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18

GUIDANCE NOTE

Validation of product shelf-life (Revision 5)

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Revision history

Revision number	Publication date	Amendments made
5	**04/11/2022**	• **General** - Update to formatting, references, and legislation • **Section 3 Labelling** - More detailed information on date marking and provision of storage instructions after opening • **Figure 1. Good practice in estimating, validating and setting shelf-life** – Replacement figure providing more detailed information • **Section 4.4.1 Durability studies; III. Establish the study conditions** – Recommended storage temperature for challenge tests and durability studies assessing the growth of *L. monocytogenes* throughout the shelf-life of chilled RTE foods was amended from 12ºC to 10ºC following the European Union Reference Laboratory for *Listeria monocytogenes* (EURL *Lm*) study of consumer storage temperature data from 14 Member States in Europe. New table with storage temperature recommendations added • **Section 5 Document, record and file** – New section added • **Appendix 2 Safety and shelf-life of foods with respect to *Clostridium botulinum*** – Updated recommendations for fresh meat that is vacuum packed (VP) or in modified atmosphere packaging (MAP) based on the revised guidance for shelf-life of VP and MAP foods published in December 2020 by the United Kingdom (UK) Food Standards Agency, which took account of the recommendations published by the UK Advisory Committee on the Microbiological Safety of Food Subgroup on non-proteolytic *Clostridium botulinum* and vacuum and modified atmosphere packaged foods in its final report published in February 2020. • **FSAI eLearning resources** – Addition of new section listing FSAI eLearning resources

Glossary

BS	British Standard
cfu	Colony forming units
DAFM	Department of Agriculture, Food and the Marine
EC	European Commission
EFSA	European Food Safety Authority
E_h	Redox potential
EN	European standard
EU	European Union
EURL	European Union Reference Laboratory
FAO	Food and Agricultural Organization of the United Nations
FIC	Food Information for Consumers
FSA	Food Standards Agency
FSAI	Food Safety Authority of Ireland
GHP	Good Hygiene Practices
GMP	Good Manufacturing Practices
HACCP	Hazard Analysis and Critical Control Point
HSE	Health Service Executive
INAB	Irish National Accreditation Board
ISO	International Organisation for Standardization
ICMSF	International Commission on Microbiological Specifications of Foods
MAP	Modified atmosphere packaging
mV	millivolts
RTE	Ready-to-eat
STEC	Shiga toxin producing *Escherichia coli*
UK	United Kingdom
VP	Vacuum packed
VTEC	Verocytotoxin producing *Escherichia coli*
WHO	World Health Organization
WPS	Water phase salt

1. Introduction

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 (European Union, 2011; European Commission, 2005).

The shelf-life of a food product is the period of time beginning with the date of production and/or packing and ending with either:

- The **'use by'** date (i.e. the last day the food product must be used). This applies to food products that are likely to, after a short period, constitute an immediate risk to human health from a microbiological point of view (e.g. raw meat and fish, chilled ready-to-eat foods, processed fruit and vegetables, fresh fruit juices, etc.). In this case, shelf-life relates to food safety.

OR

- The **'best before'** date (i.e. the '**date of minimum durability**' as defined in Regulation (EU) No 1169/2011 on the provision of food information to consumers (FIC) (European Union, 2011) is the date until which the food retains its specific properties when properly stored. This applies to food products such as canned, dried, ambient, and frozen foods where quality is an issue rather than safety. In this case, shelf-life relates to food quality (appearance, odour, texture, flavour, etc.).

Validating product shelf-life is obtaining and documenting any evidence that proves that the shelf-life of a food is accurate, and that the food will maintain its safety and/or quality until the end of that shelf-life. The responsibility for food safety rests with food business operators (European Union, 2004a; European Union 2004b; European Commission, 2002), There is no generic method to estimate and set food shelf-life. This is because many different conditions can affect product safety and quality. As such, this document outlines good practice for food business operators to estimate, set and verify the safety of food over its shelf-life.

2. Scope

The setting and validation of shelf-life as it relates to food safety is within the scope of this document. In most circumstances, these foods 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 outside the scope of this document. In most circumstances, these foods will require a 'best before' date to indicate the end of shelf-life.

3. Legal requirements and responsibilities for shelf-life

General food law

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 (European Commission, 2002).

Responsibility

Generally, the manufacturer of a food (with some exceptions) is responsible for setting and validating the shelf-life. However, this responsibility may also fall to secondary manufacturers (co-packers), re-packers, food caterers, food retail outlets etc. depending on specific circumstances (European Commission, 2002).

Microbiological criteria

Under Regulation (EC) No 2073/2005, as amended, food should "*not contain microorganisms, their toxins and metabolites in quantities that present an unacceptable risk for human health*" (European Commission, 2005). Furthermore, some food business operators may be required to demonstrate that foods they manufacture comply with specified microbiological criteria throughout the foods shelf-life under reasonably foreseeable conditions of distribution, storage and use (European Commission 2013, 2005).

Labelling

The date of minimum durability or 'best before' date of a food means "the date until which the food retains its specific properties when properly stored". In the case of foods which from a microbiological point of view, are highly perishable and are therefore likely after a short period to constitute an immediate danger to human health, the date of minimum durability must be replaced by the 'use by' date. Under Regulation (EU) No 1169/2011, as amended (European Union, 2011), once the 'use by' date has passed, a food is deemed to be unsafe in accordance with Article 14 (2) to (5) of Regulation (EC) No 178/2002, as amended (European Commission, 2002). Under this legislation it is illegal to place unsafe food on the market, meaning food cannot be sold beyond its 'use by' date.

Products which carry a 'use by' date must follow the indication with a description of the storage conditions which must be observed e.g. keep refrigerated. Where necessary, the 'best before' date must be followed by a description of the storage conditions which must be observed if the product is to keep for the specified period. Certain product specific legislation requires that the food must indicate a 'use by' date (e.g. fresh poultry meat) or a 'best before' date (e.g. eggs). See Appendix 4

of this guidance note for more information on labelling requirements under Regulation (EU) No 1169/2011, as amended (European Union, 2011).

Decision tree to determine whether a food product should be labelled with a 'use by' or 'best before' date

The European Food Safety Authority (EFSA) Panel on Biological Hazards developed the decision tree shown in Figure 1 (page 7) of this guidance note in the document "*Guidance on date marking and related food information: part 1 (date marking)"* to help food business operators decide when to apply the 'use by' or 'best before' date to their products (European Food Safety Authority Panel on Biological Hazards, 2020, p. 32, Figure 1). The decision on the type of date marking needs to be taken on a product-by-product basis, considering the relevant hazards, product characteristics, processing and storage conditions. The key steps to determine and validate the shelf-life period of food products are: (i) identification of the relevant pathogenic/spoilage microorganism and its initial level, (ii) characterisation of the factors of the food affecting the growth behaviour of the relevant pathogenic/spoilage microorganisms or their inactivation, and (iii) assessment of the growth behaviour or inactivation of the pathogenic/spoilage microorganism in the food product during storage until consumption.

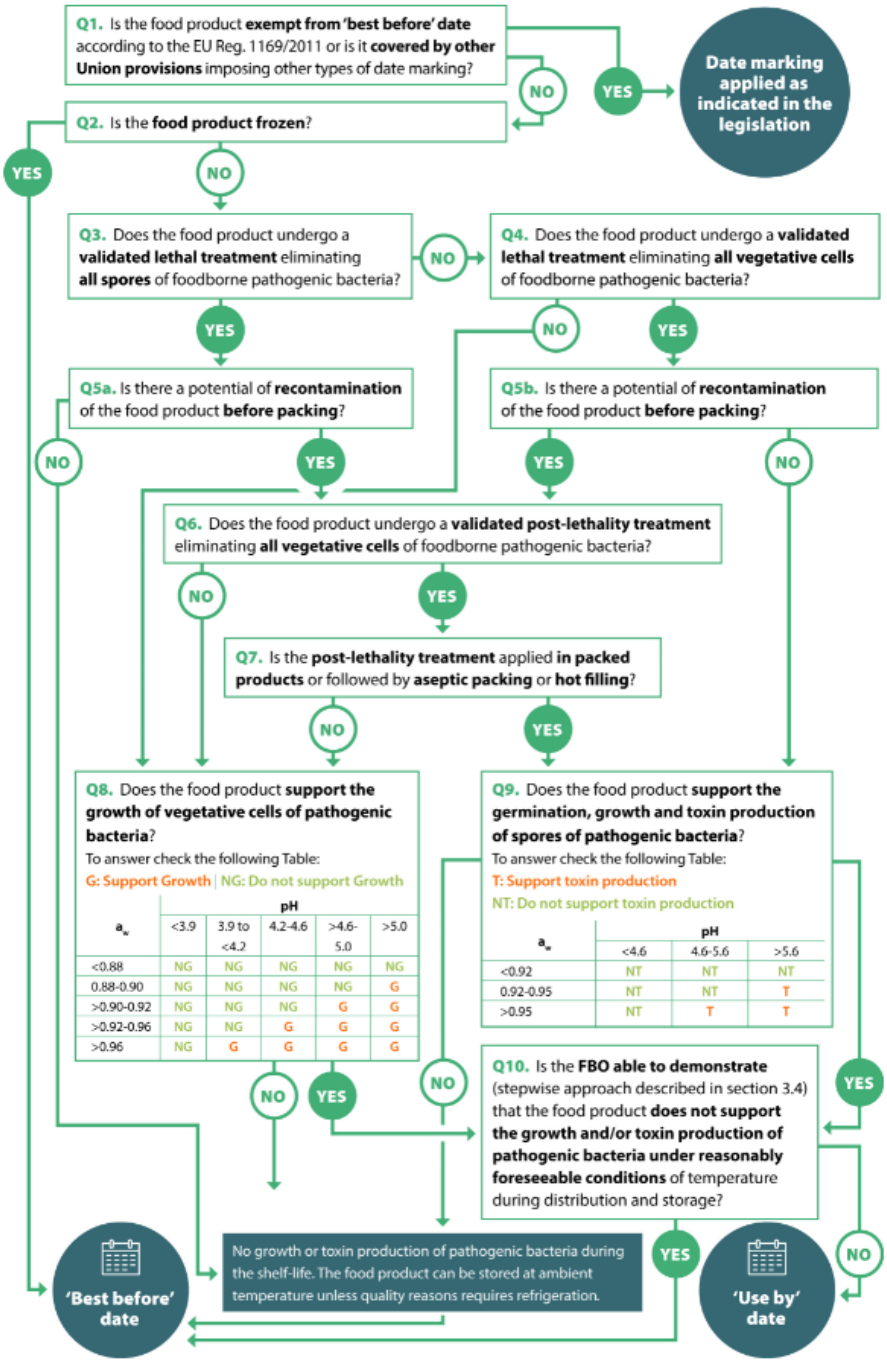

Figure 1 Decision tree on the appropriate date marking for temperature controlled prepacked foods (European Food Safety Authority Panel on Biological Hazards, 2020, p. 32, Figure 1) [1]

[1] **Reference:** European Food Safety Authority Panel on Biological Hazards (2020) *Guidance on date marking and related food information: part 1 (date marking)*. Available at: https://www.efsa.europa.eu/en/efsajournal/pub/6306

Special storage conditions and/or time limits for consumption after opening

The label on food products should outline any special storage conditions necessary to enable the consumer to maintain the safety and quality of the product. Details on how the product should be stored once the packaging is opened should be outlined, such as '*Refrigerate after opening*' or '*Store in a cool dry place*' and where appropriate, the time limit for consumption should be indicated, e.g. '*Refrigerate after opening and use within 3 days*'.

Additional guidance on food information relating to storage conditions and/or time limits for consumption after opening a food package and thawing of frozen foods has been published by the EFSA Panel on Biological Hazards (2021). After opening the package, contamination may occur, introducing new pathogens or spoilage microorganisms into the food. The intrinsic characteristics (e.g. pH and water activity [a_w]) and extrinsic characteristics (e.g. gas atmosphere within the package) of the food may change once the packaging is opened, which could potentially affect the microbiological safety of the food product. Setting a time limit for consumption after opening the package (secondary shelf-life) is complex in view of the many influencing factors and information gaps.

Bearing this in mind, the EFSA Panel on Biological Hazards developed the decision tree shown in Figure 2 (page 9) of this guidance note in the document "*Guidance on date marking and related food information: part 2 (food information)*" to assist food businesses in deciding whether the time limit for consumption after opening, due to safety reasons, is potentially shorter than the initial 'best before' or 'use by' date of the product in its unopened package (European Food Safety Authority Panel on Biological Hazards, 2021, p. 18, Figure 2). For products where opening the package leads to a change in the type of pathogenic or spoilage microorganisms present in the food and/or factors increasing their growth compared to the unopened product (e.g. anaerobic to aerobic microorganisms if the MAP is opened), a shorter time limit for consumption after opening would be appropriate.

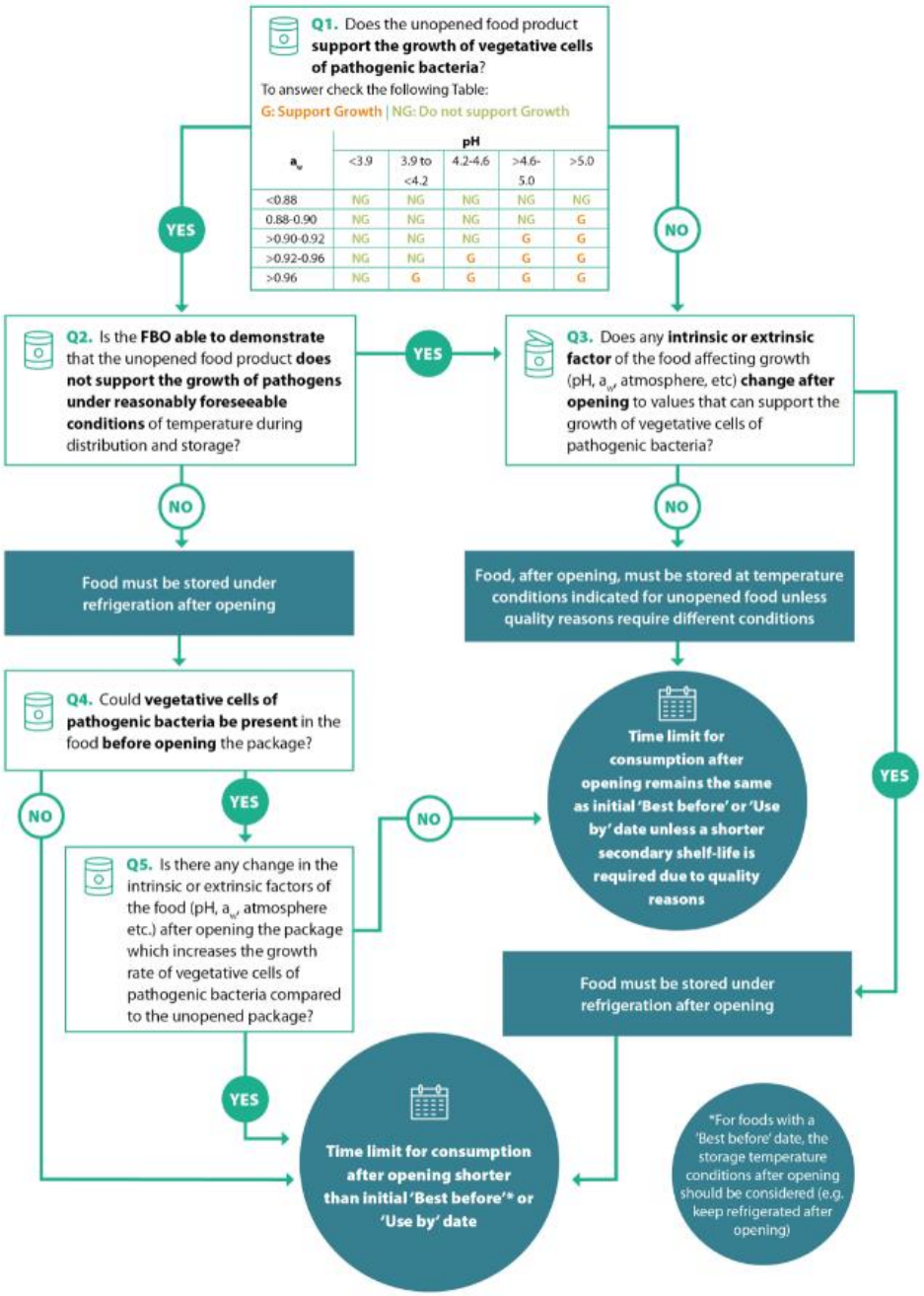

Figure 2 Decision tree on how to determine appropriate storage conditions and the time limit for consumption after opening the food product packaging (European Food Safety Authority Panel on Biological Hazards, 2021, p. 18, Figure 2) [2]

[2] **Reference:** European Food Safety Authority Panel on Biological Hazards (2021) *Guidance on date marking and related food information: part 2 (food information)*. Available at: https://www.efsa.europa.eu/en/efsajournal/pub/6510

4. Setting and validating shelf-life of food

Many different factors will affect the safety of food and lead to variation in shelf-life. As such, there is no simple answer to how long a shelf-life should be and how that shelf-life should be set and validated. However, there are good practice guides available for food business operators to follow which will help them to accurately estimate, set and validate the shelf-life of foods.

