Food Standards Scotland

For safe food and healthy eating

Shelf-life guidance

Guidance for food businesses for the setting of product shelf-life

Version 1.2 March 2025

foodstandards.gov.scot

Version control

Version	Date	Last review carried out	Next review date	Comments
1	January 2025	N/A	January 2028	
1.2	March 2025			Minor updates for clarity

Acknowledgements

Thank you to our reviewers for their feedback on the draft document: Karin Goodburn, Alec Kyriakides, Claire Tomaso, Wayne Anderson, Andrew MacLeod and members of the Scottish Food Enforcement Liaison Committee (SFELC).

Contact information

For information about the contents of this report, please contact enquiries@fss.scot

Food Standards Scotland
Pilgrim House,
Old Ford Road,
Aberdeen,
AB11 5RL.

T: 01224 285100
www.foodstandards.gov.scot

At Food Standards Scotland we have a unique role, working independently of Ministers and industry to provide advice which is impartial, and based on robust science and data.

Our remit covers all aspects of the food chain which can impact on public health – aiming to protect consumers from food safety risks and promote healthy eating.

Table of Contents

1. Introduction

In the context of food production, shelf-life refers to the period of time after manufacture that the food is considered safe for consumption, or still of the quality intended by the manufacturer. When determining the product's shelf-life the Food Business Operator (FBO) must demonstrate that that the shelf-life of a food product is appropriate, and that the food will remain safe and/or maintain its quality until the end of that life. There is no standard method to estimate or set the shelf-life of a food product because there are many different factors that can affect the product safety and quality.

Purpose
The purpose of this document is to help food businesses comply with the requirements of Regulation (EC) 2073/2005 that the food safety criteria applicable throughout the shelf-life of the product can be met under reasonably foreseeable conditions of distribution, storage and use.

It aims to outline good practice in determining and verifying the shelf-life of a food product to support FBOs, and to also help authorised food officers carry out their duties to enforce this regulation. It also provides theoretical examples of the use of experimental studies in shelf-life setting.

A number of annexes present additional information which may be useful to FBOs in setting shelf-life, for example a glossary of terms, frequently asked questions, sources of additional information, and further information on common foodborne pathogens.

There are various regulations highlighted throughout this guidance document. Please note that some of these are EU regulations which have been assimilated into UK law. These are cited throughout the document without referring to each individual regulation as assimilated.

Within scope
The setting and validation of shelf-life as it relates to food safety. Where food becomes unsafe after a certain period the food product will require a 'use by' date to indicate the end of shelf-life.

The setting and validation of shelf-life as it relates to food quality and sensory issues are discussed within this document, although they sit outside of the primary scope of this guidance. Where food does not become unsafe after a period of time the food product will require a 'best before' date to indicate when the food may no longer be of the quality intended.

Out of scope
Food intended for medicinal use and specific groups such as infant and follow-on formula have their own regulations which must be followed.

1.1 Definition of shelf-life

In the context of food production, shelf-life refers to the period of time after food manufacture that the product is considered safe for consumption, or still of the quality intended by the manufacturer.

Commission Regulation (EC) 2073/2005 on microbiological criteria for foodstuffs outlines microbiological criteria which must be met throughout the shelf-life of the product. Annex II of the regulation outlines the studies that a Food Business Operator (FBO) should conduct, where necessary, to investigate compliance with the criteria throughout the shelf-life.

The studies include:

- Specification for physicochemical characteristics of the product
- Specifications for packaging, including storage and processing conditions
- Consideration of the possibilities for contamination
- The foreseen shelf-life
- Consultation of available scientific literature and research data regarding the growth and survival characteristics of the microorganisms of concern

Where shelf-life cannot be justified using the above studies alone, an FBO should conduct additional studies which may include:

- Predictive mathematical modelling established for the food in question, using critical growth or survival factors for the microorganisms of concern in the product,
- Studies to evaluate the growth or survival of the microorganisms of concern that may be present in the product during the shelf-life under reasonably foreseeable conditions of distribution, storage and use (durability testing).
- Tests to investigate the ability of the appropriately inoculated microorganism of concern to grow or survive in the product under different reasonably foreseeable storage conditions (challenge testing).

Each of these types of studies is explored in more detail in this document.

It is also made clear in Regulation (EC) 2073/2005 that any studies that a business uses must take into account the inherent variability in the characteristics of the product, the microorganisms in question and the processing and storage conditions.

1.2 Labelling

Regulation (EU) 1169/2011 stipulates the information that must be provided to the customer. The FBO should place a date of minimum durability on the product, this can be either a ’use by’ or a ’best before’ date. Alongside the date mark to indicate the shelf-life to the consumer, associated instructions for usage and storage should also be provided.

Use by
A ‘use by’ date relates to microbiological food safety. This date mark indicates the date after which a food is deemed to be unsafe. This date is normally applied to perishable, high available water (A_w) and neutral or low acidity products as they are

most likely to support the growth of microbiological contamination and therefore after a short period may constitute a risk to human health. It is assumed by the law (Art 24(1) of Regulation (EU) 1169/2011) that a highly perishable food product is unsafe after the ‘use by’ date expires at midnight that day, and it is an offence to sell or display for sale this product after this date.

Best before

A ‘Best before’ or ‘Best before end’ date mark relates to food quality. This date mark should be placed on a food product whose quality attributes (texture or flavour, for instance) may not be as the FBO intended after this date, but will still be safe to eat. This mark is more common on shelf-stable food products, such as those that are frozen, tinned, baked or dried. A food product in this category must still be safe to eat after the indicated ‘best before’ date has expired. It should be assumed that the food product may not be of the same quality of taste and texture after the ‘best before’ date has expired, but as long as it is still safe to consume, the product can be sold after this date. The exception to this is eggs, which generally have best before dates despite that they may become unsafe to eat after a certain amount of time.

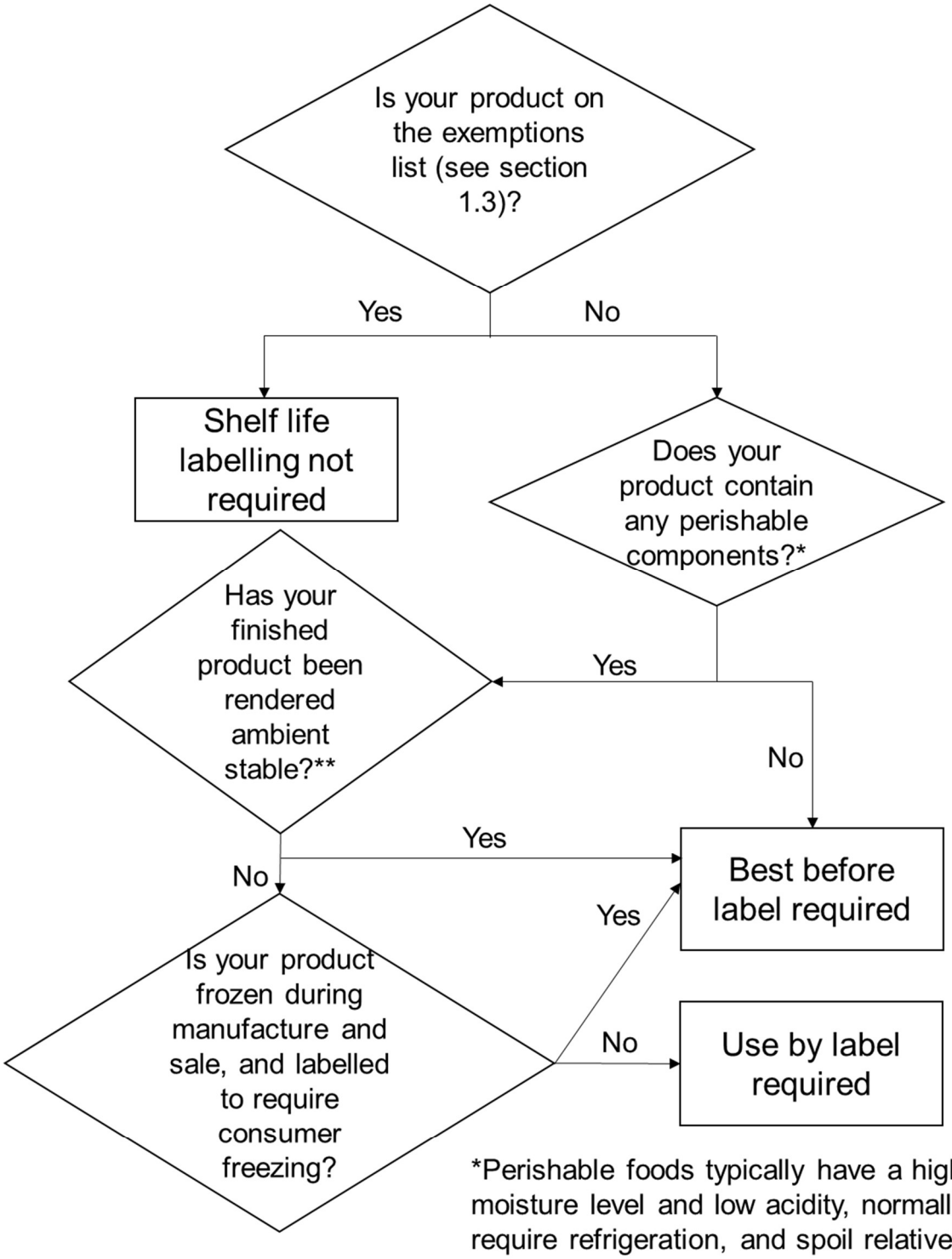
Storage conditions

It is also a legal requirement (Art 25 of Regulation (EU) 1169/2011) to provide storage instructions where special storage conditions are required after the original packaging has been opened, such as ‘once opened use within 2 days’. The wording of these instructions is not specified in regulation. It is up to each individual FBO to determine what the safe open storage requirements are for a product and ensure this is clearly labelled.

