufacturing practices (GMPs) by the manufacturer.[3, 6, 14]

4. CONDITIONS OF OPERATION

If a food business handles and/or processes foods of animal origin, it may need approval from the relevant competent authority. In the context of this document examples of such food businesses would include slaughterhouses, meat processers and meat product manufacturers.

Details of the approval process are available from the Food Safety Authority of Ireland (FSAI). Businesses requiring approval must be approved before commencing trade. Food businesses should contact the competent authority for advice at the earliest stage of their business development. Approval takes into account plans, premises, waste management, processes, Hazard Analysis and Critical Control Point (HACCP), products and throughput, among other things.

Once a food business has been approved it will be given a unique approval number which will either be stamped directly onto a carcass or cut of meat after slaughter in the form of a health mark or will appear on product packaging or labels as an identification mark.

Details of competent authorities responsible for registering and approving food businesses can be found on the FSAI website.

5. LEGISLATION

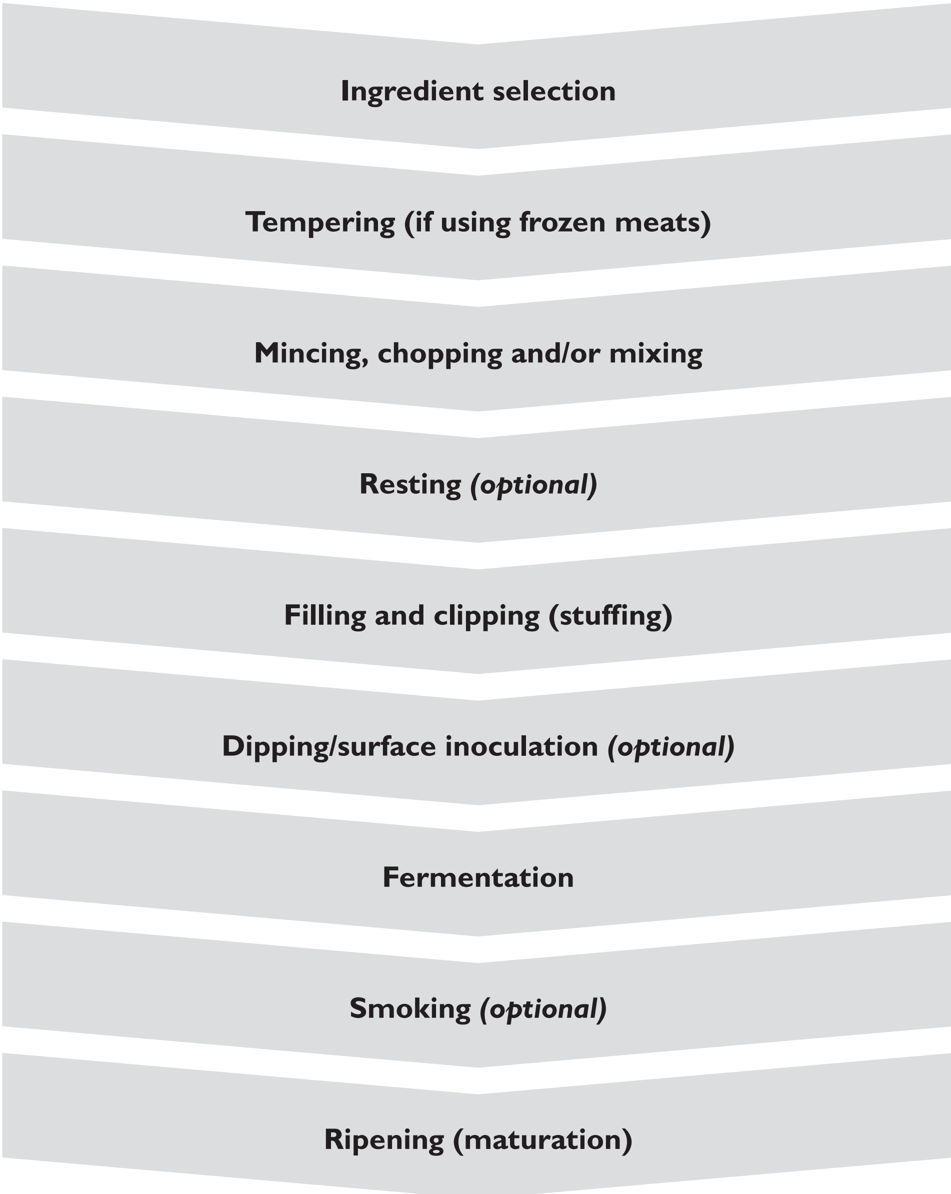
Under European Union (EU) legislation, all food businesses have a legal obligation to ensure that the foods they produce are safe and protected against contamination.[15] They must comply with any relevant EU and national legislation relating to the control of hazards in the production of food products and associated operations.

All legislation and FSAI publications referred to in this document are available on the FSAI website.

6. MANUFACTURE

The manufacture of raw fermented meat products is largely the same worldwide and involves a series of process steps, some of which are optional depending on the product being produced. Differences between products arise due to the nature of ingredients, recipe, degree of mincing (i.e. *grinding*), chopping and mixing as well as other variables such as temperature, air velocity and humidity, which control the fermentation and ripening. Figure 1 outlines the common steps:[6]

Figure 1 Steps in the manufacture of raw fermented meat products



6.1 Ingredient selection

This section provides guidance on specific control measures which can be used by raw fermented meat manufacturers to facilitate GMP during all production steps. All ingredients will have a natural level of microbial contamination present, which will vary depending on their origin and batch. As the ingredients are mixed together, handled and processed, the extent and nature of contamination will change.

An assembled meat batter used to produce a raw fermented meat product will contain a wide variety of microorganisms, many of which are beneficial, whereas others may cause product spoilage or foodborne illness. The use of poor-quality raw materials will affect both food safety and product quality. The main ingredients used in raw fermented meat products are outlined in the following sections.

6.1.1 Water

As the legal definition of food includes water intentionally incorporated into food during its manufacture, preparation or treatment, food businesses have a responsibility for the quality of water used directly as an ingredient in food production or indirectly in cleaning or processing during the processing of foods.[15–17]

Although only small amounts of water are added to raw fermented meat products, the quality of the water used by all food businesses must meet the basic standards governing the quality of drinking water (i.e. potable water) intended for human consumption as set out in Council Directive 98/83/EC and implemented in Ireland under the S.I. No. 122 of 2014.[17, 47]

Further information is available in the FSAI Factsheet on potable water quality for food businesses.[18]

6.1.2 Lean meat

It is important to use the freshest lean meat available.[6] Frozen meat can also be used, but it is important that the meat is frozen as quickly as possible after slaughter and butchering, and that it is held frozen for as short a time as possible before use *(i.e. meat that is frozen begins to oxidise immediately following freezing)*.