In estimating and setting shelf-life, the primary objective should be food safety. Therefore, an accurate shelf-life is essential. If the shelf-life is too long or food business operators assume that food is going to be produced, distributed and stored under unrealistic conditions there is an increased risk of food safety issues arising, people becoming ill and damage to the food business operator's brand and reputation.

With this in mind, shelf-life should always be an integral part of a food business operator's procedures based on HACCP (Hazard Analysis and Critical Control Point) and good hygiene practice (GHP) and should always take into account, reasonably foreseeable conditions of distribution, storage and use of the food, including consumer practices where applicable.

It is strongly recommended that food business operators document all work related to estimating, setting and validating food shelf-life. This will allow the food business operator to link together documented work to support and provide objective evidence that the declared shelf-life is accurate. It will also allow customers and inspectors alike to verify the validity of the shelf-life declared. The documentation which relates to shelf-life should be filed together and kept by the food business operator as a part of its procedures based on HACCP.

The shelf-life of food should be estimated during product development and set before the food goes on sale to consumers. The estimate of shelf-life should be made at the point in the product development process where the food business operator is confident that it can consistently produce the same food from batch to batch under real processing conditions.

Other circumstances where the shelf-life should be estimated, set and validated include:

- Where there is a legal requirement (see: Appendix 1)
- The absence of supporting evidence for the shelf-life of an existing food
- Modification or reformulation of a food or its production

For good practice, food business operators should estimate, validate and set shelf-life during product development using a shelf-life study which has the following steps as set out in Figure 3. They should also conduct periodic verification of the shelf-life set for the food product.

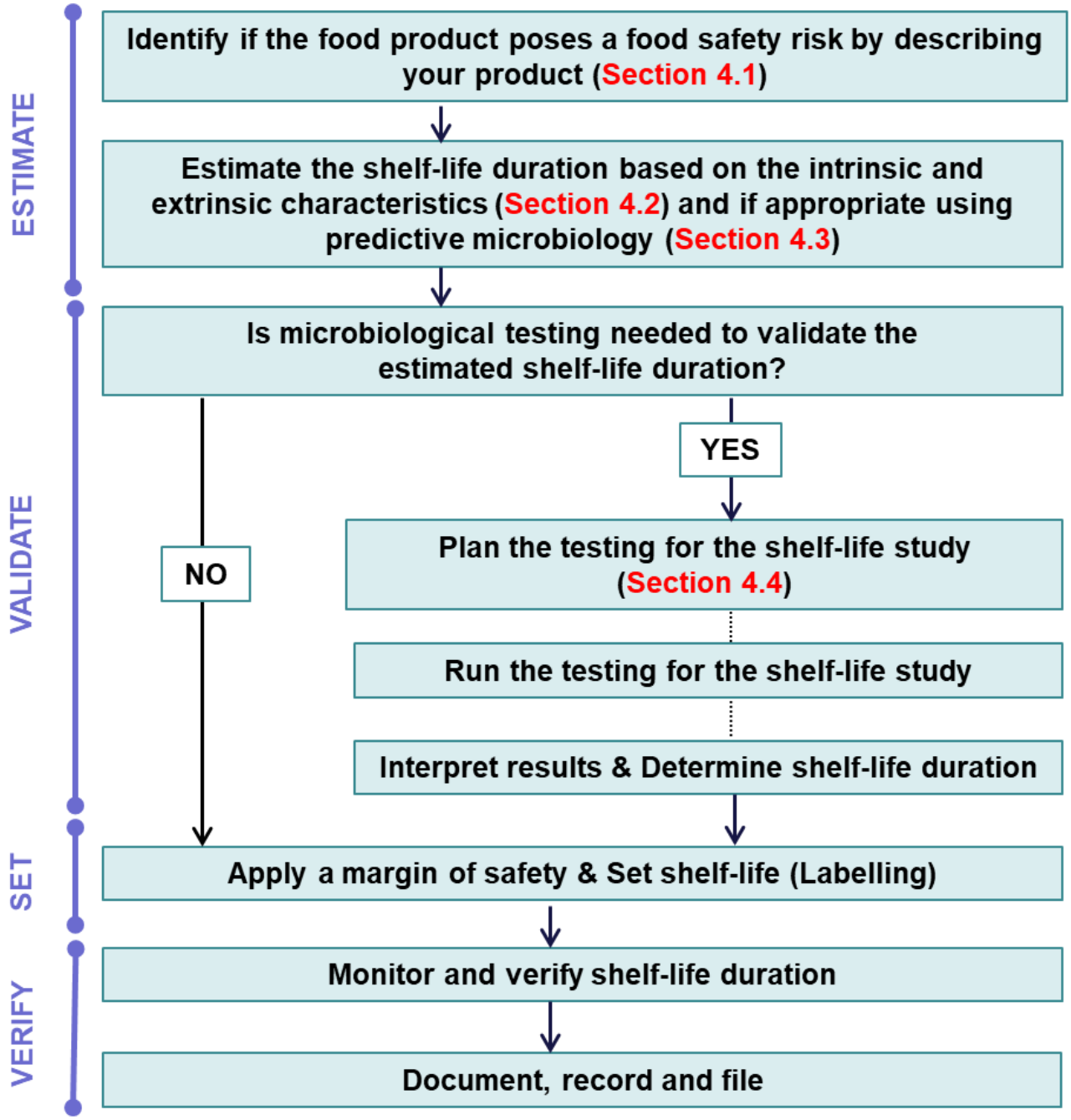

Figure 3 Good practice in estimating, validating, setting and verifying shelf-life.

4.1 Describe the food

Typically, when a food business operator is developing a food product, a preliminary product specification will be drawn up to outline all details relating to the food and its manufacture. It is important that food business operators include as much information as possible in this specification.

Ready-to-eat status of food

Food business operators should decide if the food is intended for direct human consumption without the need for cooking or other processing effective to eliminate or reduce to an acceptable level, microorganisms of concern. If this is the case, the food is considered a ready-to eat food. Where foods are considered ready-to-eat, the food business operator should document this information and ensure it is consistent with the products labelling. A decision tree to help manufacturers and producers determine if a food is ready-to-eat is provided in *FSAI Guidance Note No. 27 on the Enforcement of Commission Regulation (EC) No 2073/2005 on Microbiological Criteria for Foodstuffs* (Food Safety Authority of Ireland, 2014a).

Legal criteria for certain pathogens in certain types of ready-to-eat foods are set in Commission Regulation (EC) No 2073/2005, as amended (European Commission, 2005). With respect to *Listeria monocytogenes*, the Regulation sets legal criteria for this pathogen in all ready-to-eat foods. The Regulation emphasises the importance for manufacturers of ready-to-eat foods which can support the growth of *L. monocytogenes* and that may pose a *L. monocytogenes* risk for public health, to ensure that their products comply with the criteria throughout the product's shelf-life and lists the type of studies they should conduct in order to investigate this (European Union Reference Laboratory for *Listeria monocytogenes*, 2021a, 2013). These studies are outlined in Appendix 1 of this document.

Product specification

A product specification should be documented by the food business operator and include (but is not limited to) the following information:

- Ready-to-eat status of the food
- Ingredient list and specifications for each ingredient. Note: Some retailers will request ingredient supplier details
- Processing parameters
- Good manufacturing and hygiene practices

- Product specific procedures based on HACCP
- Quality control parameters and measures
- Packaging details and specifications for all packaging
- Labelling considerations (e.g. shelf-life declaration, allergen declaration)
- Storage, distribution and retail display conditions
- Instructions for use of the product as applicable
- Details of microbiological and compositional specifications, including limits
- Legislative requirements.

All of the above can and will have an impact on food safety and shelf-life. When the food business operator has completed the development of its food, the product specification can be amended and finalised for normal production.

4.2 Establish the characteristics of the food

All foods have their own unique characteristics which will affect food safety and shelf-life. The characteristics of the food's entire lifecycle from choice of ingredient, through processing and distribution to final consumer, will affect shelf-life. Some characteristics prolong shelf-life while others decrease it. Describing, measuring and understanding these characteristics will allow food business operators to identify what characteristics will cause food to become unsafe and affect the shelf-life.

All foods can have their characteristics broadly divided into intrinsic and extrinsic. Intrinsic characteristics are those characteristics inherent to the composition of the food such as its ingredients and formulation. Extrinsic characteristics are those characteristics which relate to the external processing environment which impact on the food such as storage temperature and packaging (Jay *et al*, 2005; Food & Drug Administration, 2003; McDonald, 1999). Table 1 outlines some the more commonly identified intrinsic and extrinsic characteristics of foods.

All microorganisms have minimum, maximum and optimal requirements for survival and growth in foods. Measuring and describing the intrinsic and extrinsic characteristics of the food will allow food business operators to determine what microorganisms may survive and grow in their food, particularly those which can cause illness (i.e. pathogens). This will allow food business operators to control the safety of food during its shelf-life by preventing or minimising survival and growth of specific pathogens. The control of product safety and shelf-life typically requires the combination of different intrinsic and extrinsic characteristics to act as hurdles to microbial growth and survival. This provides a preservation effect adequate for control of specific pathogens and shelf-life stability (Leistner and Gould, 2002). In relation to shelf-life, some intrinsic and extrinsic characteristics can

be considered hurdles to the survival and growth of microorganisms during, and up to the end of shelf-life. A carefully selected and monitored combination of these characteristics can retard or inhibit microbial growth in a food.

Table 1 Intrinsic and extrinsic characteristics [a]

Intrinsic	Extrinsic
pH and type of acid present [b]	Temperature (during production, storage, distribution and display) [b]
Water activity (a_w) [b]	Packaging [b]
Redox potential (E_h)	Gas atmosphere
Natural barriers	Relative humidity
Nutritional content of food and availability	Food processing
Antimicrobial substances	Good manufacturing and hygiene practices
Microflora	Historical data [c]
Microbiological quality of ingredients	Storage and distribution
Food formulation and composition	Consumer practices
Food assembly and structure	Procedures based on HACCP

[a] Table adapted from Jay et al. (2005), Food & Drug Administration (2003), McDonald (1999)
[b] For the majority of food business operators, the most important intrinsic and extrinsic characteristics are the pH, water activity, storage temperature and packaging of the food.
[c] May also relate to intrinsic characteristics depending on the nature of the data.

For example, foods with the following characteristics are not considered to support the growth of *L. monocytogenes* (European Commission, 2005):

- pH is ≤4.4, or
- Water activity (a_w) is ≤0.92, or
- pH is ≤5.0 and the a_w is ≤0.94
- The food is frozen.

Hurdles can be based on any number of intrinsic and extrinsic characteristics. An example of how hurdles can be used in a pre-packed, sliced cooked ham to retard or inhibit the survival and growth of pathogens such as *L. monocytogenes* and ensure product safety up to the end of shelf-life, is given in Figure 4.

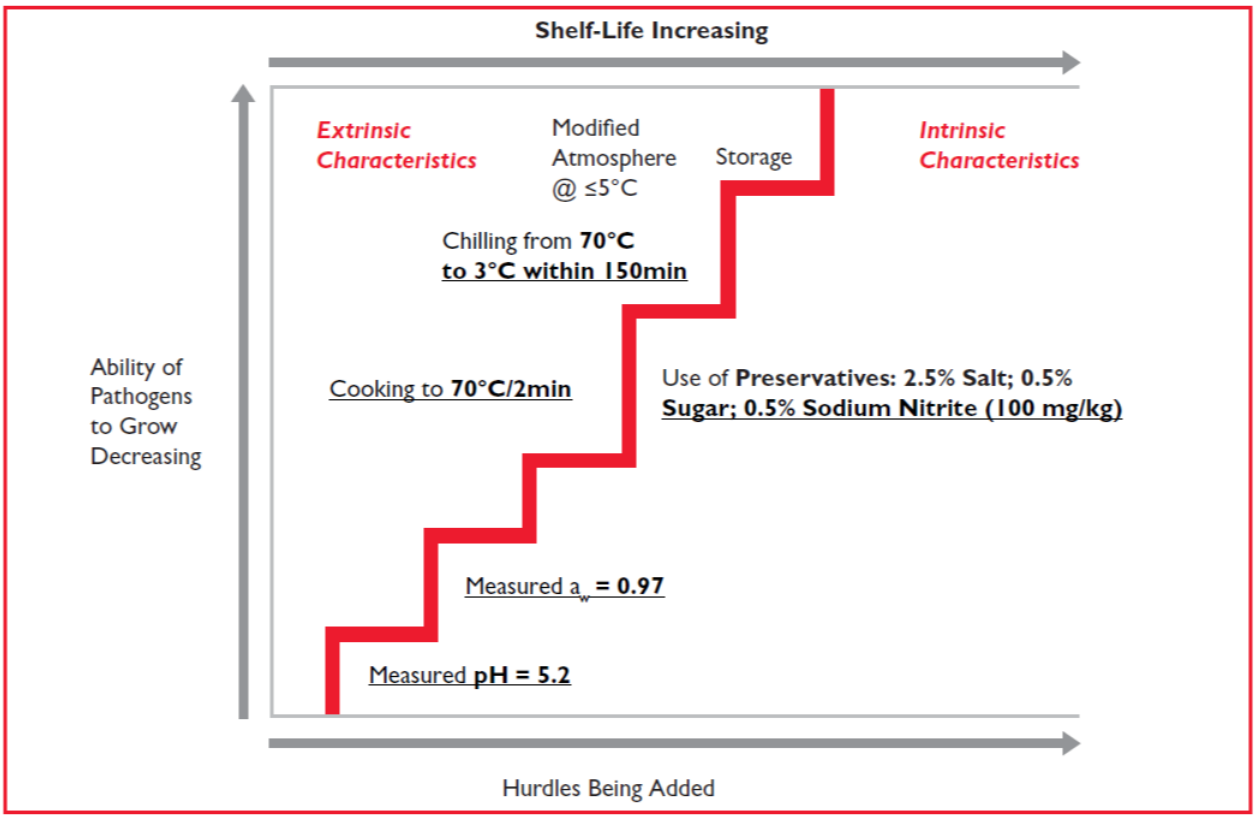

Figure 4 Hurdles used to inhibit pathogen survival/growth in cooked ham

Not all hurdles are proportional in terms of the effect they have on the ability of pathogens to survive and grow, and on the food's shelf-life. However, as each hurdle reduces the risk of a hazard occurring, they may be identified as critical control points and controlled by the food business operator as part of their procedures based on HACCP. Controlling each hurdle as a separate critical control point will help ensure that all hurdles work together to minimise the risks to food safety.