Frozen meat, frozen meat products and preparations (i.e. processed meat), and frozen unprocessed fish must be labelled with the date of freezing or the date of first freezing, using the wording ‘frozen on’, followed by the date (day, month and year, in that order). In these cases, a ‘best before’ date is also still required.

The use of additional marks such as ‘display until’ is not recommended as they are not legally defined and may cause confusion for consumers.

Use-by or best-before decision tree



*Perishable foods typically have a high moisture level and low acidity, normally require refrigeration, and spoil relatively quickly

**Typically through the use of heat and/or drying to destroy microbes and sealing in airtight packaging/containers

A best before date is applied to a food to indicate best eating quality and would remain safe to eat after the date. Examples of foods which require a 'Best before…' or 'Best before end…' date include bread; frozen food; dried herbs; dried pasta; biscuits; crisps and canned foods.

A use by date is applied to a food where it would become microbiologically unsafe immediately after the date. **Examples of foods which require a 'use by…' date include** fresh raw meat and fish; cooked sliced meat; smoked fish; prepacked sandwiches; bagged salad; pre-sliced fruit and vegetables, and pre-prepared fresh sauces and dips.

1.3 Exemptions

Most foods have to carry either a ‘use by’ or ‘best before’/‘best before end’ date. Regulation (EU) 1169/2011 lists food products which are exempt from displaying either type of date mark, these are:

- fresh fruit and vegetables, including potatoes, which have not been peeled, cut or similarly treated (this derogation shall not apply to sprouting seeds and similar products such as legume sprouts);
- wines, liqueur wines, sparkling wines, aromatised wines, and similar products obtained from fruit other than grapes, and beverages falling under customs classification CN code 2206 00 obtained from grapes or grape musts;
- beverages containing 10% or more by volume of alcohol;
- bakers’ or pastry cooks’ wares which, given the nature of their content, are normally consumed within 24 hours of their manufacture;
- vinegar;
- cooking salt;
- solid sugar;
- confectionery products consisting almost solely of flavoured and/or coloured sugars;
- chewing gums and similar chewing products.

The requirements within Regulation (EU) 1169/2011 only apply to foods intended for the final consumer, including foods delivered by mass caterers. In addition, the mandatory requirements to provide a durability or use by date apply only to prepacked foods. Therefore, the requirement to provide a date of minimum durability does not apply to whole or half carcases or primal cuts unless they are intended for the final consumer or mass caterers. FBOs that supply to other food business operators any food not intended for the final consumer, or to mass caterers, need to ensure that those other food business operators are provided with sufficient information to enable them to meet their obligations to provide accurate food information in accordance with the applicable food law and requirements at a later stage in the supply chain.

1.4 Shelf-life validation and verification

Validation
In the context of shelf-life setting, validation is the recognised scientific process to determine shelf-life. The approaches outlined in this document are the types of validation activity that a business may use to justify their use by or best before date.

An FBO must validate and document their shelf-life as part of their food safety management system before the food can be marketed. Shelf-life validation is the combination of procedures/testing/research carried out by the FBO, which is used to set an appropriate shelf-life for a food product. The details of the validation must be documented and retained as evidence to show how the appropriate shelf-life was determined.

A best before date relates to the quality of the product rather than its safety, the FBO should use appropriate tests to set the date after which the quality of a food may diminish.

Verification
Shelf-life verification activities take place once a product is on the market to verify that the shelf-life remains appropriate and is controlling any identified hazards. An example of a verification activity would be testing a stored product until the final day of shelf-life to ensure that no microbiological criteria have been breached. Where a safe, stable situation has been established, the FBO may have a sound basis to reduce the frequency of verification activity.

1.5 Altering/changing shelf-life

Once the shelf-life of a product has been established, it must be regularly reviewed. The frequency of review should reflect the risk of the individual product and any changes in its manufacture and storage conditions.

Assuming relevant historical records and verification activities show a continuous trend that the shelf-life of the product is satisfactory, it does not need to be altered.

If the business makes any changes to their formulations, recipe, manufacturing or preparation methods, storage regime, or there is a change to the hazard and risk profiles of their products, they must ensure that their shelf-life remains valid i.e. consider if any changes affect the product's ability to support the survival or growth of microorganisms. This may involve repeating any validation and verification activities as necessary.

1.6 Legal requirements, responsibilities and specific guidance

General food safety requirements are that food must not be placed on the market if it is unsafe, i.e. injurious to health, or unfit for consumption (Regulation (EC) No 178/2002).

The following four pieces of assimilated legislation include information relevant to setting shelf-life:

- Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law.

- Regulation (EC) No 852/2004 of the European parliament and of the council of 29 April 2004 on the hygiene of foodstuffs

- Regulation (EC) No 2073/2005 of 15 November 2005 on microbiological criteria for foodstuffs

- Regulation (EU) No 1169/2011 of the European Parliament and of the Council of 25 October 2011 on the provision of food information to consumers

Regulation (EC) 2073/2005 sets out microbiological criteria for the legally permissive levels of microorganisms at the end of shelf-life. For example, for chilled foods with shelf-life longer than 5 days (i.e. day of production + 4 days) that allow the growth of *Listeria monocytogenes*, the regulation states that the levels of *L. monocytogenes* must not exceed 100 cfu/g during the product's shelf-life. For chilled foods, which are modified atmosphere packed (MAP) or vacuum packed (VP), guidance states that shelf-life should not exceed 10 days if there is the possibility for the growth of non-proteolytic *Clostridium botulinum* (FSA 2020, ACMSF 2023). A 10 day shelf-life must be applied, unless the FBO can demonstrate that there are controls in place to show that *C. botulinum* will not grow. See CFA Guidelines setting shelf life of chilled foods in relation to C. botulinum. This shelf-life limitation guidance does not relate to *L. monocytogenes* however, which must be assessed separately.

After consultation with the fresh meat industry, specific 13 day shelf-life guidance has been produced for VP/MAP chilled fresh beef, lamb and pork. The 13 days can be extended if the food business can demonstrate *C. botulinum* growth is controlled after that point, e.g. by historic data/information such as that set out in BRCGS guidance.

For best before date marked products where specific legislative requirements or recommendations are not set out in regulation or guidance, the end point of shelf-life is often determined by sensory or biochemical product deterioration. This end point will vary from product to product and must be determined within the shelf-life setting process. There is commercial guidance/information available for maximising shelf-life of products by organisations such as Campden BRI. However, any shelf-life maximisation or extension should be carefully considered to ensure that the safety or the quality of the product will not be affected.

A selection of guidance documents, which may be useful when determining shelf-life of food are available in Annex 2.

1.7 HACCP principles and shelf-life

Article 5 of Regulation (EC) 852/2004 states that food businesses must implement a food safety management system based on the principles of hazard analysis and critical control points (HACCP). Shelf-life setting must be an integral part of an FBO's procedures based on HACCP principles. Further detail on the use of a HACCP based food safety management system is beyond the scope of this guidance.

2. Determining the shelf-life of food

2.1 What influences shelf-life?

The length of time a food product remains safe and of the desired quality is influenced by various factors, for example the microbiological quality of raw ingredients, manufacturing practices and their hygienic management, the product formulation, the pH, salt or available water content of the product, and the addition of additional flavourings or preservatives.

Every part of the manufacture of the food product, from the receipt of raw ingredients through the processing to the distribution to the final consumer, and the processing environment itself, should be taken into account when setting shelf-life. In order to correctly determine the shelf-life of the product, the FBO must have complete knowledge and understanding of the characteristics of their product, its distribution conditions, and use in the home. Additionally, the characteristics of a product can change when an ingredient supplier changes, and this should also be considered.

Specific food product characteristics can affect the shelf-life by prolonging it, while other characteristics can decrease shelf-life, and the aspects which should be considered when setting shelf-life are summarised in the sections below.

Food product characteristics can be separated into three groups – intrinsic characteristics, microbiology and extrinsic factors, and an understanding of these characteristics of a food product is required to understand the potential for microbial growth and set shelf-life appropriately. The following sections look at these three groups in greater detail.

2.2 Intrinsic characteristics

Intrinsic characteristics of the product (also known as the physicochemical properties of the food) are the attributes of the food itself. They will affect the likelihood of the food to support the growth and survival of microorganisms.