All meat should have good microbiological quality with low aerobic colony count (ACC), ideally $\leq 10^4$ colony forming unit per gram (cfu/g).[3, 14] High aerobic colony count can indicate temperature abuse and/or poor hygiene during handling of the lean meat, which can lead to the presence of pathogens. High microbiological levels will also compete for resources with added starter cultures and impact on their ability to facilitate fermentation. Regulatory requirements regarding microbiological criteria for raw fermented meat products are summarised in Appendix 2.

The percentage of lean meat to fat in raw fermented meat products can also be important for food safety, as it affects the amount of moisture or free water available (i.e. aqueous phase) in the product.[6] The more fat that is present, the less lean meat and the less water, which increases the effective concentration of water-soluble ingredients such as salt, nitrite, sugar, etc. on a weight-for-weight basis. This in turn impacts on microorganisms' ability to grow.[19]

Typically, raw fermented meat products will have between 20% and 35% fat and between 65% and 80% lean meat from one or more animal species.[6] As lean meat contains approximately 70–80% water (by weight), it can mean that products with a 30% fat content have a free water content approaching only 50%. This can double the effective concentration of water-soluble ingredients in the product, assuming that the water-soluble ingredients are fully dissolved and that the dissociated species are the ones with activity.[9]

Lean meat can come from a wide variety of species, with pork and beef the most commonly used. Italian and Spanish raw fermented meat products typically only use pork, whereas many German products use a combination of pork and beef. For many raw fermented meat products, the use of meats from older, more mature animals is desirable, as it benefits sensory characteristics of the product such as colour. But more importantly, from a product safety perspective, meats from older, more mature animals have less water, which facilitates the drying of products during ripening.[6]

In the United States, the use of poultry meat such as chicken and turkey, in addition to pork and beef, in products is also common. But the variety of meat used will vary considerably between countries. It is very important that meat used in raw fermented meat products has reached its final *post-mortem* pH value before use. Typically, this will be less than pH 5.8, or approximately 5.4 for beef and 5.7 for pork.

For many raw fermented meat products, a final pH after fermentation of 5.3 is considered acceptable for microbiological food safety. If higher pH meat is used (i.e. pH >5.8), or if a product of lower final pH is required, more sugar will need to be included in the product recipe. The following is recommended when choosing lean meat for use in raw fermented meat products:

- All lean meat should have good microbiological quality with low (ACC) ideally $\leq 10^4$ cfu/g.
- Ensure that all meat complies with the requirements of Regulation (EC) No 2073/2005.[5]
- Avoid using cheap meats and trims, due to higher levels of microbial contamination.
- Use meat that has reached its final *post-mortem* pH value. Some manufacturers will check the pH of the meat before starting production.
- Use meat that has been chilled as fast as possible to <5 °C (ideally within 24 hours).
- Use meat stored at a low temperature before use (ideally between -1 °C and 0 °C).
- If using frozen meat, ensure that freezing took place quickly after slaughter and butchering, and that the meat is held frozen for as short a time as possible before use.
- Trim meats to remove excess fat, sinews and soft intramuscular fat.
- Define the lean meat to fat ratio for the product recipe.

6.1.3 Fat selection

While fat is used to produce specific sensory attributes in raw fermented meat products, it is also important in the ongoing release of moisture throughout the fermentation process, thus ensuring consistency of product. Fresh chilled pork back fat is the most commonly used fat, as it is a firm, dry fat that is relatively stable without pronounced rancidity even after prolonged ripening periods.[6, 9] The following is recommended when choosing fat for use in raw fermented meat products:

- Use fat with low levels of microbial contamination.
- Use frozen fat (*approximately -10 °C to 12 °C*) if possible.
- Avoid using soft fats, as they can lead to the development of rancidity or colour instability in the final product.

6.1.4 Salt

Salt (sodium chloride) is added to raw fermented meat products for food safety, preservation, flavour, solubilisation of proteins to improve structure and product yields, and as a carrier for curing salts.

The average quantity of salt added to raw fermented meat products should be between 2.5% and 3% weight per weight (w/w).[9] However, it can be higher in some products, although excess salt may prevent the added starter culture lactic bacteria from producing lactic acid, thus impacting on the effectiveness of fermentation and increasing food safety risks.

From a food safety perspective, salt will draw water away from the meat and reduce the A_w. The addition of 3% salt will initially reduce the A_w from ≥0.99 to ≤0.97. Water loss and shrinkage which occurs during manufacture of raw fermented meat products will further lower the A_w and therefore increase the salt in water concentration (*i.e.* >4%) of the final product.[19] This will help minimise the growth of undesirable microorganisms, particularly pathogens.

6.1.5 Nitrates and nitrites (curing salts)

Curing salts are added to raw fermented meat products for the following reasons:

- Development of the characteristic cured pink colour of fermented meat products
- Support the establishment of indigenous lactic acid bacteria to aid fermentation
- Flavour development *(although the mechanism is not fully understood)*
- Antioxidant effect *(i.e. binds to iron, preventing its use as a pro-oxidant)*
- Preservation/food safety effect.

From a preservation/food safety perspective, nitrite, in combination with salt and pH, is used in cured meats to ensure their safety with respect to a number of pathogens including *Clostridium botulinum*. To cause illness, spores of *Cl. botulinum* have to be able to germinate and then grow in the meat product until a point at which *botulinum* toxin is produced by the bacteria. Nitrite exerts a concentration-dependent antimicrobial effect in meat products, including inhibition of the outgrowth of spores of *Cl. botulinum*. This effect is also pH-dependent, increasing tenfold for each unit fall in pH.[4]

The use of nitrates and nitrites in food products must comply with the provisions set out in Annex II part E of Regulation (EC) No 1333/2008 on food additives, which is in force since 1 June 2013.[20] This Regulation was transposed into Irish law by S.I. No. 330 of 2015.[21] The maximum levels of nitrates and nitrites that may be used, and also the specific foodstuffs in which they may be used, and their conditions of use, are also established by Regulation (EC) No 1333/2008 as amended.[20] These levels are set at values which ensure that a person consuming a typical diet would not exceed the Acceptable Daily Intake (ADI) established for these additives. Purity criteria have also been established for nitrates and nitrites via Regulation (EC) No 231/2012 as amended.[22]

Two main nitrite and nitrate salt forms are allowed. These are sodium and potassium nitrite and sodium and potassium nitrate. These substances have the E numbers (E250, E249, E251 and E252, respectively). In accordance with EU legislation, nitrates and nitrites are permitted for use in certain foods such as meat and may only be sold in a mixture with salt or a salt substitute when labelled for food use. This is designed to limit the amount of nitrite that can be added, and to prevent accidental poisoning through the addition of excessive quantities of nitrite to food.[20]

Sodium nitrite is commonly used as the curing salt in modern production of raw fermented meat products and in some cases with the addition of sodium or potassium nitrate also. However, the use of both nitrate and nitrite generally has the same results *(i.e. nitrate must first be reduced to nitrite by bacteria, which takes time, and therefore is more applicable to long-term ripened products, as the slow pH drop allows time for this breakdown by the bacteria).*

In products with a slow decrease in pH values and prolonged drying times, nitrate can be used. However, if only nitrate is used, the starter culture must be able to help convert the nitrate to nitrites *(i.e. nitrification)*. Further detail on curing is provided in Appendix 3.