If food business operators do not have sufficient technical expertise/resources to establish the intrinsic and extrinsic characteristics, it is recommended that relevant technical advice is sought from suitably qualified and trained personnel to ensure food characteristics are correctly determined.

4.2.1 Intrinsic characteristics

pH and type of acid

The pH and acidity are very important intrinsic characteristics affecting the survival and growth of microorganisms in food. The pH is a measure of a product's acidity or alkalinity with a scale that extends from 0 to 14. The relative strengths of acid and alkaline defined by their pH value on this scale. A 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 ten times more acidic or less acidic (e.g. pH 6 is ten times more acidic than pH 7). The pH range for microbial growth and survival is defined by a minimum and maximum value with an optimum pH for growth and survival. Most microorganisms grow best or optimally at, or near, a neutral pH of 7. Monitoring pH levels during food processing can be an important step in the production of some food products since pH values affect microbial growth.

Generally, pH is measured using hand-held pH meters with two decimal places accuracy. In-line pH measurement of food is sometimes used in larger industrial operation. It is recommended that pH is measured according to ISO 2917:1999 or other applicable method (International Standards Organisation, 1999). Typically, pH is measured on macerated food and is therefore an average value. In multi-component foods (e.g. ready meals, sandwiches etc.) each component of the food may have a different pH value. It may be necessary to measure the pH of each component separately (as far as possible) in order to assess if any component can support pathogenic growth. Taking coleslaw as an example, mayonnaise has a low pH which may not support the growth of *L. monocytogenes*, but cabbage with a higher pH could. Low acid foods (e.g. have a pH of ≥4.6) can be acidified by adding acid or acid ingredients to produce a final equilibrium pH of ≤4.6. Equilibrium pH means the final pH measured in the acidified food after all the components of the food have achieved the same acidity (Cornell AgriTech, 2022; Ingham, 2017). Recommendations for the appropriate use of pH meters and probes are provided in Appendix I of *Guidance Note No.37 Good manufacturing practices for the production of ready-to-eat unpasteurised fermented plant-based products* (Food Safety Authority of Ireland, 2021c).

It may also be necessary to measure the pH of foods over their shelf-life as pH can vary with time due to microbial activity, product composition or formulation. Some foods may be more prone to pH change than others including vegetables, fresh meats, poultry, fermented meats and some mould/smear ripened cheeses. The pH of multi-component products may also vary within the food due to diffusion and mixing limitations. In some foods, there may also be a range of different pH values which could allow growth of pathogens which otherwise would not grow at the measured pH value (e.g. foods containing meat, fats or oils can be difficult to acidify uniformly). Food business operators should take extra care with these foods (Food Standards Agency, 2020).

The type of acid used in food will also have an influence on microbial survival and growth. Organic acids such as acetic, sorbic, propionic and benzoic typically cause disruption of the microbial cell membrane. Acetic acid (i.e. vinegar) at levels greater than 0.1%, inhibits the growth of some foodborne pathogens and is used extensively in sauces and pickles, typically in combination with mild thermal pasteurisation treatments. Sorbic and benzoic acids are more typically used to control yeast and mould in the beverage industry (Jay *et al*, 2005; Food & Drug Administration, 2003).

Where pH is a controlling characteristic for food safety and shelf-life, it should be routinely monitored, ideally for each production batch (Food Standards Agency, 2020; Jay *et al*, 2005; Food & Drug Administration, 2003). Table 2 outlines the approximate pH of some common foods. It should be noted that the pH value is directly dependent on the temperature of the foodstuff the measurement was taken at. This has to be taken into consideration if pH values obtained at different temperatures are to be compared.

Water activity

Water activity (a_w) is a measure of the amount of free or unbound water available to microorganisms for growth. The a_w of most foods ranges from 0.2 for very dry foods to 0.99 for moist fresh foods (Table 3). Foods with a low a_w value cannot support microbial growth because microorganisms need water for growth. Pathogenic and spoilage bacteria do not grow in food with an a_w <0.85, but some yeast and mould can grow at a_w as low as ≤0.60 (Food Safety Authority of Ireland, 2007a; Jay *et al*, 2005; Food & Drug Administration, 2003;). The a_w of a food can be altered by processing such as drying, concentrating, freezing, or by the addition of ingredients such as salt and sugar, or the storage in atmospheres with a different relative humidity (Fennema, 1996; Beuchat, 1981). Sugar and particularly salt are used to preserve foods by decreasing the a_w by either binding free water and making it unavailable for microbial growth (e.g. sugar in jams), or by exerting osmotic pressure directly on microorganisms (e.g. salt) used in brine for some cured meats.

It's important not to confuse the a_w with the moisture content of foods (i.e. water content). While some high moisture foods may have high a_w, this is not always the case. For example, jams have a moisture content of approximately 50 to 60 % but the water present is bound to the sugar and pectin in the jam making it unavailable for microbial growth, thus giving jams a low a_w value of around 0.75 (Public Health England, 2017). Products with the same water content can also have very different a_w values. For example, salami and cooked beef have a water content of approximately 60%, but the a_w of salami and cooked beef is approximately 0.82 and 0.98, respectively (Province of Manitoba, 2022).

Table 2 Approximate pH of common foods [a-b]

Food	pH
Baking soda	≥8.0
Pure water	7.0
Fresh eggs	7.0–7.8
Fresh shellfish	6.6–7.0
Fresh fish	6.6–6.8
Cows' milk	6.2–7.3
Butter	6.1–6.4
Fresh pork/Potatoes	6.0–6.2
Fresh poultry	5.8–6.0
Bacon	5.6–6.6
Fresh beef steaks	5.5–5.9
Canned vegetables	5.4–6.5
Bread	5.3–5.8
Cheddar cheese	5.2–5.9
Bananas	4.5–5.1
Cottage cheese/Yoghurt/Mayonnaise	4.2–4.5
Tomatoes/Beer and wines	4.0–4.5
Apple/Fruit juices	3.8–4.0
Tomato ketchup	3.6–3.8
Vinegar	2.0–2.5
Lemon	2.0–2.2

[a] All values given in Table 2 are approximations only. Laboratory analysis of a food is required in order to determine an accurate pH measurement.

[b] Table adapted from United States Department of Agriculture (2017), Jay *et a*l. (2005), Food & Drug Administration (2003).

Table 3 Approximate water activity values for some foods [a-d]

Food	Water Activity
Distilled water	1.0
Fresh meats, poultry, fish and eggs	≥0.98
Fresh fruit and vegetables	≥0.98
Fresh milk	≥0.98
Fruit and vegetable juices	≥0.98
Cured meats, fresh breads, cheddar cheese	≥0.93–0.98
Dry and fermented sausages, dry cheeses, margarine, fruit juice concentrates and maple syrup	≥0.80–0.93
Soy Sauce *(will vary depending on salt concentration)*	0.70–0.80
Dried meat (*e.g. beef jerky)*	≥0.65
Dried fruits, jams, honey and flours	≥0.60–0.85
Biscuits, dry noodles, pasta and crisps	≥0.30–0.60
Whole egg powders	0.40–0.50
Dried vegetables, soups, breakfast cereals and milk powders	≥0.20–0.30
Coffee powder, Powdered Infant Formula	≤0.20

[a] Values taken at 20 °C

[b] a_w has a scale from zero (i.e. 0% water available) to one (i.e. 100% water available)

[c] The minimum a_w for microbial growth is generally determined by the addition of salt. The minimum for growth with other substances (e.g. sugars) will be different. For toxin production by most pathogens, the minimum a_w value is normally higher than that for growth

[d] Table adapted from United States Department of Agriculture (2017), Food Safety Authority of Ireland (2007a), Jay *et al*. (2005), Food & Drug Administration (2003), Fennema (1996), Beuchat (1981).

Typically, the concentration of salt in the aqueous or water phase of a food (i.e. water phase salt content; WPS) affects the a_w of the food, along with other solute concentration.

The WPS (g/100 mL) can be calculated using the following formula:

$$\% \text{ WPS} = \left(\frac{\% \text{ Salt}}{\% \text{ Salt} + \% \text{ Moisture}} \right) \times 100$$

If direct measurements for a_w are not taken, the WPS can also be used to estimate the a_w using the following formula:

Water Activity = [1- (WPS ×0.0052471)]- (0.00012206 × WPS^2) (Ross and Dalgaard, 2004)

The standard method for determining a_w is ISO 21807:2004 (International Standards Organisation, 2004). Most individual foods will have a homogenous a_w therefore, homogenisation with a blender is not required. In many cases, homogenisation is not recommended as the sample material can become hot, losing water and thereby making the a_w measurement not representative of the food been examined.

One exception is fermented meat products (e.g. fermented sausage or salami) in which an a_w gradient can form in the product during ripening/drying between the inside and outside of the product. For these foods, the a_w should be measured at a range of points distributed over the products cross-section until the a_w for the whole product has equilibrated to a final value.

The a_w of multi-component foods will like pH, vary between components. It may be necessary to measure the a_w of each component separately (as far as possible) in order to assess if any component can support pathogenic growth.

Like pH, the a_w of a food can change with time due to microbial activity, product composition, storage temperature and formulation (Jay *et al*, 2005; Food & Drug Administration, 2003). However, where a_w is a controlling characteristic for food safety and shelf-life, it should be routinely monitored, ideally for each production batch (Food Standards Agency, 2020, Jay *et al*, 2005; Food & Drug Administration, 2003).

Redox potential

The redox potential is a measure of potential difference in a system or food (E_h). The E_h of a food determines which type of microorganisms will grow in it, depending on whether they require

oxygen for growth (aerobic) or do not require oxygen for growth (anaerobic). It can be generated by:

a. Oxidation: Loss of an electron by a substance (i.e. the substance is an electron donor) known as a reducing agent

Or

b. Reduction: Gain of an electron by another substance (i.e. the substance is an electron acceptor) known as an oxidizing agent.

The redox potential is measured in millivolts (mV) because when electrons move they create an electric current, which can be measured (Jay *et al*, 2005). When the redox potential is measured, it should be referenced with the pH of the food, as redox potential is dependent on the pH of the food.

Routine measurement of the redox potential in foods is quite simple and normally taken at a pH 7.0 (Food and Drug Administration, 2003). However, difficulties may arise in taking accurate, reproducible measurements and in accounting for differences in the redox potential throughout a food product (Jay *et al*, 2005; Food & Drug Administration, 2003). Microorganisms can be broadly classified into the following groups based on their requirements for oxygen and redox potential of the food (measured in mV) (Jay *et al*, 2005; Food & Drug Administration, 2003):

- Aerobes require oxygen for growth and can grow at a redox potential between +300 to +500 mV
- Facultative anaerobes grow with or without oxygen and can grow at a redox potential between +300 to -100 mV
- Anaerobes require no oxygen for growth and can grow at a redox potential between +100 to ≤ -250 mV.

The redox potential can be influenced by the foods chemical composition and the processing and storage conditions of the food (e.g. stored in air or a modified atmosphere). A food which is stored under aerobic conditions will typically have higher redox potential (i.e. positive millivolts) than those foods stored under anaerobic conditions (e.g. canned food).

The redox potential is particularly important in ensuring the safety of products such as ambient-stable meat products (e.g. salamis, fermented and dried meats) (Leistner, 2000). However, as with pH and water activity, the redox potential of foods can be variable. It is recommended that food business operators do not use redox potential measurements solely to assess product safety due to the high variability of the redox potential and the often-low accuracy in its measurement. Table 4 outlines the approximate redox potential of some common foods.

Table 4 Approximate redox potential of common foods [a, b]

Food	Redox Potential (mV)
Fruit/Plant Foods *(e.g. fruit juices)*	+300 to +400
Minced Meats *(e.g. minced beef)*	+200
Whole or Solid Meats *(e.g. steak)*	-20
Cheeses	-20 to -200
Canned Foods	-130 to -550

[a] Food business operators should note that some foods packaged in aerobic conditions may have an anaerobic internal environment.

[b] Table adapted from United States Department of Agriculture (2017), Jay et al. (2005), Food & Drug Administration (2003), Morris (2000), Leistner (2000).

Natural barriers

Some foods will have natural barriers or coverings that provide different levels of protection from external contamination. These barriers include shells, skins and membranes commonly found on foods such as nuts, eggs, vegetables, fruit and fish. The effectiveness of these barriers to prevent contamination of foods will vary considerably, and in some cases, may actually facilitate microbial growth, particularly if the natural covering is damaged during harvesting. For example, hen's eggs are generally sterile but can be heavily contaminated on the shell, so any damage to the shell can allow microorganisms to enter (Food & Drug Administration, 2003). It is recommended that when food business operators remove natural barriers from foods, an appropriate method to reduce microorganisms (e.g. washing, filtration, trimming etc.) is used (Jay *et al*, 2005; Food & Drug Administration, 2003).

Nutrient availability

All microorganisms have basic nutritional requirements for growth and maintenance of basic metabolic functions (e.g. protein, fat, sugars, minerals, vitamins). These requirements vary depending on the microorganism. Therefore, the nutrient content and availability of nutrients in a food will influence microbial growth. Typically, bacteria have the highest nutritional requirements for growth followed by yeasts and moulds (Jay *et al*, 2005; Food & Drug Administration, 2003). However, viruses and protozoa do not grow in food.

Antimicrobial substances

Some foods will contain antimicrobial substances which retard or prevent the growth of microorganisms. There is a wide variety of antimicrobial substances with varying levels of antimicrobial activity. Some antimicrobial substances are found naturally in foods (e.g. allicin in garlic and onions; lysozyme in eggs and milk) (Jay *et al*, 2005). Some antimicrobials are also created during food processing (e.g. production of phenols during smoking or bacteriocins during fermentation) (Food & Drug Administration, 2003). Other antimicrobials can be added to foods (i.e. food additives) to the extend shelf-life and/or inhibit pathogens (European Commission, 2008).