2.2.1 pH and type of acid

Acidity is a common property of food, and its presence contributes to a variety of factors including flavour and microbiological stability and safety. The level of acidity is expressed as pH, with pH 7 being neutral (such as pure water), a pH below 7 being acidic, and a pH above 7 being basic (or alkali). The pH of a food or ingredient can vary due to natural variation and the type of storage and processing it undergoes. Cooking will affect the properties of raw foods, and may increase or decrease the pH of the final cooked product. Adding acidic ingredients such as vinegar or lemon juice to a food can increase the acidity (i.e. decrease the pH) making the food more microbiologically stable and safe.

Different types of acid are commonly used in different types of product, for example in sauces and pickles, acetic acid (i.e. vinegar) at concentrations of 0.1% and above is used to inhibit growth of foodborne pathogens (this is usually combined with a pasteurisation treatment). Other acids such as sorbic and benzoic acids are used to control for moulds and yeasts by the beverage industry. The pH of a food can vary across the shelf-life of a product (i.e. a yogurt becoming more sour) and this variation needs to be understood and considered when setting the shelf-life. The pH can also vary between different layers of a food product (e.g. between a layer of yoghurt and a layer of fruit puree) and this has to be understood and accounted for when setting shelf-life.

2.2.2 Water activity (A_w)

Microbes (like all living organisms) require water for survival and growth. The amount of water which is 'available' to microbes in a food item is indicated by the 'water activity', or 'available water' (sometimes shortened to A_w or a_w). Not all water contained in a foodstuff is available, as some maybe bound to other molecules and therefore not available for a microorganism to use. A_w is represented as a number between 0 and 1, with 1 representing pure distilled water (or complete water availability).

Perishable food products like fresh meat and fresh produce have an approximate A_w value of around 0.98, whilst less perishable food products, such as biscuits and crisps, have approximate A_w values between 0.3 – 0.6. The growth of microbes is reduced (and eventually inhibited) as the A_w decreases towards zero. Lowering the A_w of foods tends to be associated with reduced perishability of food (and therefore may allow a longer shelf-life to be set). Reducing the A_w in a food product can be achieved by removing water (e.g. drying or freezing, squeezing water out of cheese curds), or adding substances that bind water such as salt or sugar. Humectants are a type of food additive that can also be used to reduce A_w by absorbing water. Processing such as cooking will also alter the A_w through evaporation.

2.2.3 Redox potential

Redox potential is defined as the tendency for a substance to either gain (reduction) or lose (oxidation) electrons in a reaction. In the context of food safety, the most important food oxidiser is the amount of available oxygen. This is important, as a food product which has oxygen present will support the growth of aerobic bacteria. Most food pathogens (microorganism that can cause disease) are aerobic (i.e. require oxygen to grow), with the notable exception of the anaerobe *Clostridium botulinum*, the bacterium which causes botulism, which requires low oxygen (anaerobic) conditions in order to grow. Different microbes can grow in varying levels of oxygen availability, and therefore need to be considered in a specific food product on a case-by-case basis. For example *L. monocytogenes* is a facultative anaerobic bacterium meaning it is capable of surviving in the presence or absence of oxygen. Strategies to reduce the level of available oxygen include using vacuum packaging, and modified atmosphere packaging (MAP) but the increased risk of allowing the growth of *C. botulinum* must be addressed and controlled effectively (the latest guidance can be found here).

2.2.4 Product formulation, food structure and assembly

Variation in product formulation may affect the shelf-life of the product. The composition of the final product may vary as a result of manual actions such as hand weighing/measuring (causing weighing error/discrepancies) or manual application (hand salting/mixing etc) of the ingredients.

Depending on the type of the product, different components (or different layers) of the final food product can have different intrinsic characteristics. For example, hand salting of a raw meat product will result in the outer layer of the product having a higher salt concentration than the rest of the product, whereas adding salt into a raw

meat product via a brine injection will distribute the salt differently within the product. There is also natural variability in the “activity” of ingredients, for example the acidity of tomatoes can vary between different tomato varieties and different seasons. The combination of the manufacturing process with the natural variability that exists within ingredients and food product itself results in a final product formulation/assembly that is specific to that batch. This intrinsic variability should be considered when setting shelf-life, and the FBO must use the reasonable worst-case composition of a product in their validation.

2.2.5 Naturally occurring antimicrobial substances

Naturally occurring antimicrobial substances can be present in food products, for example the compound allicin which is present in garlic. These have various levels of antimicrobial activity and can inhibit pathogen growth. Additionally, antimicrobial substances can be formed via processing, for example smoking processes can form phenols, and fermenting can create bacteriocins or organic acids. However, naturally occurring or process occurring antimicrobials should not be used a sole guarantee for product safety or durability unless the specific concentration of the antimicrobial is reproducible and the efficacy against the target microorganism is clearly established.

2.2.6 Food additives – preservatives

The perishability of a foodstuff may be reduced by adding preservatives. These are considered to be food additives. According to Regulation (EC) No 1333/2008 food additives are described as:

> **“***substances not normally consumed as a food in itself and not normally used as a characteristic ingredient of food, whether or not it has nutritive value, the intentional addition of which to food for a technological purpose in the manufacture, processing, preparation, treatment, packaging, transport or storage of such food results, or may be reasonably expected to result, in it or its by-products, becoming directly or indirectly a component of such foods***”**

There is a list of additives and E numbers, including preservatives, which are authorised in the UK approved additives and E numbers. Most additives are only permitted to be used in certain foods and are subject to specific conditions of use including quantitative limits, so they should be used as set out in Regulation (EC) No 1333/2008.

Where a preservative is added to a food to extend the shelf-life, its concentration and efficacy on the target microorganisms must be established as part of the shelf-life validation.

2.3 Microbiology

The microbiology of the food refers to the bacteria and fungi that may be present in it, and which will affect the safety of the product over time.

2.3.1 Microflora

When determining shelf-life, the FBO must have knowledge of the microbiology of their product. Most food commodities naturally contain different types and concentrations of microorganisms, also known as natural microflora. The microflora of the raw ingredients can vary by batch and supplier. There are also cases where microorganisms are deliberately added during the processing for technological reasons, for example in fermented foods like yogurt or salami. It is important to consider which microorganisms are likely to be present in the final product and how they can affect the safety and/or the quality of the product.

Microorganisms in the final product can originate from the raw ingredients or contamination from processing or the environment. There are two main groups of organisms which must be considered when setting shelf-life – pathogens and food spoilage microorganisms. Pathogens are the microorganisms capable of causing human illness. Food spoilage microorganisms are generally not harmful to human health, but can affect the food's quality (i.e. causing it to spoil). These two groups of microorganisms are considered in more detail below. Other microbes may also be present, which may have no effect upon consumption (or may provide some beneficial effects to the human gut), for the purposes of shelf-life setting, they are less important to consider.

2.3.2 Pathogens

A pathogen is a bacterium, virus, or other microorganism which can cause disease. Different types of pathogenic organisms can be present in the raw ingredients, the intermediate, or the final product. Pathogens such as *Listeria monocytogenes* can actively grow in food during manufacture and/or storage, and reach dangerous levels prior the product being consumed. This can lead to food poisoning. Pathogens such as *Staphylococcus aureus* and *Bacillus cereus* can grow in food and produce toxins, which cause food poisoning once consumed. Pathogens such as *Campylobacter* and *Salmonella* spp. do not grow well at chill temperatures. *Salmonella* spp. can remain dormant in low moisture/high fat foods such as chocolate and peanut butter for long periods and cause food poisoning once the food is consumed. Certain pathogens are more likely to be associated with certain types of food, and examples of these most common pathogens and related food products can be found in Annex 4.

For each pathogenic organism, there are particular levels of pH, water activity and temperature which can promote or inhibit growth and a particular temperature/time heat treatment which can destroy the pathogen, these are summarised in the table in Annex 5. Additionally, there are specific raw ingredients which are known to be more prone to certain pathogens. The product formulation, manufacturing and storage may all provide opportunities to either eliminate or control the growth of potential pathogens.

In order to reduce the risk from foodborne pathogens, the FBO must have an appropriate HACCP in place which identifies the hazards posed by ingredients and the steps within production, and put in place measures to control microbiological contamination and/or growth. Correctly set shelf-life can help the FBO to limit the

opportunity for microbiological growth and to ensure that microorganisms do not exceed undesirable levels before the end life of the product. But shelf-life on its own should not be the only measure employed by an FBO to control microbiological contamination.

2.3.3 Food spoilage microorganisms

Food spoilage microorganisms include a wide range of bacteria and fungi, including yeasts and moulds, which are naturally present in raw materials or the environment. They cause spoilage by growing and multiplying in a susceptible food product, changing the appearance, texture and odour of the food, eventually rendering it unfit for human consumption. They may also have other impacts on the food, for example the presence of mould has been known to alter the pH of a product to a level which then allows a pathogen to grow.