6.1.6 Starter cultures

Raw fermented meat products can be produced without the use of commercial starter cultures. Back sloping is a term used to describe the use of a natural/previously used wild starter culture in fermentation. In traditional raw fermented meat products lactic acid bacteria were part of the natural flora of the meat batter.[6] Manufacturers would use low temperature *(i.e. approximately 12 °C to 22 °C)* to select for and control the growth of these bacteria from the natural flora. At the same time, low temperatures controlled the growth of spoilage and pathogenic microorganisms.

However, it is recommended that a commercial starter culture is used by manufacturers to improve consistency of product, control the process and ensure safety and quality.[23] Starter cultures are typically added to raw fermented meat products to help:[24]

- Product safety *(e.g. production of lactic acid, pH decline and rate of pH decline during fermentation; growth of starter culture outcompeting background microflora)*
- Product quality *(e.g. intensifies cured colour due to acid production; supports texture by helping protein gel formation adds flavour from the production of compounds such as diacetyl and acetoin)*.

Starter cultures are mainly blends of lactic acid bacteria species such as *Lactobacillus*, *Pediococcus* and *Streptococcus*, but may also include *Staphylococcus* and various yeast species. The precise makeup of a starter culture will largely depend on the type of raw fermented meat product being produced. However, each species will contribute different elements to lactic acid production, pH drop, flavour development, ripening, colour enhancement and product safety. The optimum fermentation temperature for starter cultures will also vary with species, from about 20 °C for *Lactobacillus* species to up to 45 °C for some *Pediococcus species*. The following is recommended when choosing a starter culture for use in raw fermented meat products:[6]

- Since all starter cultures have different requirements for nutrients, temperature, etc., it is important to seek advice on the use of starter cultures from a commercial supplier before beginning use.
- The starter culture chosen should be specifically produced for use in fermented meat products.
- The starter culture should contain microorganisms which
  - Are non-pathogenic *(i.e. microbiologically safe)*
  - Can compete successfully with naturally occurring microorganisms in the meat batter
  - Produce a controlled, rapid pH reduction in the meat batter
  - Naturally produce (in some cases) antimicrobials such as bacteriocins
- Follow all manufacturer's instructions for use and storage.
- Do not use starter cultures which have passed their shelf life.

6.1.7 Sugar

The sugar content of fresh, post-rigor pork and beef (i.e. approximately pH >5.9) meat is typically too low (approximately <0.1%) to facilitate fermentation. As such, sugar is often added in order to help with fermentation.[25] Sugars are broken down during fermentation by starter cultures to lactic acid, which in turn reduces the pH of the product. This drop in pH helps control microbial growth and is required to develop texture and flavour.

The type and quantity of sugar available to the starter culture during fermentation will directly affect the level of pH drop and the time to achieve the final or lowest pH, as starter cultures ferment different sugars in different ways. Simple sugars, such as glucose, are easily metabolised by lactic acid bacteria, but more complex sugars, such as lactose, are less easily metabolised.

In general, the best sugars to use are those that are easily fermentable and result in a rapid drop in pH. Dextrose (*i.e. glucose*) is commonly used and can be fermented directly into lactic acid by the majority of lactic acid bacteria used in commercial starter cultures, at between 0.5% and 1.0%, depending on the type of product. Lactose is also used for some products.[26]

The quantity of sugar required is largely dependent on the speed of fermentation required for a specific product, with less sugar required for slow-fermenting products than for fast-fermenting products. For example, in slow-fermented salami the pH does not generally drop lower than 5.3. But the product is microbiologically stable due to its low A_w.

The use of higher concentrations of sugar leads to a lower pH and stronger acidification in the product. Typically, 1 g (0.1%) of dextrose per 1 kg of meat can lower the pH of the meat by 0.1 pH. In practice, this means that 10 g of dextrose added to meat *(i.e. with an initial pH value of 5.4 post-mortem)* will lower the pH to 4.4. However, most raw fermented meat products will use sugar concentrations of 0.5%–0.7%, which will lower the pH to <5.0.[6]

In addition, the temperature of fermentation will also affect the quantity of sugar used, with low-temperature fermentation requiring less sugar to be added.[6] Sugar is also used in fermented meat products for flavour (although not for sweetness) and to reduce the A_w of the product. However, reductions in the A_w of the product will be minor and not sufficient to control microbial growth. The following is recommended when choosing sugar for use in raw fermented meat products:

- Only use the correct type and quantity of sugar as recommended by the starter culture supplier. This will help optimise the sugar to acid conversion by the starter culture and will facilitate the speed of pH drop and the final pH value reached in the product.

6.1.8 Spices

Spices such as pepper, paprika, cayenne, mace and cardamom are commonly used in raw fermented meat products for both flavour and colour at levels of ≤1%. In some Spanish chorizo products up to 2% paprika can be used.[6] Some spices can also aid fermentation due to their mineral content *(e.g. black pepper contains manganese, which facilitates growth of lactic acid starter cultures)*. Some research has also indicated the potential of certain spices to have an antimicrobial effect. However, the extent of these antimicrobial effects is variable and not fully understood.

Many herbs and spices are a potential source of microbial contamination. Spice products in particular can carry a high load of *Bacillus* species and may be a source of *B. cereus* spores, which can cause food poisoning.[27] The following is recommended when choosing herbs and spices for use in raw fermented meat products:

- If using fresh herbs and spices, purchase from a reputable supplier frequently and in small quantities.
- If using dried herbs and spices or their extracts, purchase varieties that have been treated to reduce bacterial contamination.
- In all cases, agree with the supplier a specification that limits microbial contamination. A typical microbiological specification for spices is given in Appendix 4.
- In all cases, use herbs and spices at the correct level, as they can inhibit some starter cultures.

6.1.9 Other ingredients

A wide range of other ingredients and additives can be added to the meat batter during manufacture, including:[6]

- Milk powders to enhance functional properties such as water binding
- Sodium caseinate for emulsification and stabilisation
- Sodium ascorbate to scavenge for oxygen, reducing its availability, stabilising product colour and preventing rancidity in the product (i.e. antioxidant)
- Whey protein concentrates to improve gelling characteristics
- Glucono-delta-lactone (GdL) and/or citric acid to rapidly reduce pH.

In the case of all the above ingredients and others, manufacturers should seek advice from a reputable supplier before beginning use and should ensure that only permitted additives listed in Regulation (EC) No 1333/2008 on food additives are used, taking into account their conditions of use.[20] Food businesses should also be cognisant of the issues surrounding the use of allergenic ingredients in raw fermented meat products, particularly in labelling. Further information on allergens and other labelling information is available on the FSAI website.