Food additives

Regulation (EC) No 1333/2008, as amended, harmonises the use of food additives in foods in the European Union (EU) and defines food additives as follows (European Commission, 2008):

"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".

This definition of food additives includes the use of food additives in foods covered by Regulation (EU) No. No 609/2013, as amended (European Commission, 2013) on foodstuffs intended for particular nutritional uses, and the use of certain food colours for the health marking of meat and the decoration and stamping of eggs[3].

Microflora

All foods naturally contain different types and concentrations of microorganisms (i.e. natural microflora). In some foods, microorganisms are added for processing and technological reasons such as lactic acid bacteria which are added to milk to make cheese and yogurt. In the case of natural microflora, the types and concentrations of microorganisms in food can vary widely. The presence of certain microorganisms in foods (e.g. lactic acid bacteria) may also retard or prevent the growth of pathogens. They can do this by outgrowing the pathogens, consuming available

[3] For more information on food additives and food additive legislation see https://www.fsai.ie/faq/additives.html

nutrients and/or producing substances in the food which retard or prevent growth of pathogens (i.e. a process known as competitive inhibition).

Microbiological quality of ingredients

The microbiological quality of ingredients will affect the safety and shelf-life of foods. Food business operators should assume that all ingredients are a potential source of microbiological contamination. Therefore, the starting point for producing safe food products with a desired shelf-life is the use of ingredients which comply with legislative requirements for food safety and hygiene, particularly microbiological criteria where applicable (European Commission, 2005).

In the absence of specific criteria set in legislation, ingredients should comply with any relevant guideline microbiological criteria that may be applicable in *Guidance Note 3 Guidelines for the Interpretation of Results of Microbiological Testing of Ready-to-Eat Foods Placed on the Market (Revision 4)* (Food Safety Authority of Ireland, 2020b) and/or in internationally published microbiological guidelines (International Commission for the Microbiological Specifications of Foods, 1996). Food business operators are also recommended to consult other information sources as relevant for guidance on the microbiological quality of ingredients and potential food safety hazards they should consider as part of their HACCP-based procedures such as Irish standards (National Standards Authority of Ireland, 2015a, 2015b), Irish guidelines (Food Safety Authority of Ireland, 2021a, 2021b, 2021c, 2019b, 2018a, 2018b, 2013a, 2007a, 2007b, 2005),and/or industry best practice guidance (Food Standards Agency, 2020; Chilled Food Association & British Retail Consortium, 2010; Campden BRI 2019, 2009; Institute of Food Science & Technology, 1993).

It is recommended that the microbiological quality of ingredients is set out in a specification agreed between the food business operator and the supplier. In this case, the specification must meet minimum legal requirements where applicable (European Commission, 2002). Good practice for food business operators is to have a written supplier approval procedure which means that ingredients are only sourced from a supplier previously approved by the food business operator.

All water and ice used as an ingredient and for preparation of food must be of drinking water standard (i.e. potable water) (European Union, 2020; Food Safety Authority of Ireland, 2015b; European Union, 1998). Where water (intended to be used as an ingredient or for preparing food) entering premises is not of potable quality or where quality is unreliable, (e.g. from a private well), appropriate treatment should be applied by the food business operator to the water to ensure it is of potable quality before use (Food Safety Authority of Ireland, 2015b; Chilled Food Association & British Retail Consortium, 2010; European Union, 2004; European Union, 1998). Under EU food

law (European Union, 2004a) where there is a reference to drinking water, it is usually defined as water which meets the standards of the drinking water legislation (European Union, 2020, 1998).

Food formulation, composition, structure and assembly

The formulation, composition, structure and assembly of food will influence food safety and shelf-life. Some foods can have non-uniform, heterogeneous internal structures and therefore, have intrinsic characteristics which vary within the structure of the food and vary from the intrinsic characteristics of the food as a whole. Table 5 gives examples of some food formulation, compositional, structure and assembly issues which may affect food safety and shelf-life.

Table 5 Some examples of food formulation, compositional, structure and assembly issues

Situation	Example of Issue
Manufacturing Error An ingredient is removed, or an incorrect quantity of ingredient is added to the product	In producing a cooked ham, a food business operator does not add the correct concentration of salt to the curing solution, resulting in a product with increased susceptibility to pathogenic growth and a reduced shelf-life.
Product Development Error Ingredients within a product are in close proximity to each other, causing migration of some components (e.g. water, fats) out of the product	A cheese-based sauce separates on standing as no emulsifier is present which results in a reduced product safety and a shorter shelf-life.
Quality of Ingredients Ingredients from two different suppliers have different microbiological quality	A supplier of raw chicken is unable to meet an order. The food business operator orders the chicken from another supplier without supplier approval. However, the microbiological quality of this new chicken is inferior to the regular suppliers resulting in a reduction in final product shelf-life.
Quality of Ingredients Ingredients of differing microbiological quality are combined together	A pre-packaged ham and cheese sandwich is prepared with a sliced, pre-packaged cheddar cheese. However, the cooked ham is sliced by the food business operator on a

Situation	Example of Issue
	poorly cleaned slicing machine increasing the food safety risks and reducing the shelf-life of the product.
Reformulating and Producing Variants of Products An ingredient is replaced with an alternate ingredient	A food business operator wants to develop a sugar-free version of its standard hazelnut flavoured yogurt. A new canned hazelnut puree sweetened with an artificial sweetener is supplied. However, the thermal process applied to the new puree formulation does not destroy spores of *Clostridium botulinum*. In addition, the aspartame-sweetened puree has a higher a_w than the original sucrose-sweetened puree, which permits outgrowth of spores and formation of toxin in the puree and/or the new sugar-free hazelnut yogurt.

4.2.2 Extrinsic characteristics

Temperature

The safety and shelf-life of most foods but in particular foods which require refrigeration, is very dependent on temperature (McDonald, 1999). Microorganisms' ability to grow at different temperatures is broad and includes those microorganisms which are (Jay *et al.*, 2005):

- Psychrotrophic (i.e. optimum temperature 20 °C to 30 °C) but many can survive and grow at or below 5 °C
- Psychrophilic (i.e. an optimum temperature of approximately 15 °C) but can survive and grow between 20 °C and 0 °C or below
- Mesophilic (i.e. optimum temperature 30 °C to 40 °C) but many can survive and grow between 20 °C to 40 °C
- Thermophilic (i.e. optimum temperature 55 °C to 65 °C) but many can survive and grow at 45 °C but not less than 30 °C.

The control of temperature during all stages of food manufacture, storage, distribution and use should be carefully considered, measured and documented by food business operators as it can significantly affect shelf-life. In particular, food business operators should consider if foods may be subject to temperature abuse during storage, distribution and use. For example, research has shown that domestic refrigerators often operate at a higher temperature than 5 °C (Ovca and

Jevšnik, 2009; James *et al.*, 2008; Lagendijk *et al.*, 2008; Kennedy *et al*., 2005; *safe*food, 2004a; 2004b). Recommended temperatures for distribution, retail and catering in Ireland are ≤5 °C (National Standards Authority of Ireland, 2015a, 2015b).

Gas atmosphere

The composition of the gas atmosphere which surrounds a food will affect its shelf-life. Typically, the gas atmosphere composition is altered using modified atmosphere packaging (MAP) (i.e. gas flushing; Food Safety Authority of Ireland, 2009) or vacuum packing to extend shelf-life (Food Standards Agency, 2020; Peck, 2019; Campden BRI, 2009; Peck *et al.*, 2006).

In vacuum packed (VP) food, the air surrounding the food packaging is removed and the pack is sealed, leaving a small residual air content in the pack. In MAP, the air surrounding the food packaging is also removed but replaced with a gas, or mixture of gases such as oxygen, carbon dioxide or nitrogen, before sealing.

The extension of shelf-life through the use of MAP or VP generally requires the control of temperature and other characteristics of the food such as pH. In addition, the specific concentrations of gases, the packaging and equipment used can all affect food safety (Food Standards Agency, 2020). For example, the permeability to oxygen and water of the packaging material, and actively respiring fruit and vegetables, can affect the composition of gases in the pack during shelf-life which in turn, can affect microbial growth and product safety.

Under current legislation, foods which have their shelf-life extended by means of packaging gases must be labelled “packaged in a protective atmosphere” (European Union, 2011). It is also recommended that the label on the packaging carries a clear statement that the labelled shelf-life is no longer valid once food packaging is opened. MAP and VP food should also carry instructions for use that include how soon the food must be consumed after the pack is opened and the storage temperature for the opened product (Figure 2).

Specific information related to the safety and shelf-life of foods with respect to non-proteolytic *Clostridium botulinum* is given in Appendix 2. However, it is strongly recommended that food business operators seek relevant expert advice before using MAP or VP for the first time. The FSAI has also produced a factsheet on the retail display of poultry from opened gas flushed packs (Food Safety Authority of Ireland, 2009).

Relative humidity

Relative humidity is a measure of how saturated air is with water vapour at a certain temperature and it is expressed in percentage. 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 water activity of foods and this should be taken into consideration by food business operators (Jay *et al.*, 2005; Food & Drug Administration, 2003). Some foods are expected to be dry (e.g. cereals), some moist (e.g. cooked meats), and others will be very wet (e.g. chilled chicken soup). 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 (Esse and Saari, 2004).

Packaging

Packaging will help to control both the composition and relative humidity of the air in contact with foods. However, food business operators should be aware that packaging will have differing properties such as its gas and water vapour permeability, which will affect food safety and shelf-life. For foods packaged in impermeable packaging, the relative humidity of the storage environment is unlikely to be important in influencing shelf-life. However, if shelf-life of the food is limited by moisture gain or moisture loss, or if the food is packaged in moisture sensitive packaging, control of relative humidity should be a consideration in setting and validating shelf-life.

The choice and use of packaging often requires specialised equipment, materials and trained personnel. The FSAI has also produced an eLearning[4] and a factsheet on food contact materials (Food Safety Authority of Ireland, 2014b). Food business operators should seek expert advice from an appropriate packaging supplier before using a specific packaging technology to ensure the safety of their food and compliance with legislation (European Union, 2011; European Commission, 2005; European Union, 2004a, 2004b, 2004c; European Commission, 2002).

Food processing

The variety and nature of food processing varies enormously depending on the food being manufactured. But typically, processing is designed to improve food palatability, safety and shelf-

[4] Available at https://www.fsai.ie/training/fcm/story_html5.html

life. Common technology such as heat treatment (i.e. cooking, pasteurisation etc). will improve food safety and extend shelf-life by destroying dangerous pathogens and reducing numbers of other microorganisms. Typically, heat treatments are mild and will not destroy all microorganisms, their spores or toxins, but rather will destroy or reduce numbers of specific microorganisms. To design and implement a safe heat treatment process requires food business operators to have an understanding of the mathematics behind heat processing and the associated effects (i.e. thermal destruction) of the process on microorganisms, particularly of pathogens (Food Safety Authority of Ireland, 2021a, 2005).

Most foodborne pathogens are not particularly heat resistant and are easily destroyed by normal cooking temperatures. However, variations in heat resistance have been observed in many pathogens and the intrinsic characteristics of the food such as salt and fat concentration, pH and presence of competitive microorganisms etc. have also been shown to have an effect. As a general guide for food safety, heat treatments should be sufficient to ensure heat penetration at the centre or thickest part of a food and reduce the number of target pathogens by 6 $\log_{10}$ cycles (i.e. a six-fold reduction in pathogen numbers). For example, from 1 million colony forming units (cfu) per gram to 1 cfu per gram.

Typically, when a temperature of 75 °C or an equivalent temperature/time combination is achieved at the centre or thickest point of the food, this should ensure a 6 $\log_{10}$ cycle reduction of viable *L. monocytogenes* cells, generally considered the most heat resistant vegetative pathogen (Food Safety Authority of Ireland, 2021a, 2018a, 2005). The FSAI has produced detailed guidance on cook-chill systems in the food service sector (Food Safety Authority of Ireland, 2018a) and the industrial processing of heat-chill foods (Food Safety Authority of Ireland, 2021a). Other processing technologies such as high pressure processing (Food Safety Authority of Ireland, 2015a), smoking, fermentation (Food Safety Authority of Ireland, 2021c; 2018b), curing, drying, chilling, freezing etc. may alter the intrinsic or extrinsic properties of the food to retard or select for the growth of specific microorganisms. Some forms of food processing such as natural smoking may also result in the formation of antimicrobial substances in foods which can retard microbial growth.

Storage, distribution and use

How a food is stored, distributed and used by consumers will affect food safety and shelf-life. It is important that food business operators consider all reasonably foreseeable conditions of storage, distribution and use when setting and validating shelf-life. An important part of reasonably foreseeable conditions of storage, distribution and use is temperature (European Food Safety Authority, 2007; Kennedy *et al.*, 2005; *safe*food, 2004a, 2004b). In many circumstances, food will

experience temperature variation (e.g. due to season of the year or abuse during storage, distribution and use) which can significantly affect food safety and shelf-life.

Therefore, in setting and validating shelf-life, the decision on which temperature or temperatures are appropriate for the food must be carefully considered by the food business operator (European Union Reference Laboratory for *Listeria monocytogenes*, 2021a, 2013). If an inappropriate storage temperature is used in setting the shelf-life compared to actual temperatures during storage, distribution and use, there may be an underestimation of microbial growth, particularly pathogens, and an overestimation of a safe food shelf-life (National Standards Authority of Ireland, 2015a, 2015b; European Union Reference Laboratory for *Listeria monocytogenes*, 2021a, 2013).

Consumer practices during purchase, storage and use of foods are predominately outside the control of the food business operator. Scientific studies of consumer practices and performance of domestic refrigerators both in Ireland and abroad have shown a relatively poor understanding of basic food hygiene and food safety, particularly temperature control among consumers (Ovca and Jevšnik, 2009; James *et al.*, 2008; Lagendijk *et al.*, 2008; European Food Safety Authority, 2007; Kennedy *et al.*, 2005; *safe*food, 2004a; 2004b). While the recommended temperature for domestic fridges in Ireland is between 0 °C and 5 °C (Food Safety Authority of Ireland, 2020c), many domestic refrigerators have been shown to operate at high temperatures around 10 °C which can significantly affect the safety and shelf-life of food products (Kennedy *et al.*, 2005; *safe*food, 2004a, 2004b).

As such, food business operators should take particular account of consumer practices in setting and validating food shelf-life and as required, specify clear storage instructions for consumers on food labels (European Food Safety Authority, 2007). Current legislation requires pre-packaged foods to be labelled with instructions for use where it would be difficult to make appropriate use of the food in the absence of such instructions (European Union, 2011). The recommended temperature for refrigerated storage during distribution, catering and retail in Ireland is ≤5 °C (National Standards Authority of Ireland, 2015a, 2015b) but food business operators should consider the possibility of a degree of temperature abuse along this food chain and by the final consumer.

Measures to control microorganisms in foods must be complimented by measures to minimise the risk of contamination or recontamination from the food processing environment. Good manufacturing practices (GMP) and good hygiene practices (GHP), and the development and implementation of procedures based on HACCP are fundamental in maintaining food safety and setting and validating food shelf-life. All food business operators, with the exception of primary producers, are legally obliged to put in place, implement and maintain, permanent procedures based on HACCP (European Commission, 2022; European Union, 2004a, 2004b). The FSAI has

produced guidance on procedures based on HACCP (Food Safety Authority of Ireland, 2007b, 2020a, 2007c). Procedures based on HACCP provide a structured systematic approach to food safety, which involves identifying potential hazards and planning for their monitoring and control.