2.3.4 Competitive microorganisms

In the context of food safety, competitive microorganisms include certain bacteria and fungi which are either naturally present in the product, or are deliberately added during its processing, that compete with any pathogens present. These organisms may be added specifically because of their effect on a pathogen, or any effect on the pathogen may be in addition to the intended purpose (for example a fermentation starter). The addition of competitive microorganisms can often render the food matrix to be less suitable for food spoilage microbes and pathogens. Typically, they achieve this through either altering the physicochemical characteristics of the product, producing bactericidal or fungicidal agents, or competing for nutrients with other microorganisms present. Common competitive microorganisms include lactic acid bacteria. Lactic acid bacteria can produce bacteriocins which can prevent some pathogen growth, additionally lactic acid bacteria growth can reduce the pH of the product, making it more acidic which then limits the growth of other microorganisms. The presence of competitive microorganism(s) such as lactic acid bacteria cannot be used as a controlling factor in determination of shelf-life. However the effect of these species on reducing pH can be measured. This in turn can be a factor used when determining shelf-life.

2.3.5 Microbiological quality of ingredients

The microbiological quality of ingredients impacts the safety and shelf-life of food products.

Ingredients should comply with legislative requirements such as microbiological criteria where they apply. If the relevant/specific microbiological criteria are not set in legislation, criteria may be available in relevant guidelines or industry best practice guidance. Additionally, commodity-specific guidance produced by industry groups may also be available for some food products, although access may incur a charge.

It is important to let the suppliers of the ingredients know the intended use of the final product, for example if it will be ready-to-eat. Note that the shelf-life of a food made of ready-to-eat (RTE) ingredients cannot exceed that of the ingredient having the

shortest shelf-life unless it has been subjected to further processing that would inhibit the growth of any microorganisms present (e.g. cooking).

If water and/or ice are used as ingredients or for food product preparation, these must be of drinking water standard. The definition of drinking water standard is provided in The Public Water Supplies (Scotland) Regulations 2014. The regulations detail the acceptable levels of certain characteristics, elements and substances allowed in drinking water. If water is not of potable quality, or where quality is unreliable (e.g. from a private well), appropriate treatment should be applied by the FBO to make sure that water is of drinking water standard prior to use.

2.4 Extrinsic factors

Extrinsic characteristics are external factors which impact a food product, but are themselves not a constituent of the food. These include temperature, atmosphere (such as gases and humidity within food packaging) and the packaging material itself.

2.4.1 Processing (including heat treatment)

During manufacture, a product will likely undergo a range of processing steps, some of which will have particular impact on extrinsic properties of the food and therefore its safety and microbial quality.

One of the most common treatments to improve end product food safety is heat processing. Heating processing can include treatments that deliver a thorough cook and those where the temperature and time combination only achieves a less than thoroughly cooked product. Thorough cooking (where the product reaches the required temperature/time combination), will eliminate pathogens such as *Salmonella* spp.*, E .coli* and *L. monocytogenes*. Less than thorough cooking (not reaching the above mentioned temperature for the required time), or pasteurisation (the process of heating in properly designed and operated equipment to a specified pasteurisation time/temperature combination) will reduce microbial populations in the product but to a lesser extent than thorough cooking. These processes need to be validated (i.e. proving the control reduces the microbial counts to an acceptable level) to determine their efficacy.

Other processing steps which may impact microbial quality and safety include smoking, freezing, high-pressure processing, cold plasma treatment, desiccating, fermenting and curing. All of these processing steps have the potential to reduce microbiological contaminants or inhibit growth, but each will need to be assessed with respect to their impact on product safety and the appropriate shelf-life of the final product.

2.4.2 Packaging

There are various considerations regarding packaging which should be taken into account when setting shelf-life. The packaging used can affect how long the food remains safe or of the desired quality due to its barrier properties allowing migration of gases, water or both through the pack. As well as the effect on microorganisms,

packaging properties can also affect chemical or enzymatic reactions within the product leading to deterioration over the shelf-life. For example, the ability to block the transmission of light is important as chemical compounds that occur naturally or are added to food products can be sensitive to light. The gas content of packaging also can have an effect and is covered in section 2.4.3 below.

Additionally, more information on packaging as an environmental consideration is provided in section 3.

2.4.3 Atmosphere

In the context of food manufacture, atmosphere is the gaseous environment around the product in its packaging. If packaging is not hermetically sealed (i.e. not airtight) the product will be exposed to standard atmospheric air. A product may also be vacuum packed (VP) to reduce as much air contact as possible, or in modified atmosphere packaging (MAP) where the gas is altered from the standard composition of air with the aim of reducing microbial growth. In generally, reducing oxygen content will slow down microbial growth (and in fresh meat maintain the red colouration of meat), although in these environments, anaerobic bacteria (which don't need oxygen to grow) will grow readily. This is particularly of concern when considering *C. botulinum*, the anaerobic bacterium which causes botulism, as this organism is inhibited by the presence of high levels of oxygen and therefore removing it provides conditions that favours its growth and the production of botulinum toxin. The risk of anaerobic microbial growth in vacuum packed and MAP products is considered in specific guidance VP and oxygen-free MAP products. The gaseous environment around a sealed food will change with time depending on the packaging (see 2.4.2) or storage temperature (see 2.4.6)

2.4.4 Relative humidity

Relative humidity (expressed in %) is a measure of how much water vapour is present in the air. There is an exchange of moisture between a food product and the atmosphere which continues until the food is in equilibrium with the surrounding atmosphere. This is why the relative humidity can affect the available water in a food product, and this should be taken into consideration when setting shelf life. Different types of food have different properties, i.e. cereals are dry, cooked meats can be moist, and the effect of relative humidity is different depending on their properties. For example, if dry products like cereals are held at high humidity, the A_w will increase.

The relative humidity is also associated with the storage and distribution temperature of foods. Typically, for lower storage temperatures, a higher relative humidity is required to ensure that product characteristics are maintained (i.e. chilled foods compared to ambient temperature foods).

2.4.5 Distribution

Product safety and quality are also affected by the conditions to which the product is exposed throughout its distribution and storage. Temperature and especially temperate fluctuations during storage will have the biggest effect over its quality,

however other conditions such as light or humidity might cause formation of condensation or other conditions favourable for microbial growth. There is guidance available for the storage and distribution of food products, for example:

- Guide to the Storage & Handling of Frozen Foods by the British Frozen Food Federation
- Cold Chain - Transportation Best Practices by the Global Cold Chain Alliance

When setting an appropriate shelf-life for a product it is important to consider how it will be distributed, the likely conditions it will experience and how that will affect the length of time the product remains safe to eat or of the desired quality. Transit trials are sometimes used as part of shelf-life determination of a product.
Annex II of Regulation (EC) No. 2073/2005 states that when performing studies related to shelf-life, the FBO should test under 'reasonably foreseeable conditions of distribution, storage and use' which should include consideration of how long a product may be transported at ambient temperature to a consumer's home.

2.4.6 Temperature

The temperatures at which food is held throughout its shelf-life, from production to consumption, will significantly impact microbial growth. Different microbes grow at different temperatures, but in general the colder the temperature, the slower microbes will grow, particularly below 5°C (See Appendix 4 for temperature ranges for some common pathogens). Temperatures between 8°C and 63°C are considered 'danger zone temperatures' (especially within the range of 25 to 40°C), and perishable foods will spoil rapidly if stored at these temperatures. Products which are considered perishable, or able to support the growth of microbes whilst still in the packaging, are typically refrigerated throughout usage by the consumer. When setting shelf-life the temperature profile at which the food will be stored throughout production, at retail and by the final consumer must be considered. A reasonable 'worst-case' scenario for storage by the consumer would be to a typical consumer fridge temperature of 8°C (FSA, 2013; FSA, 2023).

2.4.7 Consumer handling

The same issues covered in the distribution section above are also relevant here. The conditions under which the consumer purchases, stores and handles the product must be taken into account when setting the product shelf-life. Additionally, reasonably foreseeable use should include how a consumer might be expected to prepare and eat a product (for example, are they likely to treat the food as ready-to-eat).

The time out of chilled storage (e.g. whilst the consumer is taking the product home from the shop) should be considered. Holding a product at 20-22°C for 2 hours is commonly adopted in shelf-life studies to account for such occurrences.

Any additional temperate abuse which might occur should also be taken into account, for example, if a consumer may take the product out of the fridge and allow it to warm at room temperate prior to consuming.

Any instructions provided to the consumer on the packaging must also be taken into account when determining shelf-life.

2.5 Historical data

If an FBO has been operating successfully for a period of time, they will accumulate historical data in the form of records from on-going monitoring. Examples of these types of data might include

- Microbiological testing results from samples taken from ingredients, intermediaries, final products or the production environment and equipment. This could include indicator organisms (such as *Listeria* species) or pathogens (such as *L. monocytogenes*).
- Physicochemical parameters of the product which would influence microbiological survival or growth such as salt, A_w or pH.
- Details of customer complaints.

All of these data can be used to help verify the appropriate shelf-life of a product and can provide evidence to support whether the shelf-life should be reduced or might be extended.

2.6 Data available in scientific literature

Scientific journals, books and broader industry guidance contain useful data on the survival and growth of pathogens in many foods, and FBOs can use this when assessing their products' intrinsic and extrinsic characteristics to assist in determining the shelf-life of their products. However, such data should be used for indicative purposes only and should be accompanied by shelf-life studies in the actual product as even minor variations in formulation and physicochemical properties can significantly affect the growth of microorganisms in a food.