6.1.10 Casings

Casings are edible tubing prepared from natural and artificial materials that are used to contain and hold the meat batter during fermentation and ripening. There are many different types of natural and artificial casings available and manufacturers will optimise the choice of casing material to ensure consistency of product quality and safety.

Natural casings are the intestines and bladders of farmed pigs, sheep, goats, cattle or horses, which after cleaning have been processed by tissue scraping, defatting and washing, and have been treated with salt.[53] Under EU legislation, casings are not defined as such, but they are considered to be part of the group definition of treated stomachs, bladders and intestines.[54]

Artificial casings are manufactured from materials of plant origin *(e.g. cellulose)*, animal origin *(e.g. collagen)* or synthetic materials *(e.g. polymers and/or various plastic materials)*. Synthetic casings are typically impermeable to gases and water vapour and, as such, are not used in the manufacture of raw fermented meat products.

The diameter of casings used for raw fermented meat products varies enormously, but typically ranges from 30 mm to 80 mm. The diameter of the casing is important, as it affects the speed and duration of drying and smoking. In products which have mould applied *(i.e. dipping)*, small-diameter casings are required in order to ensure that sufficient oxygen is available to allow mould growth.[6] The following is recommended when choosing a casing for use in raw fermented meat products:[10]

- The production of natural casings should follow guidance issued by the European Natural Sausage Casings Association.[53]
- Natural casings should be sourced from a reputable supplier and used as per supplier instructions.
- Artificial casings should comply with Regulation (EC) No 1935/2004 and other relevant legislation on materials and articles intended to come into contact with food.[28] The FSAI has produced a factsheet on food contact materials which provides further information for food businesses.[29]
- Only approved additives listed in Regulation (EC) No 1333/2008 on food additives should be used in casings.[20]
- Casings should be strong enough to prevent bursting during the stuffing step.
- Casings should be permeable to facilitate the drying step.
- Casings should remain attached to the meat batter during shrinkage or expansion.
- Casings should be used and stored as per manufacturer's instructions.
- Casings requiring pre-soaking before use should be prepared as per manufacturer's instructions.
- Casings are typically sealed after filling, using metal clips or cord. Manufacturers should match the casing to the appropriate method of sealing before manufacture begins. It can be useful to test batches of the same product with different casings and metal clips or cord to obtain optimum product consistency.

6.2 Tempering (if using frozen meat)

Frozen meat is typically tempered at controlled temperatures between -5 °C and -1 °C to minimise microbial growth and stop fat from becoming soft, which can cause quality issues. Tempering should be carried out in a temperature-controlled and monitored chiller and can take a number of days to complete.

6.3 Mincing, chopping and/or mixing

Depending on the nature of the product, the meat and fat may be minced and/or directly chopped in a bowl chopper with the mixing of the other ingredients. In bowl chopping, the rotation speed of the bowl and knives will determine the desired particle size in the final raw fermented meat product. Most manufacturers will optimise this process to ensure consistency of product and control product temperature.

Typically, the lean meat *(pre-minced and/or chopped meats depending on product)*, starter culture, spices, sugar and other additives are added to the bowl chopper at the start of the process, with the fat and salt added at the end. Frozen fat is added at the end to ensure good differentiation of fat and lean meat in the final product. Salt is added at the end of bowl chopping to minimise extraction of soluble proteins from the meat, which can bind water and affect the efficiency of the drying during the ripening step of manufacture.

It is important to note that the process of bowl chopping and/or mixing will increase the temperature of the meat batter *(i.e. by friction)*, so the time duration of this step should be limited. Best practice is to ensure that meat batter remains at <2 °C or lower during and at the end of the process. Warming of the mixture can be minimised by using well-chilled meat and frozen fat. After mincing, chopping and/or mixing, the meat batter should be rested at <2 °C or lower, or immediately stuffed into casings.

Where raw fermented meat products are produced by mincing and mixing only, the meat and fat are coarse ground, added to a paddle mixer with spices and the starter culture, and initially blended. Later, during blending, the salt is added and, finally, fat similar to the bowl-chopped product is added. This blended meat batter is then ground to the final piece size desired, which can range between 3 mm and 30 mm.

As with bowl chopping, mincing or mixing will increase the temperature of the meat batter, so the time duration of this step should be limited. Best practice is to ensure that blended meat batter remains at <2 °C or lower (ideally -1 °C to give good definition and clean cutting) during and at the end of the process. After blending, the meat batter should be rested at <2 °C or lower, or immediately stuffed into casings.[6]

6.4 Resting (optional)

Resting or conditioning is an optional step which follows mincing, chopping and/or mixing. Resting of the meat batter has been shown to improve nitrification, allow better distribution of nitrites within the product, improve consistency and decrease the redox potential which promotes the growth of starter cultures during fermentation.

6.5 Filling and clipping (stuffing)

The meat batter should next be stuffed firmly into an appropriate type and size of casing and clipped tight with metal clips, cord or twine. It is recommended that stuffing is carried out under vacuum to minimise the presence of air, which helps product shelf life, inhibits spoilage microorganisms and promotes starter culture growth. Microorganisms present in the meat batter will quickly consume any oxygen present, which decreases the redox potential, thus promoting the growth of starter cultures during fermentation. Additives such as sodium ascorbate can also be added to scavenge for oxygen, thus reducing its availability and preventing rancidity (See Section 6.1.9).

It is also recommended that stuffing is carried out with temperature control to prevent quality defects such as fat smearing, which can impede moisture loss during the ripening step.

After stuffing and clipping, products are hung, evenly spaced on racks or trolleys to facilitate efficient air circulation during fermentation, even drying and smoking, if used. Immediately after stuffing and clipping, the meat batter is still at a very low temperature (*i.e. <2 °C*). At this point before fermentation begins it is recommended that manufacturers include a period of tempering (approximately ≤3 hours) at room temperature. This allows for temperature equilibration, which helps prevent water condensation on the surface of the casing. Condensation will occur if cold product goes straight into the warm, humid fermentation chamber and can cause surface discolouration of the product. Tempering at room temperature will also provide the conditions necessary for the starter culture to begin growing.[9]

Following tempering, products are then transferred to the fermentation room. Procedures should be in place to prevent cross-contamination of product during transfer to the fermentation room.

6.6 Dipping/surface inoculation (optional)

Some varieties of raw fermented meat product are inoculated with mould *(e.g. Penicillium spp.)* following stuffing/clipping by spraying mould on the surface or dipping directly into a solution of mould spores. The mould will grow on the product surface and is used to give products a white or grey appearance and also characteristic flavours, texture and aroma. The mould coating can also be used to control the rate of drying in some product varieties. It is important to note that the type of casing used will influence the growth of moulds. The following is recommended when choosing and using moulds in raw fermented meat products:

- Since all moulds have different requirements for nutrients, temperature, etc., it is important to seek advice on their use from a commercial supplier before beginning use.
- The mould culture used should be specifically produced for use with fermented meat products.
- The mould culture should contain microorganisms which
  - Are non-pathogenic *(i.e. microbiologically safe)*
  - Can compete successfully with naturally occurring microorganisms
  - Produce the appropriate product characteristics
- Follow all manufacturer's instructions for use and storage.
- Do not use mould cultures that have passed their shelf life.
- If producing products without mould in the same facility, procedures will need to be in place to avoid cross-contamination of products with mould spores, such as separating the application area from the rest of the facility and/or using air filtration systems.