During hazard analysis, the extrinsic and intrinsic factors of the food such as temperature and pH for example, may be identified as critical control points. In such cases, critical limits will have to be established, assigned and monitored. In this way, procedures based on HACCP applied consistently and systematically, will reduce or prevent hazards occurring and ensure that the shelf-life is achieved.

Historical data

Historical data (e.g. certificates of conformance from ingredient suppliers, routine food business operator monitoring checks, results of laboratory testing, records of staff training etc.) are an important component of records which all food business operators keep as a part of their on-going business. Some of these data are recorded as part of legal obligations while other data come from the food business operator's routine monitoring and testing as part of quality control procedures and customer requirements. These data can be used to verify the correct operation of food business operator controls for safe production of foods. Further information on historical data is outlined in Appendix 3 of this document.

4.2.3 Consultation of scientific literature

When the intrinsic and extrinsic characteristics of the food have been established, this information can be used to compare the product with existing data on the survival and growth of pathogens in scientific literature. Data on food safety, pathogens, manufacturing and shelf-life are available from scientific journals, books, industry guides, third level institutes etc. Additionally, the FSAI and other competent authorities (e.g. Department of Agriculture Food and the Marine [DAFM]; the Health Service Executive [HSE]) as well as professional and international institutions, have resources and data available. Table 6 outlines some of the key growth characteristics of common foodborne pathogens compiled from recent scientific literature. These data can be used by food business operators as a guide to determine what pathogens might be an issue for their food.

Table 6 Growth characteristics of common foodborne bacterial pathogens [a-b]

Pathogen	Temp (°C)	pH	Water Activity (a_w)	% Salt	Gas Atmos-phere	Some Commonly Associated Foods
	Min (Optimum) Max *Allowing Growth*		**Min** *Allowing Growth*	**Max** *Allowing Growth*	*Allowing Growth*	
Salmonella spp.[c]	5 (35-43) 47	3.8 (7-7.5) 9.5	0.94	4	Facultative	Eggs, meats, unpasteurised dairy products, sprouting seeds, fruit, vegetables, chocolate, infant formula, herbs, spices etc.
Clostridium botulinum (Proteolytic)	10 (35-40) 42	<4.6 (7) 8	>0.94	10	Anaerobic	Foods which are canned, vacuum packed, modified atmosphere packed, jarred (i.e. low oxygen environments)
Clostridium botulinum [d] *(Non-Proteolytic)*	3 (28-30) 35	<5.0 (7) 8	>0.97	5	Anaerobic	
Staphylococcus aureus	10 (40-45) 48	4 (7-8) 9.6	0.83[e]	10	Facultative	Eggs, poultry, meats, dairy products, confectionary, salads, sandwiches, etc.
Campylobacter spp.	32 (42-43) 45	4.9 (6.5-7.5) 9	>0.98	1.5	Micro-aerophilic	Poultry meat, unpasteurised/raw drinking milk and dairy products (e.g. cheese, butter)
Yersinia enterocolitica	-1.3 (25-37) 42	4.2 (7.2) 9.6	0.94	7	Facultative	Fresh meats (pork in particular) and unpasteurised/raw drinking milk and dairy products (e.g. cheese, butter)
Listeria monocytogenes [f]	-1.5 (30-37) 45	4.2 (7) 9.5	0.92	12	Facultative	Chilled, ready-to-eat foods (e.g. smoked salmon, sliced cooked meats, coleslaw)
Clostridium perfringens [g]	10 (43-47) 50	5.5 (7.2) 9	0.93	6	Anaerobic	Cooked meats, gravy, stocks, soup

Pathogen	Temp (°C)	pH	Water Activity (a_w)	% Salt	Gas Atmos-phere	Some Commonly Associated Foods
Shiga toxin (STEC) or Verocytotoxin (VTEC) producing Escherichia coli [h]	6.5 (30-40) 45	3.6 (6-7) 9	0.95	>6.5	Facultative	Meat, poultry, unpasteurised/raw dairy products and apple juice, sprouted seeds, salad vegetables, untreated drinking water (e.g. from a well) etc.
Bacillus cereus [i]	4 (30-40) 55	4.3 (6-7) 9.3	0.93	7.5	Facultative	Cooked rice, spices, neonatal liquid formulas
Vibrio parahaemolyticus	5 (37) 43	4.8 (7.8-8.6) 11	0.94	8	Facultative	Fish and shellfish
Cronobacter spp. [j]	5.5 (39.4) 45	3.89 (5-9) No Data	0.2[k]	9.1	Facultative	Dried infant formula, infant feeds, follow-on formula

[a] Table adapted from European Commission Union Reference Laboratory for *Listeria monocytogenes* (2021a), Food Standards Agency (2020), Food Safety Authority of Ireland (2019a, 2019b) United States Department of Agriculture (2017), European Food Safety Authority (2016, 2005a, 2005b), European Commission (2013, 2005), Food and Drug Administration (2012), European Food Safety Authority (2011a), European Food Safety Authority & European Disease Centre for Disease Control (2011), European Food Safety Authority of Ireland (2011b), Chilled Food Association & British Retail Consortium (2010), Food Safety Authority of Ireland (2010), Forsythe (2010), New Zealand Food Safety Authority (2010), Beuchat *et al.* (2009), Campden BRI (2009), Health Protection Agency (2009), FAO/WHO (Food & Agriculture Organization of the United Nations/World Health Organization) (2008), Food Safety Authority of Ireland (2007a), Gurtler and Beuchat (2007), Peck *et al*. (2006), Food Safety Authority of Ireland (2005), Jay *et al. (*2005), Food & Drug Administration (2003), Doyle (2002), International Commission for the Microbiological Specifications of Food (1996), Institute of Food Science & Technology (1993), Beuchat (1981).

[b] All values are approximate and given under optimal conditions so should only be used as a guide. Pathogens may grow outside the values given in Table 6. Further information on foodborne pathogens is available on the FSAI website. Although viruses (e.g. hepatitis A, norovirus and protozoa) and parasites (e.g. *Cryptosporidium, Giardia*) can be transmitted by food, they are not included in this table because they are unable to grow in food (i.e. they need a host in order to multiply).

[c] Most serotypes fail to grow at <7 °C

[d] See Appendix 2 for further information

[e] Under aerobic conditions. The minimum allowing growth under anaerobic conditions is 0.92–>0.99. Minimum water activity and pH for toxin formation are 0.88 and 4.5 respectively

[f] Generally, ready-to-eat foods with a pH of ≤4.4 or a_w ≤0.92, or with a pH of ≤5.0 and a_w ≤0.94 are considered to be unable to support the growth of *L. monocytogenes*. Other products may also belong to this group subject to scientific justification. While values for *L. monocytogenes* in Table 4 are for growth, the organism can survive -18 °C, pH 3.3 to 4.2, a_w <0.90 and salt ≥20% depending on nature of food and other factors

[g] Almost all outbreaks are the result of cooling food too slowly or holding without refrigeration, allowing multiplication of *C. perfringens*

[h] While the growth characteristics of STEC/VTEC appear to be broadly similar to all *E. coli* serogroups, *E. coli* O157:H7 and other STEC/ VTEC strains have a tolerance to acid at the extreme range of the *E. coli* family

[i] *B. cereus* causes two kinds of foodborne disease: (1) Emetic (vomiting) intoxication due to the ingestion of the toxin cereulide which is pre-formed in the food. The toxin is extremely stable and can survive at 126 °C/90 minutes. No emetic toxin formation at temperatures below 10 °C (2) Diarrhoeal infection due to the ingestion of bacterial cells which produce enterotoxin. This toxin is inactivated by heating at 56 ºC/5 minutes

[j] *Cronobacter* spp. are resistant to desiccation over a wide range of a_w (0.25 to 0.86). In research trials carried out over 12 months storage, the pathogen survived better in dried formula and cereal at low a_w (0.25 to 0.30) than high a_w (0.69 to 0.82)

[k] Can survive in infant formula at this a_w

[l] Salt expressed as percentage sodium chloride in the aqueous phase of the food.

4.3 Predictive microbiology

Predictive microbiology uses mathematical models (built with data from laboratory testing) and computer software to graphically describe the responses of microorganisms to intrinsic or extrinsic characteristics (European Union Reference Laboratory for Listeria monocytogenes, 2021a, 2013).

Predictive microbiological models are initially useful to help estimate food safety and shelf-life having established the food's intrinsic and extrinsic characteristics. In product development, a predictive microbiological model may allow a food business operator to evaluate the safety and stability of new formulations and identify those which may give a desired shelf-life. They are also useful when food with an established shelf-life is subject to a minor process or formulation change. A predictive microbiological model can then be used to establish if the change might have any effect on the safety and shelf-life of the food.

However, predictive microbiological models do not replace laboratory analysis or the training and judgement of an experienced food microbiologist. Food business operators should never rely solely on any predictive microbiological model to determine the safety of food or its shelf-life. Data generated from predictive microbiological models should only be used as a guide to the response of microorganism(s) to a particular set of characteristics and should be verified by a durability study or challenge test. This is particularly pertinent when the conditions in the food are near the boundaries of the models parameters. Consultation with a competent body is strongly recommended before their use.

Historical data can be useful in relation to pathogens such as *L. monocytogenes* to complement the results of predictive microbiological models (Chilled Food Association & British Retail Consortium, 2010). However, historical data could also be used in combination with data generated by carrying out durability studies or challenge tests, environmental monitoring, ingredient and final product testing. The aim is to provide sufficient evidence to give the food business operator and competent authorities confidence that such ready-to-eat foods will not pose a risk to public health throughout their shelf life. The level of confidence increases with the amount of data available (European Union Reference Laboratory for *Listeria monocytogenes*, 2012a, 2013). However, food business operators should be aware that historical data from microbial testing for pathogens that consistently fails to detect the target pathogen, does not confirm the absence of the pathogen in the food (International Commission on Microbiological Specifications for Foods, 2017). See Appendix 3 for a list of potential sources of historical data and information on how that data can be used to demonstrate evidence of a food business operators ability to produce safe food under its HACCP-based procedures.

Predictive microbiological models are normally developed assuming that microbial responses are consistent (Institute of Food Science & Technology, 1993). While predictive models can provide a cost-effective means to minimise microbiological testing in determining shelf-life, there may be occasions when the model's predictions may not be accurate, due to inconsistent microbial responses and variations in the growth media. Research has indicated that this is often why some predictive microbiological models fail to accurately predict the survival, growth or inactivation of pathogens in food products (Dens and Van Impe, 2001).

Initiatives to develop and improve microbiological modelling programs have been ongoing in the United States, the United Kingdom, Denmark, France, Australia and other countries for a number of years. These programs have resulted in the development of a wide range of microbiological modelling software packages becoming available (Food Safety Authority of Ireland, Accessed 06.10.2022).

4.4 Laboratory testing

The next step in a shelf-life study is often the planning and design of laboratory testing of the food. In this regard, microbiological tests are predominately used to make the critical decisions regarding food safety and shelf-life. Microbiological tests are also used to estimate food quality over the shelf-life and are often carried out in conjunction with tests to establish safety. However, the quality aspects of shelf-life are not discussed here. Two types of laboratory testing, durability studies (Section 4.4.1) and challenge testing (Section 4.4.2) can be used in relation to determining shelf-life.

4.4.1 Durability studies

Durability studies aim to verify the shelf-life of a food product under given storage conditions. Most food business operators will carry a durability study which determines the growth of microorganisms in the food as manufactured, under reasonably foreseeable conditions of distribution, storage and use. One of the limitations of a durability is that pathogens of concern for a product may not be present in every batch. Before beginning a durability study, it should be properly designed and planned.

If the durability study is specifically for *L. monocytogenes* in ready-to-eat foods, the EC guidance should be followed (Appendix 1) (European Commission, 2021a, 2013). The aim of durability studies for *L. monocytogenes* is to estimate the proportion of ready-to-eat foods exceeding the quantitative limit of 100 cfu/g at the end of the shelf-life after a storage period reflecting the

foreseeable conditions of distribution, storage and use. While durability studies to evaluate the growth or survival of *L. monocytogenes* that may be naturally present in a food during their shelf-life, under reasonably foreseeable conditions of distribution, storage and use may be considered more realistic than a challenge test, as the contamination is naturally occurring, their use in shelf-life validation is limited. This type of study is not suitable on its own to validate the microbiological shelf-life of ready-to-eat foods for *L. monocytogenes* because of the low prevalence, low level of contamination and the heterogeneous distribution of *L. monocytogenes* contamination in food products. In most cases, results will be obtained from samples not contaminated with *L. monocytogenes*, making it difficult to accurately show the potential growth of *L. monocytogenes* in the food product. Combining the results of durability studies with other studies, such as challenge tests or predictive microbiology, is recommended to validate the shelf-life of a ready-to-eat food related to *L. monocytogenes*. It is not recommended to solely implement durability studies to validate a shelf-life related to *L. monocytogenes*, and its use is more appropriate for shelf-life verification (European Commission, 2021a).

For durability studies which aim to verify the shelf-life of a food products in relation to microorganisms other than *L. monocytogenes*, food business operators should follow the twelve good practice steps outlined below:

I. Confirm the samples to be tested

Samples of food should, where possible, represent the worst-case formulation (e.g. in an acidic product use the pH closest to neutral), processed under worst-case processing conditions (e.g. where product is stored before final processing, the longest storage period should be selected). To identify these worst-case scenarios, the food business operator should establish product and process variability. In so doing, the results of durability testing will be valid for the commercial product.

II. Establish the study duration

Initially, the durability study should run up to and beyond the target shelf-life required by the food business operator. For example, if the target shelf-life is 28 days, testing could last 28 days plus seven days. If, after this time, the qualifying microbiological criteria are still being met, the testing may be continued until they are exceeded. Under some circumstances, a product may exceed its qualifying criteria before its target shelf-life. At this point, testing should stop, and the food business operator either accepts the estimated shelf-life or continues with product development and further testing until the desired shelf-life is achieved.

III. Establish the study conditions

To estimate, set and validate the shelf-life requires laboratory testing to be carried out under realistic conditions which mirror reasonably, foreseeable conditions of storage, distribution and use. This in particular relates to using storage temperatures for the food which reflect normal practice, even if these temperatures are different to the recommended temperatures. For example, consumers are advised to store chilled foods at ≤5 °C, but this is not always achieved. If the actual storage temperatures are known for a food product, the food business operator may use its own storage temperatures for the duration of the study (Table 7). However, the food business operator must consider temperature abuse and justify which temperatures are used, considering available data from temperatures during transport and storage by consumers (European Commission, 2021a, 2013).