2.7 Experimental studies to aid shelf-life determination

The information identified in relation to sections 2.2-2.4, i.e. the intrinsic characteristics of the product, the microbiology of the product, and the extrinsic factors can be used to compare the product to data available in the scientific literature, and also in experimental studies to aid in determination of an appropriate shelf-life. This section provides information on the experimental studies that an FBO may decide to use when determining the shelf-life of a product.

2.7.1 Predictive (mathematical) microbiology

Predictive microbiology involves using software (such as ComBase) to predict the growth rate of various foodborne pathogens or indicators in a food product with defined physicochemical characteristics. It is often referred to as modelling. For the software to be used correctly, the physicochemical properties of the food product must be known (for example pH, A_w, aqueous salt concentration (% salt in water)), in addition to the expected storage temperature. As the specific physicochemical characteristics are likely to vary slightly between individual products, the parameters used must be representative of the worst-case of the product (i.e. the highest Aw and pH that the product may have). When determining the physicochemical

properties of a multi-component composite product (e.g. a RTE sandwich consisting of meat, lettuce, bread, butter and mayonnaise), it is important to measure the characteristics of each individual component separately. It is not appropriate to homogenise the product under investigation by first subjecting it to blending, mixing or dilution prior to analysis of its physicochemical characteristics (e.g. pH, Aw). It is important to determine the characteristics of the constituent ingredients in multi-component composite food products as one component may support the growth of microorganisms better than others (e.g. RTE meat with a high pH and Aw will support the growth of *L. monocytogenes* better than mayonnaise which has a low pH). If modelling is being used to predict the growth rate of various foodborne pathogens or indicators in a multi-component composite food product, the Aw and pH used for the model should be that of the worst-case constituent ingredient.

Modelling allows the estimation of pathogen growth over the entire shelf-life of the product. Scenarios using specifically programmed time/temperature combinations can be run to allow the potential for pathogen survival and growth in the product to be determined. Models require that you enter an initial concentration level of a microorganism and this should be determined based on what would be a representative starting level of this organism for the product, for example using historic data on contamination of raw ingredients and final food products at the end of manufacturing.

It is important to be aware that most data used to develop predictive models has come from broth-based studies in laboratory conditions, and any modelling needs to be interpreted with caution as food products will have their own unique characteristics which can influence pathogen growth rates. For example, a model may not include the impact of competing microorganisms that could change the conditions of the food, or interact with the pathogen under study.

As well as broth-based data, ComBase also includes food-based models for *C. perfringens* (Perfringens Predictor) and for *Salmonella* spp. in egg.

For detailed advice on how to use predictive modelling in shelf-life determination it is recommended to seek technical expertise. More general tutorials on how to use ComBase can be found on their website.

2.7.2 Durability studies

Durability studies are sometimes known as shelf-life trials, and their purpose is to monitor the microbiological quality of a given food under reasonably foreseeable conditions during the course of its proposed shelf-life. These studies may be carried out in-house where the FBO has the facilities and expertise required, or performed by an external contractor.

A durability study is an experimental study, conducted in laboratory conditions, to determine that the microbiological quality and safety of a food product is maintained over the proposed shelf-life period. An FBO may also consider conducting tasting trials, to ensure the organoleptic (colour, taste, smell, texture) characteristics of the product are maintained to their satisfaction during the shelf-life. Tasting trials can only be carried out after the product has been demonstrated to be safe to eat

through good food safety practices, a completed and implemented HACCP plan and satisfactory microbiological test results.

In order to determine the microorganisms to assess in the durability study it is important to consider the raw materials, processing, packaging and proposed storage and usage of the product. Understanding the physicochemical properties of the food will also aid the identification of microorganisms for the study. Further guidance can be found in the sources of additional information provided in Annex 2.

The following considerations must be taken into account when conducting a durability study:

Test product manufacture

- The ingredients and manufacture of a test product should be under standard conditions producing an identical product (or as feasibly identical as possible) to the ongoing manufacture of the intended product for retail.
- The tested product should be packaged in the same conditions in which it is going to be retailed (e.g. in air packaging, modified atmosphere packaging (MAP), vacuum packaging (VP), hermetically sealed cans, etc.).
- In an experiment, sufficient product should be used to allow for testing across multiple time points throughout the proposed shelf-life if required. However, it may not be necessary to test across multiple time points, for example if the shelf-life is very short.
- Sufficient replicate samples should be used to ensure that initial contamination levels are representative.
- Storage of the product should represent reasonable worst-case conditions to replicate what might be expected in reality.
- The testing should be conducted beyond the foreseen shelf-life to demonstrate a margin of error.
- Testing multiple products from more than one production run on each sampling occasion will increase confidence in the validity of the durability study.

Product whilst under commercial control

- The environmental conditions (namely temperature) during the commercial control stage (stored in-house, cold store, transportation to retailer, on display at retailer) should be applied to the tested product as it would under normal operating conditions. The time in this stage as a proportion of the total shelf-life should be decided by the manufacturer and/or retailer.

Product whilst under consumer control

- The test should incorporate conditions to simulate transport from the retailer to the consumer’s home. For instance, a refrigerated product could be taken out of refrigeration conditions for 2 hours, kept at ambient temperature and then placed back into refrigeration.
- The test must also be conducted in reasonably foreseeable conditions of consumer storage and use. For instance, where a product label will state it must be stored in refrigerated conditions, testing should utilise a fridge temperature of around 8°C (FSA, 2023, or a different temperature, as long as

evidence is provided to support it). It should not be assumed that a consumer's fridge will maintain a temperature below 5°C.

The types of microbiological tests required in a durability study will vary depending on the product. For perishable ('use by') products, a hygiene indicator test, such as *Enterobacteriaceae* spp., aerobic colony count (ACC), or generic *Escherichia coli (E.coli)* counts could be considered. Specific spoilage organisms should be considered for relevant foods e.g. yeast and mould for chilled, sugary foods and ambient bakery products; *Pseudomonas* species for raw meat such as chicken, etc. Any pathogens associated with the primary ingredients or as environmental contaminants should also be tested for presence/absence, and ready-to-eat (RTE) products should comply with the legal limits for *L. monocytogenes* as outlined in Regulation (EC) No 2073/2005. A recognised limitation of durability studies is that they rely on natural contamination being present in the product undergoing testing.

2.7.3 Accelerated shelf-life testing

For products with a long shelf-life (typically ambient stable products such as tinned, bottled or dried commodities) which may require many months or even years to reach the end of proposed shelf-life, the process of accelerated shelf-life testing (ASLT), may be more appropriate to standard durability studies.

ASLT involves placing products in temperatures and humidity conditions above normal, with the aim of accelerating the rate of product deterioration. This allows shelf-life testing to be conducted in a shorter time frame. ASLT requires specialist equipment to ensure the correct environmental conditions are met.

2.7.4 Challenge testing

Challenge testing allows a business to understand if their product is capable of supporting the growth of a pathogen and how long a safe shelf-life can be set for. Challenge tests are conducted in a similar way to durability studies, but before starting the study the product is *deliberately* contaminated (inoculated) with a known (normally high) amount of a pathogen. The product is then monitored to see if the pathogen survives and/or grows over the course of the proposed shelf-life. The inoculated pathogen should be in its rapid growth (log) phase, and have not been stressed by cold or biocides, which would be the barriers to rapid growth in well controlled FBO production areas. Additionally, the product should be formulated to reasonable 'worst-case' conditions (i.e. highest A_w and pH that may occur in the product) to ensure that the results are applicable to any batch of the product.

Challenge testing is typically carried out in products that are likely to support the growth of particular pathogens for example *L. monocytogenes*.

At the beginning of the test, finished packed product is deliberately contaminated with a known amount of a pathogen in a laboratory and kept under reasonable worst-case storage conditions. The laboratory samples the product throughout the shelf-life to monitor changes in pathogen concentration.

Interpretation of the results of a challenge test will vary depending on the product and the type of pathogen used to deliberately contaminate it. Absence of pathogen growth or reduction in pathogen numbers is typically considered to indicate that the physicochemical properties, temperature, and shelf-life of the product are successfully preventing growth of the pathogen. To determine whether pathogen growth has occurred a 'growth potential' will be calculated, which for *L. monocytogenes* is usually a 0.5 $\log_{10}$ increase (EURL Lm Guidance, 2023) i.e. this is the increase at which the pathogen can be said to have grown.

If laboratory testing determines that the pathogen can grow above an acceptable level the FBO will need to consider changes to their manufacturing process, or hurdles via ingredient formulation to make the conditions of the product less favourable for pathogen growth. Alternatively, they may consider shortening the shelf-life.

Another important consideration when designing a challenge test is the specific strain of pathogen to be used. Strains which have originally come from a similar food product would be the most appropriate. More complex challenge tests may involve more than one strain of a particular pathogen to allow for comparison. For example a cocktail of 3 strains can be used, where 2 strains are isolates from similar food and 1 strain is from a human isolate.