6.7 Fermentation

The fermentation step is where the pH of the product decreases to its lowest value *(i.e. optimal acidification)*. When it has reached this value, the fermentation step is completed. Stuffed and clipped products are moved on their rack/trolleys to the fermentation room/chamber. A number of factors will have an impact on the fermentation process and require control at this step or in previous manufacturing steps.[6] These factors include the following:

- Nature, choice and handling of starter culture
- Level of starter culture inoculation
- Level of microbial contamination in meat batter
- Sugar concentration in meat batter
- Initial pH of meat batter
- Speed *(i.e. time)* of pH drop to final pH
- Final pH of product
- Salt level and A_w of meat batter
- Nitrite concentration of meat batter
- Type of casing holding meat batter
- Diameter *(i.e. calibre)* of casing holding meat batter
- Presence of mould on casing holding meat batter
- Temperature of fermentation chamber
- Humidity of fermentation chamber
- Air velocity *(i.e. speed of airflow over the product)* in fermentation chamber
- Air flow/balance and loading pattern of the fermentation chamber.

The above conditions and duration of fermentation are typically set by the manufacturer, based on the type of raw fermented meat product being produced. It is recommended that all these conditions are established and documented by the manufacturer as part of their validation process. Validation is a key step required in the development of HACCP-based procedures for raw fermented meat products. Every batch of product produced thereafter should then comply with the same conditions. The rate and extent of fermentation should be monitored by measuring the pH, using a calibrated instrument, at regular intervals during fermentation on every batch of product.

6.7.1 pH

Fermentation uses lactic acid bacteria from the starter culture to convert sugar to lactic acid, which reduces the pH of the meat batter. Typically, a high fermentation temperature in the chamber and a high A_w in the meat batter will increase the growth of the starter culture, thus rapidly producing lactic acid and reducing the pH.

It is recommended that the final pH of the product is at least <5.3 (although the pH is typically ≤5.0) and is achieved within a defined time period *(i.e. range from ≤12 hours to ≥48 hours)* to prevent pathogens from growing. The decrease in pH also allows coagulation of proteins to occur, reducing water-holding capacity of the meat batter and allowing for more efficient product drying during ripening. Further detail on monitoring pH is provided in Appendix 5.

6.7.2 Temperature

Ideally, the temperature of the meat batter should increase as fast as possible to the starter culture's optimum value, which will allow the starter culture to grow and out-compete the natural microflora in the meat batter. In Europe, *(e.g. Germany, Italy, etc.)* temperatures of between 18 °C and 24 °C for between one and three days are commonly used during fermentation, depending on the product style/variety. In some traditional French and Spanish products, fermentation temperatures can be ≤17 °C for up to seven days. In the United States, where faster production times are the preference of the industry, temperatures can be as high as 28 °C to 42 °C in order to decrease fermentation time to ≤10 hours. Further detail on monitoring temperature is provided in Appendix 5.

6.7.3 Relative humidity and air velocity

A high relative humidity *(approximately 90–95%)* coupled with low air velocity *(i.e. 0.8 to <1 m/s)* is required at the start of fermentation to allow the starter culture to grow and prevent the casing from drying out too quickly. As the fermentation precedes the temperature in the fermentation room it is gradually decreased by a few degrees (depending on the product) and the relative humidity is decreased to 80–90% before the product is ready for the next step in the process.

It is important to control humidity carefully. If it is too high, there will be excessive surface moisture, resulting in bacterial growth and slime production. If it is too low, it will result in case hardening and cracking of the product from the centre out. As a rule of thumb, the relative humidity of the air should be maintained approximately 2–5% below the A_w of the product during fermentation. Thus, if a product with an A_w of 0.95 is being fermented, the relative humidity of the fermentation room should between 90% and 93%.[9, 30] Further detail on monitoring relative humidity and air velocity is provided in Appendix 5.

6.8 Smoking (*optional*)

Smoking is sometimes used in the manufacture of raw fermented meat products, particularly in Northern European countries, as the drying conditions are less favourable than in Southern European countries. This is because while smoking provides flavour/aroma to products, it also is antimicrobial and stops the growth of undesirable mould on the surface of products.

For most raw fermented meat products cold smoking is used in the first days of fermentation. The temperature of the cold smoking process should be similar to the fermentation temperature. Otherwise, the fermentation process within the product will be affected. The duration of smoking is determined by the characteristics required for the product

In some cases, manufacturers may use smoke flavourings instead of traditional smoking to provide smoked flavour in raw fermented meat products. As with additives and other ingredients, manufacturers should seek advice from a reputable supplier before beginning use of smoke flavourings. Manufacturers should ensure that only permitted smoke flavourings are used, taking into account their conditions of use. [31–33] Further information on smoke flavouring is available on the FSAI website.

6.9 Ripening (maturation)

The ripening (maturation) step is the period of time from the end of fermentation to the point where the product's A_w has decreased to its lowest value (i.e. optimal A_w) and the desired weight loss for the product has been achieved. The fermented stuffed and clipped products are moved (or can remain in same room) on their rack/trolleys to the drying chamber for ripening. The rate and amount of drying achieved during ripening (although some drying takes place during fermentation) is dependent on a number of factors which require control at this step and in previous manufacturing steps, including:[6]

- Final product pH following fermentation
- Fat content of product *(i.e. increasing fat will decrease rate of drying)*
- Density of product *(i.e. denser products such as vacuum-stuffed products will dry faster as the air has been removed, allowing moisture migration to increase)*
- Temperature of drying chamber
- Humidity of drying chamber
- Air velocity in drying chamber
- Air flow/balance and loading pattern of drying chamber
- Type of casing used for product
- Diameter *(i.e. calibre)* of product *(i.e. larger products take longer to dry)*
- Desired ripening time.

The above conditions and duration of ripening are typically set by the manufacturer, based on the type of raw fermented meat product being produced. It is recommended that all these conditions are established and documented by the manufacturer as part of their validation process. Validation is a key step required in the development of HACCP-based procedures for raw fermented meat products. Every batch of product produced thereafter should then comply with the same conditions.

The rate, duration and extent of drying during ripening should be monitored by measuring the A_w and/or weight loss of the product using calibrated instruments at regular intervals during drying on every batch of product (Appendix 5). The rate, duration and extent of drying will vary enormously depending on the product type.