Food businesses operators responsible for manufacturing ready-to-eat foods that are able to support the growth of *L. monocytogenes,* and that may pose a *L. monocytogenes* risk for public health, have additional requirements for shelf-life under Article 3(2) and Annex II of Commission Regulation (EC) No 2073/2005, as amended (see Appendix 1 for more information). In order for the growth of *L. monocytogenes* to be as realistic as possible when conducting experimental shelf-life studies to assess the growth of *L. monocytogenes* in chilled ready-to-eat food products, it is recommended that the temperature storage conditions model each step of the cold chain (i.e. distribution of the product, storage at retail and storage in domestic refrigerators), while allowing for reasonably foreseeable variations in storage temperature ranges due to possible temperature abuse at each step of the cold chain. If an inappropriate storage temperature (lower temperature than the usually encountered) is used, there may be an underestimation of *L. monocytogenes* growth and an overestimation of the safe shelf-life length.

For durability studies and challenge tests (Section 4.4.2) assessing the growth of *L. monocytogenes* throughout the shelf-life of chilled RTE foods, it is recommended by the European Union Reference Laboratory for *Listeria monocytogenes* (EURL *Lm*) that the storage time is divided into three stages, (i.e. manufacturer storage and distribution, retail display and consumer storage) with two thirds of the time at 7 °C (representative of the 95th percentile of the chill chain in Ireland) and one third at 10 °C (representative of storage in domestic refrigerators) (European Union Reference Laboratory for *Listeria monocytogenes*, 2021a). Therefore, if a stored sample is tested after six days, it should have been subjected to four days storage at 7 °C and two days storage at 10 °C before testing, and so on for the remaining storage samples and times (Table 7).

The consumer storage temperature of 10°C was recommended by the European Union Reference Laboratory for *Listeria monocytogenes* following a review of consumer storage temperature data from 14 Member States in Europe (European Union Reference Laboratory for *Listeria*

monocytogenes, 2021b). The collected data was considered in order to (i) get a better knowledge of refrigerator temperatures at consumer level and (ii) to better assess the shelf-life of RTE food regarding *L. monocytogenes*. On this basis, the report recommends using the temperature of 10 °C when simulating the storage of ready-to-eat foods at consumer level in challenge tests assessing the growth potential or when conducting durability studies for chilled food products related to *L. monocytogenes* (European Union Reference Laboratory for *Listeria monocytogenes*, 2021b). While Table 7 is a recommendation specifically for *L. monocytogenes*, food business operators producing foods where *L. monocytogenes* is not a risk, can also use this table as a resource for determining storage conditions for durability studies for chilled foods.

Table 7 Recommended experimental storage temperature conditions to evaluate potential growth of *L. monocytogenes* in chilled ready-to-eat food [a]

<table>
<tr><th rowspan="2">Stage of cold chain</th><th colspan="3" rowspan="2">Storage (incubation) temperature</th><th colspan="4">Storage (incubation) duration</th></tr>
<tr><th rowspan="4">Duration justified by detailed information</th><th rowspan="4">Or if not known</th><th>Shelf-life ≤21 days</th><th>Shelf-life >21 days</th></tr>
<tr><td>Manufacturer storage and distribution</td><td rowspan="3">Temperature justified by detailed information [b]</td><td rowspan="3">Or if not known</td><td>7 °C</td><td>One third of the shelf-life</td><td>7 days</td></tr>
<tr><td>Retail</td><td>7 °C</td><td>One third of the shelf-life</td><td>Half of the remaining shelf-life [c]</td></tr>
<tr><td>Consumer</td><td>10 °C</td><td>One third of the shelf-life</td><td>Half of the remaining shelf-life</td></tr>
</table>

[a] Table adapted from Table 4 on page 22 in "*Technical guidance document on challenge tests and durability studies for assessing shelf-life of ready-to-eat foods related to Listeria monocytogenes, Version 4 of 1 July 2021* "(European Union Reference Laboratory for *Listeria monocytogenes*, 2021a).

[b] Temperature justified by detailed information and based on the 95th percentile of the food business operator's data observation and the 95th percentile of the observations for the country where the stage of the cold chain is located.

[c] The remaining shelf-life is calculated by subtracting 7 days from the full shelf-life duration assigned.

IV. Establish the frequency of testing

The frequency of testing during the durability study should be based on experience with similar foods and the established characteristics of the food. For example, perishable food with a target

shelf-life of seven days may require testing at daily intervals while less perishable foods may only require twice weekly or weekly testing intervals.

V. Establish the number of samples to be tested

At each interval in the durability study where testing takes place, it is important that a sufficient number of sample replicates are tested to account for product variability. This is because the distribution of microorganisms in foods is typically not uniform. The size of the food business operator's production batch will help determine the number of samples required. The International Commission on Microbiological Specifications of Food (ICMSF) has produced extensive guidance and a software tool on microbiological sampling plans which can be used by food business operators in determining product safety and shelf-life (International Commission for the Microbiological Specifications of Foods, 2018, 2017, 2011). In the absence of a specified sample number, it is recommended that at least three replicate samples from three separate production batches are tested at each interval during the durability study. This will help to ensure that the samples tested are representative of the food during its production. However, the larger the number of replicates tested per interval, the greater the degree of confidence a food business operator can have in the estimated shelf-life.

VI. Choose the testing laboratory

Although not a legal requirement, the FSAI strongly recommends that food business operators only use laboratories which are accredited to conduct the specific test in that food (Food Safety Authority of Ireland, 2021b). The Irish National Accreditation Board (INAB) is the national body with responsibility for accreditation of laboratories (i.e. private and public in Ireland). Accreditation is the formal recognition of a laboratory's competence to conduct testing in compliance with the international standard ISO 17025. Compliance with this standard requires laboratories to demonstrate competence, impartiality and integrity. A list of accredited laboratories and the specific tests for which they are accredited is available on the INAB website. Guidance on how to choose third-party analytical laboratories with the right expertise, accreditations, and who use the appropriate methods for microbiological analysis of food has been published by the Chilled Food Association in the United Kingdom, in association with Food Standards Scotland (Chilled Food Association, 2021).

VII. Establish the tests to be performed

Due to the wide variety of foods, it is impossible to accurately describe all the microbiological tests that may be used in a durability study. The type of pathogen(s) which could be expected to be present in the food will depend on the intrinsic (Section 4.2.1) and extrinsic (Section 4.2.2) characteristics of the food. As such, food business operators should be aware that it's not always necessary to test for all pathogens in all foods (Table 6). However, pathogens of concern should have already been identified by the food business operator through hazard analysis conducted as part of its procedures based on HACCP. Food business operators should also note that they must comply with any requirements of legislation on the microbiological criteria of food products (e.g. there is a legal microbiological criterion for *L. monocytogenes* in ready-to-eat foods; see Appendix 1 for more information) (European Commission, 2005). For ready-to-eat foods placed on the market, the guideline microbiological criteria in Guidance Note 3 (Food Safety Authority of Ireland, 2020b) can be used if legal microbiological criteria do not exist for a particular combination of food and microorganism.

The decision to carry out specific microbiological tests should only be made by a trained food microbiologist or in consultation with a competent body. Consultation with a competent body is recommended where a food business operator has insufficient resources to decide which microbiological tests may be required to determine product safety and shelf-life. The results of microbiological tests are dependent on the analytical method used, and therefore, a given reference method should be associated with each microbiological test performed (European Commission, 2005). It is recommended that all microbiological tests are carried out using a recognised reference method (e.g. ISO).

If testing against legal microbiological criteria set out in Regulation (EC) No 2073/2005, the method for analysis is specified (European Commission, 2005). Article 5.5 of the Regulation allows for alternative methods to be used if the methods are validated against the specific reference method provided in Annex I of the Regulation in accordance with the protocol set out in standard EN ISO 16140-2 (Food Safety Authority of Ireland, 2021b). Proprietary methods with a trademark/brand name, which are owned and marketed by a commercial company may be used as alternative analytical methods, provided they meet the requirements set in Article 5.5 of the Regulation and they are certified by an independent certification body (Food Safety Authority of Ireland, 2021b; European Commission, 2005). Analytical methods that are validated or certified using protocols other than EN ISO 16140-2 by organisations such as AOAC International and NordVal are also permitted where such methods have been validated in accordance with internationally accepted protocols and their use has been authorised by the competent authority (Food Safety Authority of

Ireland, 2021b). Furthermore, food business operators should request the analysis of specific product characteristics such as pH during the durability test if variability is expected.

The FSAI has produced guidance on selecting an external consultant (Food Safety Authority of Ireland, 2008), microbiological tests and associated microbiological criteria for foods (Food Safety Authority of Ireland, 2020b; Food Safety Authority of Ireland, 2014a), and factsheets which outline alternative proprietary methods and best practice for testing foods when assessing compliance with Regulation (EC) No 2073/2005 (Food Safety Authority of Ireland, 2021b).

VIII. Perform and document the durability study

Ensure all samples are stored under agreed storage conditions and tests are performed on the appropriate samples at the appropriate time intervals. It is recommended that all sample details, conditions of storage, tests performed, procedures, results etc. are documented. All documentation should be filed to allow it to be readily available to the food business operator and competent authorities alike should they wish to review it.

IX. Interpret the test results and set the shelf-life

The results of durability studies reflect the natural contamination of food products. However, it is known that the distribution of microbiological contamination in a food can be heterogeneous (i.e. it is not uniformly contaminated). Some of the reasons for this include how the food is contaminated (on the surface of the food or throughout the food product), a clustered distribution of microorganisms in the food, or how the intrinsic and extrinsic characteristics of different food matrices affect microbial growth and survival (International Commission for the Microbiological Specifications of Foods, 2017). Food business operators should be aware that detection test results of ‘not detected in X g’ of food or liquid or enumeration test results of ‘<10 cfu per X g’ of food or liquid are not proof that the batch of food from which the samples came is not contaminated, due to the low probability of detecting pathogens in a contaminated batch, the low number of microbial cells initially present and their uneven distribution in the food (International Commission for the Microbiological Specifications of Foods, 2017).

The interpretation of the test results should only be made by a trained food microbiologist in consultation with the testing laboratory. Consultation with a competent body is also recommended in some cases. However, the results from microbiological analysis should be first compared to any applicable legislation requirements then any relevant standards and guidelines. At a point during the durability study, testing will begin to display results which are close to or no longer meet

legislative requirements and/or agreed test parameters. Using these results and other data recorded (e.g. intrinsic and extrinsic characteristics), the food business operator must assign an appropriate shelf-life which ensures food safety. If results appear unsatisfactory or inconsistent, further testing may be required. In some cases, if the estimated or target shelf-life determined during product development is not achieved in the durability study, the product may have to be redeveloped or modified. Ultimately, the safety of foods should be ensured by a preventative approach incorporating product and process design, application of GHP and GMP and procedures based on HACCP. It is now widely accepted that food product testing alone cannot guarantee the safety of foods. However, testing for specific microorganisms is a useful tool in setting the shelf-life and its ongoing verification.

Note: The microbiological counts (where applicable) associated with each replicate sample at a time point will vary naturally. It is recommended that food business operators do not use the average or median count resulting from statistical analysis of the results but rather use a higher percentile value such as the 90^{th} or 95^{th} percentile count. This ensures that safety is ensured by accounting for the variability in microbial growth throughout the product. This can only be done if a minimum of three replicates are used at each time point.

X. Applying a margin of safety

While the accuracy and reproducibility of shelf-life will be affected by the characteristics of the food, it is unrealistic to expect the shelf-life of foods to be consistently accurate and reproducible under all circumstances. In addition, the shelf-life will never be an absolute value that terminates at an exact time and date. Rather, there will be a distribution of times and dates around an average shelf-life. As such, it is strongly recommended that a margin of safety is applied to the shelf-life of the food. The margin of safety should be determined and applied by the food business operator after examining all reasonably foreseeable conditions of processing, storage, distribution and use.

It is not possible to define exact margins of safety for food products as it will vary between products. However, possible variations in the characteristics of foods (e.g. pH or storage temperature) should be taken into consideration when applying the margin of safety. Applying a margin of safety will reduce the shelf-life of the food to a shorter time interval. However, this allows the food business operator to take account of reasonably foreseeable conditions of use which may affect product safety and shelf-life. The rationale behind an applied margin of safety should be documented by the food business operator and the food product specification and labelling finalised.

XI. Labelling of shelf-life

Foods which are microbiologically perishable and may consequently, after a short period of time, pose a risk to public health, will generally have their shelf-life indicated by a ‘use by’ date (European Union, 2011; European Commission, 2005). Foods which are typically consumed or intended to be consumed without further preparation or after treatment unlikely to be sufficient to destroy pathogens and toxins or metabolites which may be present (i.e. ready-to-eat foods) will also have their shelf-life indicated by a ‘use by’ date. The ‘use by’ date will indicate the date up until which the product can be safely consumed. In the case of ready-to-eat foods, the manufacturer of a food has to decide whether the product is ready to be consumed as such, without the need to cook or otherwise process it in order to ensure its safety (European Commission, 2005). Further details on labelling requirements for shelf-life are given in Appendix 4.

XII. On-going monitoring and verification

Typically, it should not be necessary to repeat any work carried out to estimate and set food shelf-life unless the food or its production process is modified or changed. However, it is good practice to verify product safety and shelf-life periodically as subtle changes can arise in products over time. Samples of food products may also be taken by food business operators at different points in the distribution chain or as a result of customer complaints and tested to verify the foods safety and shelf-life.

4.4.2 Challenge testing

When a new food product with a unique set of intrinsic and extrinsic characteristics is developed by a food business operator, data on the effect of the intrinsic and extrinsic characteristics on specific pathogens may not be available in the scientific literature. Accordingly, it may be necessary to evaluate the safety of the food using challenge testing. Challenge testing involves experiments that determine whether pathogen(s) when deliberately added to the food, can grow and/or survive in the food during foreseeable conditions of storage, distribution and use and if so, how fast it will grow (i.e. growth potential). Challenge testing will also establish and validate the safety of foods over a set shelf-life.

In a challenge test, a food is inoculated with several strains of a known pathogen or non-pathogenic microorganism with similar characteristics, at a specific inoculation level. It is recommended to use at least three strains with known growth characteristics, of which two should preferably be isolates from similar foods and one should preferably be a human isolate. The food is

then stored under reasonably foreseeable conditions of distribution and use by the laboratory (see Section 4.4.1.III) and the survival and growth of the inoculated microorganisms is measured. In the majority of cases, food business operators will not require challenge testing of their foods. But for those foods which may require challenge testing, it is important to note that challenge testing is highly specialised, complex, expensive, and generally only applicable only to the specific food being tested.

In particular, the purpose of the *L. monocytogenes* challenge testing is to demonstrate the compliance of the ready-to-eat food with the limit of the food safety criterion set for *L. monocytogenes* throughout its shelf-life (i.e. 100 cfu/g). Challenge tests aim to provide information on the behaviour of *L. monocytogenes* artificially inoculated in a food before storage under given conditions. These tests can be implemented for two different purposes: to assess the growth potential or to estimate the growth parameters (e.g. maximum growth rate) (European Union Reference Laboratory for *Listeria monocytogenes,* 2013).

The determination of the microbiological shelf-life of foodstuffs shall always include the consideration of the different factors such as: food sector, type of product and type of process (European Union Reference Laboratory for *Listeria monocytogenes,* 2013). Challenge tests should also consider the variability of the foods and the variability of the process used to produce the food. Some of the factors that influence the growth of *L. monocytogenes*, may vary within a batch (intra-batch variability) or between batches (inter-batch variability) and these variabilities have to be assessed before starting a challenge test (European Union Reference Laboratory for *Listeria monocytogenes*, 2021a). It is recommended that the batch(es) used for the challenge testing represent the worst-case scenario (most favourable conditions for growth/survival) in terms of the physico-chemical properties of the product as produced under real world conditions, and storage temperatures for reasonably foreseeable conditions of distribution, storage and use (European Union Reference Laboratory for *Listeria monocytogenes*, 2021a, 2013).