As these tests can be quite complex, and involve the deliberate contamination of products with high levels of potentially dangerous bacteria, they should be performed by a laboratory accredited for the specific pathogen/food combination who will perform the test in controlled conditions. ISO 20976-1:2019 outlies the requirements and guidelines for conducting challenge tests of food and feed products.

2.8 Using different methods to determine shelf-life

The methods outlined in this guidance can be used either individually or in combination to validate product shelf-life.

An FBO could use predictive microbiology at the start of the process to indicate that growth would not occur during the proposed shelf-life of the product under representative storage, distribution, retail and consumer use. When using a model the FBO must take into account the considerations and limitations outlined in section 2.7.1. If the predictive model shows no growth or growth within acceptable limits, this experimental data, alongside the studies outlined in Annex II of Commission Regulation (EC) 2073/2005 (see section 1.1) may be sufficient to validate the shelf-life. Alternatively, and depending on the microbiological risk associated with the food type, the FBO may choose to conduct a durability study or challenge test. Predictive models are generally conservative as although they model conditions of pH and A_w/salt concentration they do not take into account all of the inherent properties of the food that may affect microbiological growth. If predictive microbiology suggests growth may be possible, a durability study or challenge test should be performed to assess if growth will occur in the product in reality.

In the following section, three hypothetical scenarios illustrate how different methods of shelf-life determination could be used alone or in combination.

SCENARIO 1: Predictive microbiology

- A food business wants to sell a freshly prepared tomato sauce for pasta, the sauce is pasteurised prior to packaging and must be refrigerated throughout its shelf-life.
- The business needs to determine an appropriate use-by date for the product. They believe that the sauce is unlikely to provide conditions suitable for the growth of microorganisms due to its acidity.
- The company sends samples from three distinct batches of tomato sauce, produced during different shifts, to a laboratory to assess the inherent variability in the pH and Aw values of the product. Based on this data, the company has chosen the highest Aw and pH values to represent a reasonable worst-case scenario for the product's composition. The business wants to model the growth potential of several pathogens identified as potential hazards in their HACCP Plan. They use ComBase to enter the physicochemical characteristics of the product alongside reasonably foreseeable transport and storage temperatures (5°C for 24 hours post manufacture and transport to the retailer, 6°C for 72 hours whilst on display at retail, 21°C for 2 hours to model consumer transport from retailer to their home, and 8°C for 142 hours to model storage in consumer fridge until end of shelf-life).
- In Combase, an initial level of 0 was used for each pathogen to represent 1 bacterial cell. (The model uses a log scale, in the case of 1 bacterial cell this equates to $\log_{10} 1 = 0$) This was determined by the business as an appropriate starting level as this is a pasteurised product produced in a closed system.
- The ComBase models demonstrated that the pathogens could not grow (because there was a less than log 0.5 increase from the initial value), and the business was satisfied that their 10 day shelf-life was suitable to maintain product safety.

SCENARIO 2: Durability study

- An FBO produces cold-smoked salmon.
- They are aware that fresh salmon can be naturally contaminated with *L. monocytogenes* (and their historical testing data shows contamination in some incoming fish), therefore elimination in the finished product might be difficult. Because of this, the food business wishes to check whether any naturally occurring *L. monocytogenes* would be able to grow above 100 cfu/g in their finished product by the end of shelf-life. After predictive microbiology indicated that growth of *L. monocytogenes* would be possible in the product, they decided to utilise a food testing service to carry out a durability study.
- To allow for accurate durability testing, the FBO provided estimates of time/temperature conditions that the finished product could reasonably be expected to experience, including transport to retail, time with retailer, and time with the consumer until end of shelf-life.
- The food testing service carried out the durability study by subjecting the product to the specified conditions, and tested the product for presence and enumeration of *L. monocytogenes.* The business work with the food testing

service before the study began to identify the number of samples required to ensure that initial contamination levels are representative, it is noted that this required a fairly high number of samples.
- Results from the tests indicated presence of *L. monocytogenes*, but samples were all below the limit of detection (so therefore could not be enumerated).
- The business also used their data on the level of *L. monocytogenes* contamination in historic testing of incoming fish to provide confidence that the level of contamination in the incoming fish was equal to or less than the levels in the durability study.
- The business therefore concluded that the current controls, as specified in their HACCP, were sufficient to make a product which maintained safety throughout shelf-life.

SCENARIO 3: Challenge testing

- A food business produces a cooked ham product and they want to determine that their shelf-life is appropriate to prevent growth of *L. monocytogenes* to a level beyond 100 cfu/g by the end of shelf-life.
- They have two different possible formulations of the ham product, both have an A_w of 0.96, but one formulation has a pH of 6.4 (formulation A), and the other has a pH of 6.1 (formulation B).
- They undertake predictive modelling, which calculates that *L. monocytogenes* will grow above 100 cfu/g during the intended shelf-life of both of the pH formulations. As predictive modelling is generally fail-safe, they decide to commission challenge testing to determine if growth occurs in the actual product.
- They utilise a food testing service to deliberately contaminate finished product with a known amount of *L. monocytogenes* in the laboratory, then measure the growth throughout the shelf-life of the product.
- To allow for accurate challenge testing, the FBO provides estimates of time/temperature conditions that the finished product could reasonably be expected to experience including transport to retail, time with retailer, and time with the consumer until end of shelf-life.
- The results from the testing service indicate that despite the small differences in pH, there were significant differences between formulation A and formulation B with respect to *L. monocytogenes* growth potential. Formulation A supported growth of *L. monocytogenes* by almost 2 logs (i.e. from 10 cfu/g to 1000 cfu/g) by end of shelf-life, whilst formulation B showed only 0.5 log (i.e. from 10 cfu/g to 50 cfu/g) of growth by end of shelf-life. The testing service advised that this difference may be because the conditions in formulation B extended the lag time, where *L. monocytogenes* cells took longer to adapt to the slightly more acidic conditions.
- With the results of the test, the food business adopted formulation B for their final product, instead of reducing the shelf-life to allow formulation A to be safely used.

3. Packaging and shelf-life as an environmental concern

The packaging used for a food product must be physically robust to protect the product within and not become damaged itself. If packaging fails or has not been carefully selected, a food product may become unsafe or spoil before the end of its shelf-life. There is a lot of performance data for packaging formats which have been used by the food industry for a long time, for example different types of plastic. Their performance over the shelf-life of specific food types in most cases is well established.

Due to environmental concerns, an FBO might be interested in reducing the amount of packaging, or trying a new type of packaging. However, it is important to prioritise product safety for consumers by ensuring any reduction or replacement of packaging doesn't compromise food safety.

If an FBO wishes to alter the packaging used for a product then they must consider any impact that the new or altered packaging may have and review their HACCP system in relation to this change. For example, changes such as weight or colour may affect the durability of the packaging, the rate of gas mitigation or the impact of light penetration. If packaging is changed it may be necessary to re-validate the product shelf-life.

Some FBOs may choose to use reusable packaging. In this case it is crucial that strict hygiene measures are employed during cleaning and decontamination of the packaging to avoid contamination of future product.

Annex 1. Glossary

Anaerobe	A microorganism which cannot grow in the presence of oxygen.
Available water	Also referred to as water activity, A_w, or a_w. The proportion of water that is not chemically bound to other molecules in a substance. This 'unbound' water is therefore available to be used for microbial growth in a food product. It is represented as a value between 1 (distilled water) and 0 (bone dry). It is important to note that A_w doesn't mean the same thing as total water content, as some water can be 'locked' away in the food structure, such as being bound to gelatine in a jelly.
Bacteriocins	Proteins and similar compounds which are produced by a range of different microbes, and have a killing effect against other bacteria.
Best before	A date mark which indicates quality, usually applied to less perishable food products. The product should still be safe to eat after the best before date.
Challenge testing	A laboratory test to determine whether a food product can support growth of a particular microbe that has been deliberately added to the food in the laboratory.
Date of minimum durability	A date applied to a food product to either indicate it should not be eaten after this point (a *use by* date) or that it may not have the quality intended by the manufacturer after this point (a *best before* date).
Durability study	Also referred to as a shelf-life trial. Product is held under typical storage conditions over a set time, and is periodically tested to monitor changes, notably microbial growth and taste/smell (organoleptic changes) over time. In contrast to a challenge test, no microbes have been deliberately introduced.
Facultative anaerobe	A microorganism which can grow both in the presence of oxygen or without presence of oxygen.
Food Business Operator (FBO)	According to Regulation (EC) 178/2002, an FBO is the person(s) (or business) responsible for ensuring that the requirements of food law are met within the food business under their control. A 'food business' also includes businesses carrying out any stage of production, processing, and distribution of food. More generally a 'food business' means any undertaking, whether for profit or not, carrying out any of the activities related to any stage of food production, and whether or not the food they produce is sold or given away.
Food matrix	Refers to the food's physical structure, and how chemical components which make up the food interact.
HACCP	HACCP stands for Hazard Analysis and Critical Control Point. It is a management system in which food safety is addressed through the analysis and control of biological,