Some moist, short-maturing products such as German Mettwurst have little or no ripening period, as most drying is achieved during fermentation, with small weight losses of between 10% and 15% normal. As the A_w of these products is still high (i.e. ≥0.95), they rely on a low final pH (i.e. typically ≤4.4) to maintain their food safety and shelf stability. However, for the majority of raw fermented meat products the ripening step is anywhere from <12 days to >60 days.[10]

Drying essentially starts during the fermentation step, with high relative humidity *(approximately 90–95%)* and low air velocity. This allows moisture to evaporate from the surface of the product casing but prevents surface hardening. In the ripening chamber the temperature is held between 12 °C and 18 °C, with a relative humidity of between 80% and 90% *(although it can be as low as 70–75%)* and a low air velocity *(i.e. ≤0.5m/s)*.

However, all these parameters vary considerably depending on the product type. It is very important for both food safety and quality that manufacturers achieve uniform drying of products during the ripening step. The rate of moisture loss from the surface of the product during drying should not be higher than the rate at which the moisture moves from the inside of the meat product to the surface. If moisture loss from the surface exceeds moisture movement from inside the product, defects such as case hardening and dry rim will occur.[6]

From a food safety perspective, case hardening can prevent water movement to the surface, which in turn affects the overall A_w of the product. As a rule of thumb, the relative humidity of the air should be maintained approximately 5% below the A_w of the product during drying. As the drying process continues and the rate of moisture decreases, the differential between the relative humidity of the air and A_w of the product can increase by up to 10%.[9, 30] Further detail on monitoring A_w is provided in Appendix 5.

7. CLASSIFICATION OF RAW FERMENTED MEAT PRODUCTS

The traditional manufacture of raw fermented meat sausages in different countries over many years has resulted in hundreds of different varieties of products worldwide. Notwithstanding the huge variety of products, the terminology used with raw fermented meat products is often a confusion of historic, regional, seasonal and political nomenclature *(e.g. traditional Polish Keilbasa sausage is often referred to as salami outside Poland)*, all of which makes classification of these products difficult. However, a broad classification of products based on the degree of drying is given on the opposite page in Table 1:[7, 9,10, 23, 34–39]

Table 1 Broad classification of raw fermented meat products [a]

Category [b]	Final pH	Final A_w	Fermentation temperature (°C)	Fermentation time (Days) [c]	Ripening temperature (°C)	Ripening time (Days)	Weight loss (%)	Product examples
Moist *(short maturing)* [d]	≤4.4 to 4.6	≥0.95	≤28 to 38	2 to 3	<16	<3 to 14	10 to 15	German Mettwurst, Spanish Sobrasada
Semi-dry [e]	4.4 to ≤ 5.3	0.90 to 0.95	≤18 to 24	<1 to 3	10 to 16	10 to ≥20	20 to 30	Most products made in Germany, the Netherlands, United States and Scandinavia
Dry [f]	5.3 to ≤5.8	≤0.90	≤16 to 18	<1 to 7	12 to 16	≥20 to 60	≤30	Italian Salami (Milanese, Calabrese), Saucisson Sec, Hungarian Salami
Very dry *(long maturing)* [g]	≤5.8	<0.80 to ≤0.90	≤16 to 18	5 to 7	≤12 to 16	≥60	≥30	

[a] All values are approximate and are used for illustration purposes only. Values will vary considerably depending on product type and manufacturing process.

[b] Many products in the United States are typically cooked, no cure added, fermented at >32 °C for <15 hours to a final pH of 4.8, smoked, no mould added, with final product produced in 10–20 days. Products in the United States can be defined as dry when the A_w is <0.90 and semi-dry when the A_w is between 0.90 and <0.95 e.g. *American Pepperoni*; *Bologna*.

[c] Typically <1 day = very fast fermentation; <3 days = fast fermentation; >3–5 days = normal fermentation; 5–7 days = slow fermentation

[d] Fast fermentation and short ripening times are normal.

[e] The pH of these products makes them very acidic, with a characteristic tangy flavour.

[f] The final pH of these products is usually higher than semi-dry varieties and can increase during a long ripening process.

[g] Typically matured at low temperatures of 12–15 °C to a final moisture content of between 30% and 35%.

8. SHELF STABILITY OF RAW FERMENTED MEAT PRODUCTS

If properly manufactured, many raw fermented meat products can be sold as ambient ready-to-eat meat products that do not require refrigeration *(i.e. shelf-stable)*. The safety and shelf stability of these raw fermented meat products is due to a combination of hurdles whose interaction minimises or inactivates the growth of pathogens in the product (Appendix 1).

The most important hurdles for raw fermented meat products are pH and A_w. However, the presence of salt, nitrates and nitrites *(i.e. curing salts)*, a low redox potential, a competitive starter culture and good manufacturing practices also contribute to food safety and product stability.[40]

For a raw fermented meat product to be considered shelf-stable, the ingoing amount of nitrite should be between 50 and 150 ppm nitrite,[1] contain 2.5% of salt, and meet one of the following specific requirements for pH and/or A_w:[1, 11, 19, 23, 38, 39, 41–43]

- The pH of the finished product is ≤4.6 (ideally ≤4.4) regardless of the A_w.
- The A_w of the finished product is ≤0.85 regardless of the pH[2].
- The pH of the finished product is ≤5.3 at end of fermentation and the A_w is ≤0.90.

Any raw fermented meat products that do not meet these requirements must be labelled with a refrigeration statement and stored at <5 °C. Manufacturers can propose other combinations of pH and A_w hurdles for raw fermented meat products, but they must be able to scientifically validate and document these hurdles if required to do so by the competent authority. It is very important that the levels of pH and A_w are measured accurately using calibrated instruments. Further detail on monitoring of pH and A_w is provided in Appendix 5 and also in FSAI Guidance Note No. 18 on validation of product shelf life.[4]

[1] In a 2003 opinion, the European Food Safety Authority (EFSA) indicated that levels of nitrite between 50 and150 mg/kg are necessary to inhibit the growth of *Cl. botulinum*. These levels aim to keep exposure to nitrosamines as low as possible while maintaining the microbiological safety of food products. In addition, in line with the EFSA's recommendations, controls on the level of nitrites and nitrates in meat products are usually based on ingoing rather than residual amounts in the product. In 2017, the EFSA re-evaluated nitrates and nitrites intentionally added to foods. They concluded that the existing safe levels for nitrites and nitrates are sufficiently protective for consumers [41, 44–46]

[2] All these values are erring on the side of caution. In many cases, less strict values could be considered. For example, in Australia, shelf-stable is considered to be ≤0.92.[38]

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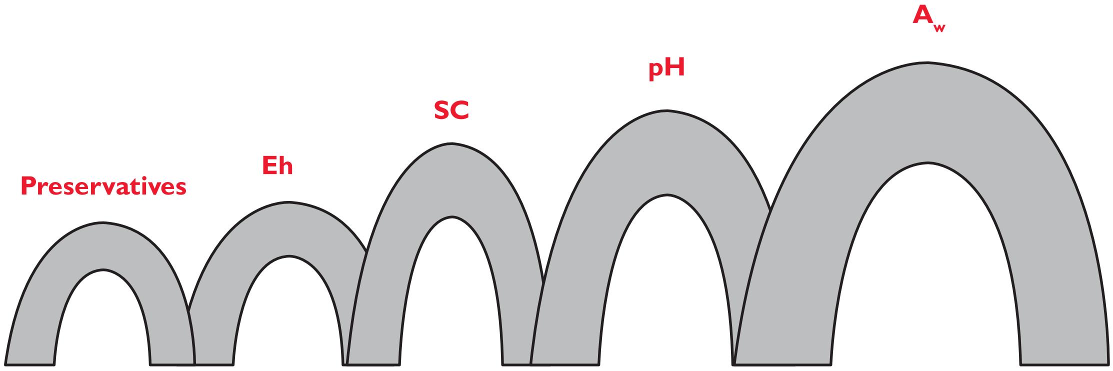
APPENDIX I HURDLES

A sequence of hurdles is used in the manufacture of raw fermented meat products to produce a consistent and safe food. A typical sequence of these hurdles is outlined in Figure 2.