The specific contamination of the food should be with an inoculum size that is similar or only slightly higher to that likely to be naturally found in the food. Standardisation of the preparation of the inoculum is particularly important to be able to inoculate the ready-to-eat food at the expected concentration of 100 cfu/g or ml (range 50 to 200 cfu/g) (European Union Reference Laboratory for *Listeria monocytogenes*, 2021a). The challenge tests should be conducted using the typical packaging conditions under which the food product is placed on the market. For example for food products packed under MAP conditions, it may be removed from its packaging, inoculated, and then repacked under similar gas conditions as an unopened pack (consumer pack), or maintained in its original packaging by inoculating through a septum which is immediately covered by a

second septum to maintain exact gas conditions (European Union Reference Laboratory for *Listeria monocytogenes*, 2021a).

Inoculating food products so that the growth of *L. monocytogenes* is monitored under realistic conditions that are representative of packaging types, levels of contamination, the heterogeneity of the contamination and physiological state of the bacteria in the food are difficult to mimic and laboratories carrying out challenge testing of foods for *L. monocytogenes* are recommended to follow the challenge testing method provided in the European Union Reference Laboratory for *Listeria monocytogenes* in the *Technical guidance document on challenge tests and durability studies for assessing shelf-life of ready-to-eat foods related to Listeria monocytogenes* (European Union Reference Laboratory for *Listeria monocytogenes*, 2021a). The European Union Reference Laboratory for *Listeria monocytogenes* has also published a guidance document to evaluate the competence of laboratories implementing challenge tests and durability studies related to *Listeria monocytogenes* in ready-to-eat foods (European Union Reference Laboratory for *Listeria monocytogenes,* 2018). This document is intended for use by national Competent Authorities, National Reference Laboratories and other organisations that are involved in assessing whether laboratories are competent to conduct shelf-life studies related to *L. monocytogenes*. This assessment may be undertaken through an audit, or based on a shelf-life study report.

The International Standard ISO 20976-1:2019 is available for conducting challenge tests of food and feed products which specifies protocols for conducting microbiological challenge tests for growth studies on vegetative and spore-forming bacteria in raw materials and intermediate or end products (International Standards Organisation, 2019). Consultation with a competent body or an appropriately experienced laboratory is strongly recommended before deciding to use challenge testing.

5. Document, record and file

It is essential that all the documentation you have gathered in relation to estimating, setting and verifying the safety of your food product(s) over its shelf-life is filed together in a logical manner and is readily available on demand. This is so you are able to demonstrate to the satisfaction of the competent authority that the shelf-life you have established for your food product(s) is accurate and evidence based, and that the food will maintain its safety and/or quality until the end of the shelf-life duration you have determined as being appropriate for the food. This documentation should include supporting information (e.g. determination of product characteristics for your product along with a copy of any relevant scientific literature or best practice guidance), along with records of any relevant verification testing you have carried out as a part of your GHP and HACCP–based procedures (See: Section 4.1, 4.2 and 4.3).

References [5]

Advisory Committee on the Microbiological Safety of Food (2020) Subgroup on non-proteolytic *Clostridium botulinum* and vacuum and modified atmosphere packaged foods, final report. Link

Beuchat, L. R. (1981) Microbial stability as affected by water activity. *Cereal Foods World*, **26**(7), 345-349.

Beuchat, L.R. Kim, H. Gurtler, J.B. Lin, L.C. Ryu, J.H. & Richards, G.M. (2009) *Cronobacter sakazakii* in foods and factors affecting its survival, growth, and inactivation. Int. *J. Food Microbiol*., 136(2), 204-213. Link

Campden BRI (2009) A code of practice for the manufacture of vacuum and modified atmosphere packaged chilled foods Guideline No. 11 (second edition). Link

Campden BRI (2019) Evaluation of microbiological shelf-life of foods Guideline 46 (second edition). Link

Chilled Food Association & British Retail Consortium (2010) Shelf-life of ready-to-eat food in relation to *Listeria monocytogenes* – Guidance for food business operators. Link

Chilled Food Association (2021) Guidance for food business operators: Getting the best from third party laboratories. First edition. Link

Cornell AgriTech (2022) The science of pickling. Acid & acidified foods. Link (Accessed 25.10.2022)

Dens, E. J. & Van Impe, J. F. (2001) The need for another type of predictive model in structured foods. *Int. J. Food Microbiol.*, 64(3), 247-260. Link

Doyle, E. (2002) Survival and growth of *Clostridium perfringens* during the cooling step of thermal processing of meat products – A review of the scientific literature. *FRI Briefings*. Link

Esse, R. & Saari, H.A. (2004) Shelf-life and moisture management. In: Steele, R., (Ed), *Understanding and measuring the shelf-Life of food*, (pp. 24 – 41). Cambridge, England: Woodhead Publishing Ltd.

[5] All European Union/European Commission legislation documents are available to download at https://eur-lex.europa.eu/homepage.html. All amendments published to legislation should be taken into consideration. European Commission and FSAI publications are available to download at www.fsai.ie

European Commission (2002) Regulation No 178/2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety.

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

European Commission (2008) Regulation (EC) No 1333/2008 of the European Parliament and of the Council of 16 December 2008 on food additives.

European Commission (2013) Regulation (EU) No 609/2013 of the European Parliament and of the Council of 12 June 2013 on food intended for infants and young children, food for special medical purposes, and total diet replacement for weight control and repealing Council Directive 92/52/EEC, Commission Directives 96/8/EC, 1999/21/EC, 2006/125/EC and 2006/141/EC, Directive 2009/39/EC of the European Parliament and of the Council and Commission Regulations (EC) No 41/2009 and (EC) No 953/2009.

European Commission (2022) COMMISSION NOTICE on the implementation of food safety management systems covering Good Hygiene Practices and procedures based on the HACCP principles, including the facilitation/flexibility of the implementation in certain food businesses (2022/C 355/01).

European Food Safety Authority & European Disease Centre for Disease Prevention & Control (2011) Joint Rapid Risk Assessment – Cluster of haemolytic uremic syndrome (HUS) in Bordeaux, France 29 June 2011. Link

European Food Safety Authority (2005a) Opinion of the Scientific Panel of Biological Hazards on *Bacillus cereus* and other *Bacillus* spp. in foodstuffs. *The EFSA Journal*, 175, 1-48. Link

European Food Safety Authority (2005b) Opinion of the Scientific Panel of Biological Hazards on the request from the Commission related to *Clostridium* spp. in foodstuffs. *The EFSA Journal*, 199, 1-65. Link

European Food Safety Authority (2007) Request for updating the former SCVPH opinion on *Listeria monocytogenes* risk related to ready-to-eat foods and scientific advice on different levels of *Listeria monocytogenes* in ready-to-eat foods and the related risk for human illness. *The EFSA Journal*, 599, 1-42. Link

European Food Safety Authority (2011a) Urgent advice on the public health risk of Shiga-toxin producing *Escherichia coli* in fresh vegetables. *EFSA Journal*, 9(6), 1-50. Link

European Food Safety Authority (2011b) Tracing seeds, in particular fenugreek (Trigonella foenum-graecum) seeds, in relation to the Shiga toxin-producing *E. coli* (STEC) O104:H4 2011 outbreaks in Germany and France. Question Number: EFSA-Q-2011-00817. Link

European Food Safety Authority (2016) Risks for public health related to the presence of *Bacillus cereus* and other *Bacillus* spp. including *Bacillus thuringiensis* in foodstuffs. *EFSA Journal*, 14(7). Link

European Food Safety Authority Panel on Biological Hazards (2020) Koutsoumanis K, Allende A, Alvarez-Ordóñez A, Bolton D, Bover-Cid S, Chemaly M, Davies R, De Cesare A, Herman L, Nauta M, Peixe L, Ru G, Simmons M, Skandamis P, Suffredini E, Jacxsens L, Skjerdal T, Da Silva Felicio MT, Hempen M, Messens W and Lindqvist R. Guidance on date marking and related food information: part 1 (date marking). *EFSA Journal* 18(12):6306, 74 pp. Link

European Food Safety Authority Panel on Biological Hazards (2021) Koutsoumanis K, Allende A, Alvarez-Ordóñez A, Bolton D, Bover-Cid S, Chemaly M, Davies R, De Cesare A, Herman L, Hilbert F, Nauta M, Peixe L, Ru G, Simmons M, Skandamis P, Suffredini E, Jacxsens L, Skjerdal T, DaSilva Felicio MT, Hempen M, Messens W and Lindqvist R. Guidance on date marking and related food information: part 2 (food information). *EFSA Journal* 19(4):6510, 45 pp. Link

European Union (1998) Council Directive 98/83/EC of 3 November 1998 on the quality of water intended for human consumption.

European Union (2004a) Regulation (EC) No 852/2004 of the European Parliament and of the Council of 29 April 2004 on the hygiene of foodstuffs.

European Union (2004b) Regulation (EC) No 853/2004 of the European Parliament and of the Council of 29 April 2004 laying down specific hygiene rules for food of animal origin.

European Union (2004c) Regulation (EC) No 1935/2004 of the European Parliament and of the Council of 27 October 2004 on materials and articles intended to come into contact with food.

European Union (2011) Regulation No (EU) 1169/2011 on the provision of food information to consumers.

European Union (2020) Directive (EU) 2020/2184 of the European Parliament and of the Council of 16 December 2020 on the quality of water intended for human consumption (recast).

European Union Reference Laboratory for *Listeria monocytogenes* (2021a) Technical guidance document on challenge tests and durability studies for assessing shelf-life of ready-to-eat foods related to *Listeria monocytogenes* Version 4 of 1 July 2021. Link

European Union Reference Laboratory for *Listeria monocytogenes* (2021b) Temperatures of the food cold chain at consumer level in Europe. Report. Version 2 – 08/06/2021. Link

European Union Reference Laboratory for *Listeria monocytogenes* (2018) Guidance document to evaluate the competence of laboratories implementing challenge tests and durability studies related to *Listeria monocytogenes* in ready-to-eat foods (Version 2 – 7 May 2018). Link

European Union Reference Laboratory for *Listeria monocytogenes* (2013) Guidance document on *Listeria monocytogenes* shelf-life studies for ready-to-eat foods under Regulation (EC) No 2073/2005 of 15 November 2005 on microbiological criteria for foodstuffs. Link

FAO/WHO [Food & Agriculture Organization of the United Nations/World Health Organization] (2008) *Enterobacter sakazakii* (*Cronobacter* spp.) in powdered follow-up formulae – meeting report. *Microbiological Risk Assessment Series No.15*, Rome. 90pp. Link

Fennema, O.R. (1996) Water and ice. In: Fennema, O.R. (Ed), *Food Chemistry 3rd Edition*, (pp. 17-94). New York: Marcel Dekker Inc.

Food & Drug Administration (2003) Evaluation and definition of potentially hazardous foods. *Comp Rev Food Sci*., 2 (Supplement), pp. 1-109. Link

Food and Drug Administration (2012) In: Appendix 3 – Factors that affect microbial growth in food. Lampel, K.A., Khaldi, S.A. & Cahill, S.M. (Eds.), *Bad bug book: Handbook of foodborne pathogenic microorganisms and natural toxins (2nd Edition).* Centre for food safety and applied nutrition, of the Food and Drug Administration (FDA), U.S. Department of Health and Human Services. Link

Food Safety Authority of Ireland (2005) The control and management of *Listeria monocytogenes* contamination of food.

Food Safety Authority of Ireland (2007a) Factsheets for *Bacillus cereus*, *Campylobacter*, *Enterobacter sakazakii*, *Staphylococcus aureus*, *Listeria monocytogenes*, *Salmonella spp.* and *Microbial Toxins*

Food Safety Authority of Ireland (2007b) Guidance Note No. 11 — Assessment of HACCP compliance.

Food Safety Authority of Ireland (2007c) Guidance Note No. 23 — Development and assessment of recognised national voluntary guides to good hygiene practice and the application of HACCP principles.

Food Safety Authority of Ireland (2008) How to select an external HACCP consultant.

Food Safety Authority of Ireland (2009) Retail display of poultry from opened gas flushed packs.

Food Safety Authority of Ireland (2010) The prevention of verocytotoxigenic *Escherichia coli* (VTEC) infection: A shared responsibility – *2nd Edition*.

Food Safety Authority of Ireland (2013a) Guidance Note No. 10 — Product recall and traceability.

Food Safety Authority of Ireland (2013b) Guidance Note No.6 — Guidance on the implementation of European Communities (infant formulae and follow-on formulae) Regulations 2007 and 2009.

Food Safety Authority of Ireland (2013c) Dietary foods for special medical uses.

Food Safety Authority of Ireland (2014a) Guidance Note No. 27 — Guidance Note on the enforcement of Commission Regulation (EC) No. 2073/2005 on microbiological criteria for foodstuffs.

Food Safety Authority of Ireland (2014b) Toxicology factsheet series — Food contact materials.

Food Safety Authority of Ireland (2015a) High pressure processing of foods.

Food Safety Authority of Ireland (2015b) Potable water quality for food businesses.

Food Safety Authority of Ireland (2018a) Guidance Note No. 15 — Cook-chill systems in the food service sector.

Food Safety Authority of Ireland (2018b) Guidance Note No.33 — Good manufacturing practices for the production of ready-to-eat raw fermented meat products.

Food Safety Authority of Ireland (2019a) Advice on Shiga toxin-producing *Escherichia coli* (STEC) detection in food.

Food Safety Authority of Ireland (2019b) Shiga toxin-producing *Escherichia coli* (STEC) in food.

Food Safety Authority of Ireland (2020a) Food safety management system (FSMS) guide for low-throughput cattle, sheep, goat and pig slaughterhouses.

Food Safety Authority of Ireland (2020b) Guidance Note No 3 — Guidelines for the interpretation of results of microbiological testing of ready-to-eat foods placed on the market.

Food Safety Authority of Ireland (2020c) Home Cooking and Storage.

Food Safety Authority of Ireland (2021a) Guidance Note No. 20 – Industrial processing of heat-chill foods.

Food Safety Authority of Ireland (2021b) Best practice for testing foods when assessing compliance with the microbiological criteria specified in Commission Regulation (EC) No 2073 of 2005 (Issue 3).

Food Safety Authority of Ireland (2021c) Guidance Note No.37 — Good manufacturing practices for the production of ready-to-eat unpasteurised fermented plant-based products.

Food Safety Authority of Ireland (2021d) Food information — FIC (labelling).

Food Safety Authority of Ireland (2022) Predictive microbiology and shelf-life. Link (Accessed 06.10.2022)

Food Standards Agency (2020) The safety and shelf-life of vacuum and modified atmosphere packed chilled foods with respect to non-proteolytic *Clostridium botulinum*. Link

Forsythe, S.J. (2010) Basic aspects. In: *The microbiology of safe food* (*Second Edition)*. Published by Wiley-Blackwell. pp. 73.