	chemical, allergen and physical hazards during food production.
Microbiological criteria	The limit or limits to the level of a particular microorganism in a given sample size which govern whether the food or process is acceptable. The microbiological criteria for pathogens and indicator organisms in food can be found in Regulation (EC) No 2073/2005. Not all microbiological criteria are set out in legislation, for example the UKHSA guidelines for assessing the microbiological quality for RTE foods and some industry-specific criteria.
Microflora	The name given to the community of microorganisms which live in different environments e.g. food, water, soil, etc.
Modified atmosphere packaging (MAP)	Airtight food packaging where the air sealed with the product is replaced (completely or partially) by a specific gas (or group of gases).
Organoleptic properties	The effect food or drink product has on an individual's senses, including taste, sight, smell and touch/texture.
Pathogen	A bacterium, virus, or other microorganism which can cause disease.
pH	A figure expressing the acidity or alkalinity of a solution or substance, most food items are acidic (i.e. have a pH below 7).
Physicochemical properties	The chemical and physical characteristics of a food product (pH, available water, salt concentration, oxygen concentration, etc.).
Predictive Microbiology (predictive modelling)	Using software (typically online) to model the growth of a particular microorganism in specific conditions specified by the user.
Redox potential	A physicochemical property which indicates if the food item is oxidative or reductive. It influences microbial growth in the food.
Shelf-life	The time period from food manufacture (usually packing), which can be considered 'day zero', to either the use by, or best before date.
Use by	A date mark which relates to microbiological food safety, usually applied to perishable products. A food product is defined as unsafe to eat after the use by date.
Vacuum packaging (VP)	Airtight food packaging in which air has been removed, such that the amount of contact the food item has with air is negligible.

Annex 2. Sources of additional guidance

Examples of relevant guidelines are the following:

- UK Health Protection Agency, Guidance for ready-to-eat foods, incudes guidance on ingredients Guidelines for Assessing the Microbiological Safety of Ready-to-Eat Foods Placed on the Market
- Chilled Food Association, Guide to setting shelf-life of RTE food in relation to *Listeria monocytogenes* Shelf-life of RTE Food in Relation to Listeria monocytogenes
- Chilled Food Association, Shelf-life establishment with respect to *Listeria monocytogenes* Shelf-life Establishment with respect to Lm - Epidemiologically Effective Alternatives to Challenge Testing
- Chilled Food Association, Guidelines for Setting Shelf Life of Chilled Foods in Relation to Non-proteolytic Clostridium botulinum
- Food and Drink Federation (FDF) Industry Guidance on Setting Product Shelf-Life
- Institute of Food Science and Technology (IFST) Handbook of Microbiological Criteria of Foods
- Food Standards Agency and Food Standards Scotland, Guide to food safety and shelf-life of MAP/VP chilled foods with respect to non-proteolytic Clostridium botulinum
- Food Standards Scotland, online tool for fresh produce growers Fresh Produce Tool | Food Standards Scotland
- Food Standards Scotland, online tool for smoked fish production Safe Smoked Fish Tool | Food Standards Scotland
- British Frozen Food Federation Guide to the Storage & Handling of Frozen Foods Guide to the Storage & Handling of Frozen Foods
- Global Cold Chain Alliance - Cold Chain – Transportation Best Practices
- The Business Companion website providing information on composition, labelling and packing for food and drink selling Food and drink | Business Companion

Annex 3. Frequently asked questions (FAQs)

Shelf-life general questions

I'm a completely new food business, where do I start?

A: Food Standards Scotland has Advice for New Business on our website. We also have pages for Labelling and Composition standards ; General food law and other helpful information.

In terms of shelf-life, this guidance should provide an introduction to what it is and how to set it. There is an additional list of useful resources about shelf-life listed in Annex 2. It is also a good idea to look for an industry specific guidance developed by organisations/trade bodies.

What is shelf-life?

A: In the context of food production, shelf-life refers to the period of time after food manufacture that the product is considered safe for consumption, or still of the quality intended by the manufacturer.

If I produce a product which is exempt from date marking, do I need to do anything else?

A: Despite being exempt from date marking, the product will still have to be compliant with other legislation and labelling regulations. This might require storage instructions, a list of ingredients, information about allergens or other details to be included on the label. Regardless of any labelling requirements, all food must be safe and fit for human consumption to be placed on the market.

What is the difference between an 'opened' and 'unopened' shelf-life?

A: If you produce a packed ready-to-eat product it must have an appropriately determined shelf-life, and also instructions for how long the product can be consumed after opening. This instruction is the 'open' shelf-life.

For example, a packet of sliced, cooked meat will have a use by date (date after which the product should not be consumed). The length of time from product manufacture until the use by date is the "unopened" shelf-life. If the product is opened by the consumer (before the use by date) and the full quantity not used immediately, then the manufacturer will provide instruction about how long after opening the product can still safely be consumed. For the sliced meat example this might be something like "Once opened use within 3 days and do not exceed the use by date".

If you produce a product with a best before date you may also need to consider providing instructions on an 'opened' shelf-life. For example, products which can be stored in the cupboard, but should be refrigerated after opening to maintain safety and quality may require additional information such as "refrigerate after opening and consume within X days".

Is it possible to use the shelf-life of a similar product to determine my product's?

A: No. Whereas it might be beneficial to look at available data from similar products, it is not possible to simply copy the shelf-life of another product. No two products will be identical in terms of ingredient supply, recipe, manufacturing process and hygiene control, so shelf-life validation/verification will still need to be applied when determining the shelf-life of a new product.

What is the difference between shelf-life 'verification' and shelf-life 'validation'?

A: Shelf-life validation is the combination of procedures/testing/research carried out by the FBO, which then results in a shelf-life to be applied to the food product.

Shelf-life verification is checking that the previously determined shelf-life is still applicable to the food product.

How often does shelf-life verification need to be carried out once validated?

A: Similarly to your HACCP plan, the shelf-life applied to your products should be up-to-date at all times and reflect any changes that may have taken place (e.g. change of an ingredient or its supplier or of equipment or recipe) since shelf-life validation has been carried out. It is recommended that shelf-life is reviewed on a routine basis (the frequency of which will depend on the product's characteristics, the potential hazards, and historical data). However, if anything in the processing or the characteristics of the product changes, this should be recorded and a validation should be carried out immediately to ensure that the shelf-life is still applicable for producing safe food.

Methods for validating shelf-life normally require testing in conditions a consumer would be 'reasonably expected' to keep them in. What is reasonable?

A: Reasonable conditions are conditions in which a consumer is likely to keep the product. For example, if a product is labelled to be chilled, then it is expected that the consumer is going to store this product in the fridge. It will not be reasonable to expect a consumer to store a chilled product in a cupboard.
However, it would also be unreasonable to expect that the consumer's fridge will be at the same low temperature which can be guaranteed by manufacturers and retailers. For example, if the product is stored at 4°C during manufacture and on retail, it cannot be assumed that the consumer is also storing the product at 4°C. It is not unreasonable to consider a consumer's fridge temperature to approach 8°C*****, which is frequently found in fridges performing poorly. Thus in this scenario for testing conditions a consumer would be 'reasonably expected' to keep a product, an FBO might wish to test at temperature of 8°C for the time period under consumer's control.

*****Current understanding (FSA 2013, FSA 2023) is that realistic temperature of consumer's fridge could be up to 8°C, but more recently published evidence may be taken into account when determining an appropriate reasonably likely fridge temperature for UK consumers in the future.

Labelling

Is there guidance on what best before and use by date labels have to look like?

A: Yes, this guidance is provided on the FSS website Labelling and Composition standards, the FSA website Packaging and labelling and the Gov.uk website Food labelling: giving food information to consumers. There is also guidance on the Business Companion website Food and drink | Business Companion

Testing

How do I know if I need to carry out testing to validate my shelf-life?

A: Testing for shelf-life validation purposes will depend on the product itself, the shelf-life you are hoping to apply, and the perishability of the product. If your product is ready-to-eat and/or perishable, it is likely you will need to test in order to validate shelf-life.

If you are unsure, it is recommended that you seek guidance from your Local Authority (or appropriate authority for approved establishments). Alternatively, you can hire a technical expert or consult with your chosen laboratory.

What tests should be carried out on my product for shelf-life validation?

A: In terms of testing to validate or verify shelf-life, the tests required are likely to include microbiological tests (such as testing for pathogens or indicator organisms) and physicochemical tests (such as testing for pH and A_w, salt content etc).
If you are unsure, it is recommended that you seek guidance from your Local Authority (or appropriate authority for approved establishments). Alternatively, you can hire a technical expert or consult with your chosen laboratory.

Is there a legal requirement to carry out food testing?

A: There is a legal requirement to ensure that food is safe. To demonstrate safety, testing might be necessary, it is recommended that you seek guidance from your Local Authority (or appropriate authority for approved establishments).

How often should product shelf-life verification be carried out?

A: This will depend on the product being manufactured, its perishability, and whether it's a ready-to-eat product or not. If you change your processing or ingredients you will need to review your shelf-life to ensure that it is still appropriate. It is recommended that you seek guidance from your Local Authority (or appropriate authority for approved establishments) if you are unsure.