Figure 2 Typical hurdles in raw fermented meat products



Where: Preservatives (e.g. salt, nitrite); Eh = redox potential; SC = starter culture *(i.e. competitive microflora)*; pH = acidity; A_w = water activity. Adapted from[12]

The first hurdle is the addition of preservatives such as salt and nitrite to inhibit *Cl. botulinum* in the raw meat batter. The redox potential (Eh) of a food determines which type of microorganisms will grow in it, depending on whether they require oxygen for growth (aerobic) or not (anaerobic). A food that is stored under aerobic conditions will typically have higher redox potential than foods stored under anaerobic conditions.[4, 12, 37]

The Eh is reduced by aerobic microorganisms present in the raw meat batter, which give a selective advantage to lactic acid bacteria present in the starter culture. The growth of the starter culture as a competitive microflora will help minimise the growth of pathogens by decreasing the pH of the meat batter and using up available nutrients.

The pH is the next hurdle in the process. How quickly and how much the pH drops in the meat batter is affected by temperature and how much sugar is available during the fermentation step. The final pH and the time to achieve that pH are determined by the type of product being produced. However, typically it is recommended that the final pH of the product is at least <5.3 and is achieved within a defined time period.

The A_w of the product will initially drop by a small level due to the addition of salt and sugar into the meat batter during mixing. More significantly, the A_w will drop during the ripening (maturation) step, thus becoming a very important hurdle. As with the pH, the final A_w and the time to achieve that A_w are determined by the type of product being produced *(i.e. product formulation, ripening temperature, relative air humidity, etc. in the ripening chamber)*.

APPENDIX 2 MICROBIOLOGICAL CRITERIA

As stated previously in this guidance document, the production of safe raw fermented meat products should focus on the application of GMPs. While routine testing of shelf-stable raw fermented meat products is not recommended,[48] the European Union has established legal microbiological criteria for foods under Regulation (EC) No 2073/2005.[5]

Under Article 3 of Regulation (EC) No 2073/2005, food businesses are required to ensure that foods comply with the relevant microbiological criteria and limits set out in the Regulation. As such, the Regulation specifies food safety criteria which define the acceptability of a product or a batch of foodstuff.[5]

When testing against food safety criteria provides unsatisfactory results, the product or batch of the foodstuffs must be withdrawn or recalled from the market. Furthermore, corrective actions at the production plant, according to procedures based on HACCP, shall be taken.[5]

While there is no specific food category for raw fermented meat products in Regulation (EC) No 2073/2005, they do fall under a number of broader food categories set out in the Regulation.[5]

Food businesses should also note that a number of process hygiene criteria are set out under the Regulation and may be relevant to the specific ingredients such as meats used in the manufacture of raw fermented meat products.[5]

In all cases, it is strongly recommended that food businesses producing raw fermented meat products consult with the competent authority to determine which criteria apply to their products.

In addition to the mandatory legal requirements set out in Regulation (EC) No 2073/2005 the FSAI has produced Guidance Note No. 3, which provides guideline limits that can be used if legal microbiological criteria are not provided in Regulation (EC) No 2073/2005 for a particular combination of food and microorganism.[5, 27]

APPENDIX 3 CURING

Traditionally, cured meat products in Ireland were sold raw and included products such as rashers of bacon, hams, gammon steaks and corned beef. All of these products require cooking by the consumer before consumption. More recently, many of these products have become available as pre-packaged, ready-to-eat products such as cooked, sliced ham. These products normally require refrigeration (i.e. 0 °C to 5 °C) and suitable packaging to maintain product safety and quality throughout their shelf life.

Another group of cured meat products (more traditional in continental Europe) that has become more common in Ireland in recent years is fermented sausages (e.g. salami). These products are not cooked by the manufacturer and do not require cooking by the consumer before consumption. Typically, the meat used in these products is cured raw meat.

Methods of curing meats

Dry curing

This method involves the direct application of salt (and other ingredients) into intact meat cuts. The meat is then stored at a low temperature (i.e. 0 °C to 5 °C) in covered tanks (often piled on top of each other) to cure. During curing, the salt enters the muscle tissue, releasing water from the meat. During dry curing, the meat should be regularly turned or re-piled to ensure even and consistent distribution and penetration of the curing ingredients throughout the meat. The duration of curing depends on many factors, including the weight and dimensions of the meat cuts, presence of fat, relative humidity and the storage temperature. Dry curing can last for several weeks depending on the product.

Injection curing (wet)

This method involves injecting a pre-prepared low-temperature brine solution (i.e. solution of water, salt, curing salts and other ingredients) into the meat. Injection is typically achieved using an injection machine which can have a single needle with multiple openings, or multiple needles with single openings, to inject the brine solution into the meat. The majority of commercially produced cured meat in Ireland is produced using multiple needle injection machines.

Immersion curing (wet)

This method involves direct immersion of the meat in a brine solution, or injecting the meat with a brine solution followed by direct immersion for three days or more. Immersion curing is a traditional method of curing practiced in Ireland often associated with products such as Wiltshire bacon.

Tumbling

Many producers of cured meats in Ireland use tumbling machines to massage meats as they are cured. Tumbling allows the cure or brine solution to be absorbed quicker by the meat and to extract proteins from the meat that are useful in forming boneless cured meat products.

Minimising microbial contamination

To minimise the microbial contamination of cured meat during dry, injection and immersion curing and tumbling, the following is recommended:

- Only potable water should be used to prepare brine solutions and ice.
- Ideally, brine solutions should be used and prepared fresh, and covered and refrigerated at ≤3 °C until use.
- Unused and used brine solutions should not be stored for further use.
- Overflow brine solutions produced during injection curing should be discarded.
- All equipment should be adequately cleaned and sanitised before use. Particular attention should be given to needle injection equipment and mechanical tumblers.
- After each use, all equipment used should be disassembled and sanitised as per manufacturer's instructions.