If testing on my product needs to be done, who does it?

A: Typically a laboratory capable of testing food products. It is recommended that they are accredited to ISO17025 for the specific test you need, in the specific food type you produce (in the UK, you can check the accreditations of labs using the

UKAS website). The "Getting the Best from Third Party Laboratories" guidance by the Chilled Food Association, which was developed with FSS gives more information on what to look for and what to ask for from a laboratory.

Other

Some products have best before dates whilst others have use by dates. Which should I use?

A: 'Best before' or 'Best before end' date mark relates to food quality. This date mark should be placed on a food product whose quality (texture or flavour, for instance) may not be as the FBO intended after this date, but will still be safe to eat. A food product in this category must still be safe to eat well after the indicated 'best before' date has expired.

A 'use by' date relates to food safety. This date mark should be placed on a food product which may not be safe to eat after this point. It should be assumed in law that the food product is unsafe after the 'use by' date expires at midnight that day, and it is an offence to sell or display for sale this product after this date.

It is up to each FBO to determine, which mark should be used for their food product, based on their HACCP plan and shelf-life validation.

If I use an ingredient with a use by date in production of my final product, do I have to keep the original date?

A: It will depend on what further processing the ingredient undergoes. If you receive a raw product, which then undergoes cooking, then you do not need to keep with the original use by date. If the ingredient does not undergo any further down processing, then you will need to comply with the original use by date.

Annex 4. Table of most common pathogens and related food products

Table adapted from Guidelines for Assessing the Microbiological Safety of Ready-to-Eat Foods Placed on the Market, UKHSA 2024

Hazard	Food types most often associated with human infections
Bacillus cereus	Cooked rice (emetic syndrome). Meat products, soups, vegetables, puddings and sauces (diarrhoeal syndrome)
Bacillus spp. (other pathogenic *Bacillus*)	Cooked meats, poultry, vegetables and starchy products such as rice and bread.
Campylobacter spp (thermotolerant)	Chicken, chicken and duck liver pâté and parfait, unpasteurised milk and dairy products, untreated drinking water
Clostridium perfringens	Cooked meat and poultry dishes, leftover food, stocks and gravies.
Escherichia coli O157 (and other Shiga toxin producing *E. coli* (STEC))	Undercooked red meats, for example, beefburgers; salads and other leafy greens; unpasteurised milk and dairy products; fermented meats and untreated water
Listeria monocytogenes	Ready-to-eat foods such as sandwiches, soft ripened cheese, pâté, smoked fish, butter and cooked sliced meat.
Salmonella spp. (non-Typhi/Paratyphi)	Inadequately cooked eggs and poultry, or products containing these ingredients, such as egg mayonnaise. Pork, beef, dairy products, seeds, herbs, salad, vegetables, fruit, coconut, spices, nuts, fruit juice, chocolate and snack products.
Staphylococcus aureus and other coagulase-positive staphylococci	Dairy and confectionery (milk, cream filled cakes, cheese, ice cream), cooked meats
Vibrio cholerae	Imported shellfish
Vibrio parahaemolyticus	Imported seafood
Yersinia enterocolitica and Y. pseudotuberculosis	Meat, dairy products, and salad vegetables

Annex 5. Growth conditions required by common foodborne pathogens

Name	Minimum growth temperature	Optimum growth temperature	Maximum growth temperature	Minimum Aw for growth	pH range for growth	Additional details
Bacillus cereus	4°C	30-40°C	55°C	0.912	4.9-9.3	-
Campylobacter jejuni	30°C	42°C	approx. 46°C	0.987[1]	4.9-7.5[2]	Grow best in 5% oxygen and 10% CO_2 environments[1]
Clostridium perfringens	6°C	43-47°C	50°C	0.93	5.0-9.0	Sodium chloride concentration of 5-8% (depending on strain) prevents growth
Listeria monocytogenes	-1.5°C[3]	30-37°C[3]	45°C[3]	0.9[3]	4.0-9.6[3]	-
non-proteolytic *Clostridium botulinum*	3°C[4]	28-30°C[4]	37°C[4]	0.97[4]	5.0-?[4]	-
pathogenic *Escherichia coli*	8°C[5]	37°C	45°C[5]	0.95[5]	4.3-10	-
proteolytic *Clostridium botulinum*	12°C[4]	35-45°C[4]	48°C[4]	0.94[4]	4.6-?[4]	-
Salmonella spp.	5°C[6]	37°C[6]	47°C[6]	0.83[7]	4.1-9.0[8]	-
Staphylococcus aureus	7°C	40-45°C	46°C	0.83	4.5-9.3	-
Vibrio spp.	10°C	30-37°C	43°C	0.97	5-9.6	Grows only between 0.1% - 4% sodium chloride concentration
Yersinia enterocolitica	0°C	25-30°C	45°C	0.96[9]	4.0-10	-

Taken from Bintsis (2017) unless numbered with superscript. [1] Facciola et al. (2017) , [2] Summers et al. (2024), [3] Lado and Yousef (2007), [4] ACMSF (2023), [5] BfR (2020), [6] D'Aoust (1989), [7] Jin (2020), [8] Keerthirathne (2016), [9] Bari (2011).

References

ADVISORY COMMITTEE ON THE MICROBIOLOGICAL SAFETY OF FOOD (ACMSF), 2023. Report on Botulinum Neurotoxin-Producing Clostridia: Occurrence, Growth and Survival. https://acmsf.food.gov.uk/node/7171

BARI, M.L., HOSSAIN, M.A., ISSHIKI, K. and UKUKU, D.O., 2011. Behavior of Yersinia enterocolitica in Foods. Journal of pathogens, 2011(2011), pp. 1–13.

BINTSIS, T., 2017. Foodborne pathogens. AIMS microbiology, 3(3), pp. 529–563.

D'AOUST J. -Y, 1989. Salmonella. Foodborne Bacterial Pathogens, pp. 327–445.

EU REFERENCE LABORATORY FOR and LISTERIA MONOCYTOGENES, 2023. EURL Lm Guidance document to evaluate the competence of laboratories implementing challenge tests and durability studies related to Listeria monocytogenes in ready-to-eat foods. EU Reference Laboratory for Listeria monocytogenes, ANSES - French Food Safety Authority. EURL Lm Guidance

FACCIOLÀ, A., RISO, R., AVVENTUROSO, E., VISALLI, G., DELIA, S.A. and LAGANÀ, P., 2017. Campylobacter: from microbiology to prevention. Journal of preventive medicine and hygiene, 58(2), pp. E79–E92.

FOOD STANDARDS AGENCY, 2023. Storing chilled foods at incorrect temperatures. Food Standards Agency. Storing chilled foods at incorrect temperatures

GERMAN FEDERAL INSTITUTE FOR RISK ASSESSMENT, 2020. Escherichia coli in flour – sources, risks and prevention. Escherichia coli in flour – sources, risks and prevention (bund.de)

INTERNATIONAL ORGANISATION FOR STANDARDISATION, 2019. ISO 20976-1:2019 Microbiology of the food chain — Requirements and guidelines for conducting challenge tests of food and feed products.

JIN, Y., TANG, J. and ZHU, M., 2020. Water activity influence on the thermal resistance of Salmonella spp.in soy protein powder at elevated temperatures. Food control, 113, pp. 107160.

KEERTHIRATHNE, T.P., ROSS, K., FALLOWFIELD, H. and WHILEY, H., 2016. A Review of Temperature, pH, and Other Factors that Influence the Survival of Salmonella spp.in Mayonnaise and Other Raw Egg Products. Pathogens, 5(4), pp. 63.

LADO AND YOUSEF, 2007. Characteristics of Listeria monocytogenes Important to Food Processors. Listeria, Listeriosis, and Food Safety. United Kingdom: CRC Press, pp. 175–232.

MARY BRENNAN, SHARRON KUZNESOF, HELEN KENDALL, PATRICK OLIVIER, &. and CASSIM LADHA, 2013. Activity Recognition and Temperature Monitoring (ART) Feasibility Study. Food Standards Agency. 819-1-1498_FSA_ART_Final_Report_10-07-13.pdf (food.gov.uk)

NEW ZEELAND FOOD SAFETY AUTHORITY (NZFSA), 2010. Yersinia enterocolitica pathogen datasheet. New Zeeland Food Safety Authority. https://www.mpi.govt.nz/dmsdocument/11039-Yersinia-enterocolitica-Microbial-pathogen-data-sheet

SUMMERS, J., KVALSVIG, A., FRENCH, N. and BAKER, M.G., 2024. Campylobacter. In: G.W. SMITHERS, ed, Encyclopedia of Food Safety (Second Edition). Oxford: Academic Press, pp. 95–110.

UKHSA FOOD WATER AND ENVIRONMENTAL and MICROBIOLOGY SERVICES LABORATORIES, 2024. Guidelines for assessing the microbiological safety of ready-to-eat foods placed on the market. The UK Health Security Agency. Guidelines for assessing the microbiological safety of ready-to-eat foods placed on the market 2024 (publishing.service.gov.uk)