APPENDIX 4 MICROBIOLOGICAL SPECIFICATION FOR SPICES

A typical microbiological specification for use with suppliers of spices is provided in Table 2.[49–52]

Table 2 Microbiological specification for spices

Microorganism	Microbiological parameters			
	n	**c**	**m** (cfu/g)	**M** (cfu/g)
Bacillus cereus	5	1	10^3	10^4
Clostridium perfringens	5	1	10^2	10^3
Salmonella species	5	0	Absent in 25 g	
Escherichia coli	5	1	10	10^2

Where:

n = number of sample units

m = limit at or below which all results are satisfactory

M = limit above which results are unsatisfactory

c = number of sample units falling between m and M and considered acceptable provided the rest of the results are at or below m

cfu/g = colony forming units per/gram

For B. cereus, C. perfringens and E. coli the status of a batch is considered to be:

- **Satisfactory** where all the values are at or below m
- **Acceptable** where the maximum of c values are between m and M and the rest of the values are at or below m
- **Unsatisfactory** if one or more values are above M or more than the prescribed c values between m and M.

In relation to Salmonella spp. the status of a batch is considered to be:

- **Satisfactory** where all the values are not detected in 25 g
- **Unsatisfactory** where one or more values are detected in 25 g.

APPENDIX 5 MONITORING

Temperature

The temperature of the fermentation and ripening rooms must be carefully controlled to ensure that every batch of product manufactured is consistently safe. Some manufacturers use automated continuous temperature monitoring systems such as data loggers, whereas others use manual systems. The following recommendations are provided in relation to temperature monitoring:

- Raw materials, refrigerated/frozen storage and processing areas should be monitored and recorded at a frequency which confirms that set temperature targets are being reached.
- Air and product temperature should be monitored and recorded during fermentation and ripening at a frequency which confirms that set temperature targets are being reached.
- All instrumentation used in temperature monitoring should be regularly calibrated, as per manufacturer's instructions, by an externally accredited service provider.
- As part of HACCP-based procedures, corrective action procedures should be established by the manufacturer for non-compliance issues relating to temperature.

Relative humidity and air velocity

The relative humidity and air velocity of the fermentation and ripening rooms must be carefully controlled to ensure that every batch of product manufactured is consistently safe. Some manufacturers use automated continuous monitoring systems, whereas other use manual systems. The following recommendations are provided in relation to relative humidity and air velocity monitoring:

- Relative humidity and air velocity should be monitored and recorded during fermentation and ripening at a frequency which confirms that set relative humidity and air velocity targets are being reached.
- All instrumentation used in relative humidity and air velocity monitoring should be regularly calibrated, as per manufacturer's instructions, by an externally accredited service provider.
- As part of HACCP-based procedures, corrective action procedures should be established by the manufacturer for non-compliance issues relating to relative humidity and air velocity.

pH

The pH of every batch of product should be carefully monitored to ensure that the appropriate pH drop is achieved during fermentation in the appropriate time and that the final target pH is achieved. The following recommendations are provided in relation to pH monitoring:[4]

- pH should be monitored according to EN ISO 2917:1999 or other applicable method.
- pH should be monitored and recorded during fermentation at a frequency which confirms that the set pH drop is attained and the final product pH target is reached within the appropriate timeframe.
- pH should be measured and recorded at the end of ripening to confirm that the final product pH target is reached.
- pH measurement of raw fermented meat products can be difficult, due to their high fat content. Manufacturers should seek advice from suppliers of pH measurement instrumentation to ensure that it is appropriate for use with raw fermented meat products.
- All instrumentation used in pH monitoring should be regularly calibrated, as per manufacturer's instructions, by an externally accredited service provider.
- As part of HACCP-based procedures, corrective action procedures should be established by the manufacturer for non-compliance issues relating to pH.

A_w

The A_w of every batch of product should be carefully monitored to ensure that the appropriate A_w is achieved. Manufacturers should note that during the ripening step raw fermented meat products will have an A_w gradient between the inside and outside of the product due to the process of drying. In cases where the manufacturer is monitoring the A_w, different points distributed over the cross-section of the product should have their A_w measured. Eventually, when ripening is complete, a point will be reached where the A_w has equilibrated across the product. The following recommendations are provided in relation to A_w monitoring:[4]

- A_w should be monitored according to ISO 21807:2004 or other applicable method.
- A_w should be monitored and recorded during ripening at a frequency which confirms that the final product A_w target is reached within the appropriate timeframe.
- A_w should be monitored and recorded during ripening at different points distributed over the cross-section of the product until the A_w has equilibrated across the entire product.
- A_w should be measured and recorded at the end of ripening to confirm that the final product A_w target is reached.

- All instrumentation used in A_w monitoring should be regularly calibrated, as per manufacturer's instructions, by an externally accredited service provider.
- If A_w measuring instrumentation is not available, manufacturers can use "product weight loss" to estimate A_w.
- As part of HACCP-based procedures, corrective action procedures should be established by the manufacturer for non-compliance issues relating to A_w.

Product weight loss

In those cases where manufacturers do not have access to A_w measuring instrumentation, estimation of the A_w can be achieved by measuring product weight loss.

However, before using this system, a correlation between the product weight loss and its A_w has to be established and documented for each product. As long as the product's formulation and manufacturing steps do not change, the correlation between A_w and weight loss should not change for a product. The following recommendations are provided in relation to product weight loss monitoring.[38, 42]

- All weighing scales should be regularly calibrated, as per manufacturer's instructions, by an externally accredited service provider.
- All weighing scales should have an appropriate accuracy which reflects normal product weights.
- As part of HACCP-based procedures, corrective action procedures should be established by the manufacturer for non-compliance issues relating to product weight loss.

To establish a correlation between product weight loss and A_w the following recommendations are provided:

- Initially, discuss the proposal with the competent authority.
- Ensure that the scales are calibrated and have the appropriate accuracy. In other words, do not put a 100 g product on a weighing scales designed to weigh up to 500 kg, as its accuracy will not be sufficient to support the correlation.
- Have a laboratory determine the A_w on each product you manufacture.
- Ensure that products tested in the laboratory have achieved their final weight loss before testing.
- Before beginning testing, agree with the competent authority a suitable number of laboratory A_w tests for each product you manufacture.

- Weigh a representative number of product units (e.g. ≥10 product units) using an appropriately accurate, calibrated, weighing scales.
- Tie a label on each product unit and write the starting weight and the date on the label.
- Ensure that product units are chosen from different locations within the ripening room, in order to identify variability in the drying process due to physical parameters such as temperature, relative humidity and air velocity. A map of product locations can be used by the manufacturer.
- Reweigh the product units at an appropriate frequency and write the new weight and date on the label. Replace the product in its previous location within the ripening room.
- Reweigh the products and record weight and date until the desired weight loss is achieved in each product unit.
- Record each individual weight of all product units used (i.e. do not average the readings) as this will allow the manufacturer to identify variability in the drying process (e.g. locations in the ripening room where drying is too fast or too slow).
- Record and retain all results as part of this correlation exercise.
- If any changes are made to the manufacturing process, product formulation or facilities, the correlation between product weight loss and A_w will have to be repeated.

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