Gurtler, J.B. & Beuchat, L.R. (2007) Survival of *Enterobacter sakazakii* in powdered infant formula as affected by composition, water activity and temperature. *J. Food Prot*., 70(7), 1579-1586. Link

Health Protection Agency (2009) Guidelines for assessing the microbiological safety of ready-to-eat foods placed on the market. London: HPA. Link

Ingham, B. (2017) Measuring pH of acidified foods. Link (Accessed 25.10.2022)

Institute of Food Science & Technology (1993) Shelf-life of foods — Guidelines for its determination and prediction.

International Commission for the Microbiological Specifications of Foods (1996) In: Roberts, T.A., Baird-Parker, A.C & Tompkin, A.C. (Eds), *Microorganisms in Foods 5 — Characteristics of microbial pathogens*. London: Blackie Academic & Professional. Link

International Commission for the Microbiological Specifications of Foods (2011) *Microorganisms in Foods 8 – Use of data for assessing process control and product quality*. Springer, New York. Link

International Commission for the Microbiological Specifications of Foods (2017) 08 "*Microbiological testing and distribution of microorganisms*", Marcel H Zwietering. Link

International Commission for the Microbiological Specifications for Foods (2018) Software tool (Standard program version 10) to determine the performance of statistical sampling plans that are used to assess the microbiological quality of batches of food. Link (Accessed 17.10.2022).

International Standards Organisation (1999) Meat and meat products: Measurement of pH – reference method (EN ISO 2917:1999).

International Standards Organisation (2004) Microbiology of food and animal feeding stuffs: Determination of water activity (EN ISO21807:2004).

International Standards Organisation (2019) Microbiology of the food chain — Requirements and guidelines for conducting challenge tests of food and feed products — Part 1: Challenge tests to study growth potential, lag time and maximum growth rate (ISO 20976-1:2019).

James, S.J., Evans, J. & James, C. (2008) A review of the performance of the domestic refrigerators. *J. Food Engineering*, 87(1), 2-10.

Jay, J.M., Loessner, M.J. & Golden, D.A. (2005) Intrinsic and extrinsic parameters of foods that affect microbial growth. In: Jay, J.M., Loessner, M.J., Golden, D.A. (Eds), *Modern food microbiology, 7th Edition*, (pp. 39 – 60). New York: Springer Science & Business Med Inc.

Kennedy, J., Jackson, V., Blair, I.S., McDowell, D.A., Cowan, C, & Bolton, D.J. (2005) Food safety knowledge of consumers and the microbiological and temperature status of their refrigerators. *J. Food Protection*, 68(7), 1421-1430.

Lagendijk, E., Assere, A., Derens, E. & Carpentier, B. (2008) Domestic refrigeration practices with emphasis on hygiene: analysis of a survey and consumer recommendations. *J. Food Protection*, 71(9), 1898-1904.

Leistner, L. & Gould, G. (2002) The hurdle concept. In: Leistner, L. & Gould. G. (Ed), *Hurdle technologies — Combination treatments for food stability, safety & quality*, (pp. 17 – 28). New York: Kluwer Academic/Plenum Publishers

Leistner, L. (2000) Minimally processed, ready-to-eat, and ambient-stable meat products. In: Man, C.M. &. Jones, A.A. (Ed), *Shelf-Life evaluation of foods 2nd Edition* (pp. 242 - 263). Gaithersburg, United States: Aspen Publishers

McDonald, K. (1999) Predictive food microbiology for the meat industry: A review. *Int. J. Food Microbiol*. **52**, 1-27. Link

Morris, J.G. (2000) The effect of redox potential. In: Lund, B.M., Baird-Parker, T.C. & Gould, G.W. (Eds.), *Microbiological safety and quality of Food: Volume 1.* Aspen Publishers, Maryland, USA, pp. 235-250.

National Standards Authority of Ireland (2015a) Irish Standard I.S. 340:2007/A1:2015 — Hygiene in the catering sector.

National Standards Authority of Ireland (2015b) Irish Standard I.S. 341:2007/A1:2015 — Hygiene in food retailing and wholesaling.

New Zealand Food Safety Authority (2010) Pathogen data sheets: *Cronobacter* spp.

Ovca, A. & Jevšnik, M. (2009) Maintaining a cold chain from purchase to the home and at home: Consumer opinions. *Food Control*, 20(2), 167–172.

Peck, M. W. Goodburn K. E. Betts R. P. & Stringer S. C. (2006) *Clostridium botulinum* in vacuum packed and modified atmosphere packed chilled foods — Final project report (B13006).

Peck, M.W. (2019) Risk assessment of botulism from chilled, VP/MAP (vacuum packed/modified atmosphere packed) fresh meat held at 3 °C to 8 °C. Link

Peck, M.W., Webb, M.D and Goodburn, K.E. (2020) Assessment of the risk of botulism from chilled, vacuum/modified atmosphere packed fresh beef, lamb and pork held at 3 °C–8 °C. *Food Microbiol*. 91, 103544. Link

Province of Manitoba (2022) Water content and water activity: Two factors that affect food safety. Link (Accessed 30.09.22)

Public Health England (2017) Determination of water activity in food. National infection service food, water and environmental microbiology. Document number FNES67, Version number 2, Effective date 15.12.17. Link

Ross, T. & Dalgaard, P. (2004) Secondary Models. In: McKeller, R.C. & Lu, X. (Eds.), *Modeling Microbial Responses in Foods* (pp. 63-150). CRC Press, Boca Raton, USA

***safe*food (2004a)** A study of consumer food safety knowledge, microbiology and refrigeration temperatures in domestic kitchens on the island of Ireland. Link

***safe*food (2004b)** Issuing temperature guidance to consumers on the cooking and storage of food.

United States Department of Agriculture (2017) Pathogen modelling program online. Link

Food Safety Authority of Ireland's eLearning resources [6]

Food additives:

- Module 1: Basic information on food additives
- Module 2: Takes you through an ingredients list of some commonly available products

Microbiological criteria:

- Module 1: Identifying relevant microbiological criteria
- Module 2: Sampling and testing

Shelf-life:

- FSAI Breakfast Bite on shelf life. Link (Accessed 06.10.2022)

Microbiological testing of food:

- *Safe*food Knowledge Network webinar in partnership with the Food Safety Authority of Ireland. Link (Accessed 06.10.2022)

Food contact materials:

- Module 1: Basic information you need to know about food contact materials

Food information for prepacked foods:

- Module 1: Information on requirements for prepacked foods as outlined in the Food Information Regulation 1169/2011 (FIC)
- Module 2: Nutrition information under FIC – explains the rules on nutrition labelling and gives you the opportunity to check compliance of labels

Food flavourings:

- Module 1: Legislation and safety assessment, labelling and enforcement of food flavourings

Brexit:

- Module 1: What are you importing?
- Module 2: Importing composite products

[6] All FSAI Elearning modules available for free at https://www.fsai.ie/food_businesses/food_safety_training/online.html

Appendix 1 Shelf-life studies for *L. monocytogenes in* ready-to-eat foods under Regulation (EC) No 2073/2005 on microbiological criteria for foodstuffs

Listeria monocytogenes has specific characteristics that increase its importance as a foodborne pathogen. *L. monocytogenes* is able to grow at refrigerated temperatures, survive harsh environments, drying and salting. Furthermore, *L. monocytogenes* is able to grow at low oxygen concentrations, and even without available oxygen, giving the organism an advantage in vacuum-packed (VP) and modified atmosphere packaged (MAP) foods.

The EU has established legal microbiological criteria for *L. monocytogenes* in all ready-to-eat foods in Regulation (EC) No 2073/2005 (European Commission, 2005). Article 3 of the Regulation indicates that food business operators shall ensure that foodstuffs comply with the relevant microbiological criteria and limits set out in the Regulation. Furthermore, Article 3 refers to the shelf-life studies (listed in Annex II of the Regulation), that the food business operator shall conduct in order to investigate compliance with the criteria throughout the shelf-life (European Commission, 2005). In particular, this applies to ready-to-eat foods that are able to support the growth of *L. monocytogenes* and that may pose a *L. monocytogenes* risk for public health (European Union Reference Laboratory for Listeria monocytogenes, 2021a, 2013).

The specific food safety criteria for *L. monocytogenes* in ready-to-foods are laid down in Annex I of the Regulation (European Commission, 2005). The Regulation specifies the food category, sampling plan, microbiological limits, analytical methods and stage where the criterion applies. Food safety criteria define the acceptability of a product or a batch of foodstuff applicable to products placed on the market (European Commission, 2005). When testing against food safety criteria provides unsatisfactory results, the product or batch of the foodstuffs shall be withdrawn or recalled from the market. Furthermore, corrective actions at the production plant according to procedures based on HACCP shall be taken (Food Safety Authority of Ireland, 2014a; European Union Reference Laboratory for Listeria monocytogenes, 2013).

Annex II of the Regulation (European Commission, 2005) describes the types of shelf-life studies that the food business operator can conduct in order to investigate compliance with the criteria throughout the shelf-life. These shelf-life studies shall always include:

- Specifications of physico-chemical characteristics of the product (such as pH, a_w, salt content, concentration of preservatives and the type of packaging system) considering the processing steps and conditions, storage and the possibilities for contamination and the foreseen shelf-life (See: Section 4.2.1 & 4.2.2)

and

- Consultation of the available scientific literature and research data regarding the survival and growth characteristics (See Section 4.2.3).

When the studies mentioned above are not able to give the necessary confidence in relation to the safety of the product, the food business operator should conduct additional studies. These additional studies should consider the inherent variability linked to the product and the processing and storage conditions. These studies may include:

- Predictive microbiological (mathematical) modelling established for the food in question, using critical survival or growth characteristics for the microorganisms of concern in the product (See: Section 4.3)

  and/or

- 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 referred to as durability studies (See: Section 4.4.1) or adequate historical data (See: Appendix 3)

  and/or

- 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 referred to as challenge tests (See: Section 4.4.2).

Each one of these tools has advantages and disadvantages and when necessary, different tools can be combined. Food business operators may collaborate with each other and seek advice from various food laboratories (e.g. research institutes or reference laboratories) when they conduct these shelf-life studies. Further detail on *L. monocytogenes* in ready-to-eat foods is given in FSAI Guidance Note No. 27 on Regulation (EC) No 2073/2005 (Food Safety Authority of Ireland, 2014a). The Food Safety Authority of Ireland's eLearning on the microbiological criteria (module 1 and 2) is also available to assist food business operators understanding of how to comply with the requirements of Regulation (EC) No 2073/2005 for *L. monocytogenes* in ready-to-eat food (See: Food Safety Authority of Ireland's eLearning resources, pp. 52).

Food requiring shelf-life studies under Regulation (EC) No 2073/2005

A wide range of products may require shelf-life studies to investigate compliance with the criteria for *L. monocytogenes* throughout their shelf-life. As such, it is difficult to provide an exhaustive list of all foods. Table 8 provides some examples of products falling under the food safety criteria for *L. monocytogenes* in the Regulation (European Commission, 2005).

Table 8 Foods falling under the food safety criteria for *L. monocytogenes* [a]

Food Category	Examples of Food
1.1 Ready-to-eat foods intended for infants and ready-to-eat foods for special medical purposes	**Ready-to-eat foods considered food category 1.1 include:** • Infant formula and follow-on formula • Prepared recipes, cooked and sterilised, sold in cans, jars, pouches etc. • Rusk biscuits used directly or after adding liquid • Desserts and drinks based on dairy or soy protein • Fruit, vegetable and herbal drinks containing controlled amounts of sugar • Ready-to eat dietary food for special medical purposes [b]
1.2 Ready-to-eat foods **able** to support the growth of *L. monocytogenes*, other than those intended for infants and for special medical purposes	**Ready-to-eat foods are considered food category 1.2 if they do not fall into food category 1.1, or the food business operator cannot demonstrate they fall into food category 1.3 and include:** • Soft cheese, pate, smoked salmon • Pre-packed (sliced) cooked meats and salads • Ready-to-eat food with a shelf-life of five days or greater
1.3 Ready-to-eat foods **unable** to support the growth of *L. monocytogenes*, other than those intended for infants and for special medical purposes	**Ready-to-eat food is considered food category 1.3 if:** • Products with pH ≤4.4 or a_w ≤0.92 • Products with pH ≤5.0 and a_w ≤0.94 • If it's a frozen food • If its growth potential is ≤0.5 $\log_{10}$ cfu/g • If its shelf-life is less than five days (i.e. total shelf-life) from day 0 (day of production) [c] • Other ready-to-eat food if the food business operator can provide scientific justification for their decision

a See footnotes (4) to (8) in Chapter 1: Food Safety Criteria of the Regulation for further information1. Further detail on *L. monocytogenes* in ready-to-eat foods is given in FSAI Guidance Note No. 27 (Food Safety Authority of Ireland, 2014a)

b Some dietary foods for special medical purposes are intended specifically for use by infants. If a food which is intended to be used by infants is deemed to be a food for special medical purposes, it must also comply with the legislative rules for dietary foods for special medical purposes (Food Safety Authority of Ireland, 2013b, 2013c).

c The food must comply with the limit of 100 cfu/g throughout the shelf-life.

Appendix 2 Safety and shelf-life of foods with respect to *Clostridium botulinum*

Foodborne botulism is a potentially fatal paralytic illness caused by botulinum toxin produced by the pathogen *Clostridium botulinum*. Foodborne botulism happens when a person consumes a food in which *C. botulinum* has been able to grow and produce toxin. Classic early symptoms are double and/or blurred vision, drooping eyelids and slurred speech. If left untreated symptoms progress to difficulty swallowing, muscle paralysis, respiratory failure and in rare cases death. Symptoms generally begin 12 to 36 hours after consuming the toxin in food, but in rare cases symptoms can occur as early as 6 hours, or as late as 2 weeks after exposure. Most people recover from botulism, but the recovery period can take months.

Spores of *C. botulinum* are widely distributed in the environment. The pathogen survives difficult conditions by forming spores that are resistant to heat, chemicals and drying. Under favourable conditions such as low oxygen concentrations (called an anaerobic environment), the spores can germinate into bacteria and the bacteria grow in the food. During growth they produce a potent neurotoxin (nerve toxin called botulinum toxin) that causes the illness. Outbreaks of foodborne botulism have been associated with foods sealed in airtight containers including foods that are vacuum packed (VP) and in modified atmosphere packaging (MAP) (Advisory Committee on the Microbiological Safety of Food, 2020; Food Standards Agency, 2020). Control of *C. botulinum* in foods requires destruction of the spores through processing (e.g. effective canning at high temperatures for long periods of time) or prevention of bacterial growth through product formulation (e.g. keeping pH below 4.6, reducing the amount of available water), temperature control, or a combination of these factors. Failure of one or more of these control measures, (e.g. cans not being heated sufficiently to kill the spores of *C. botulinum*) may enable the organism to grow and produce the toxin in the food.

Although non-proteolytic *C. botulinum* food poisoning is very rare in Ireland, there is a risk of human illness should the spores be present in certain foods which have intrinsic and extrinsic characteristics that could be favourable for growth (e.g. the anaerobic environment in VP and MAP foods). This could allow any spores potentially present in certain VP and MAP foods to germinate and produce toxin. Any business engaged in producing VP and MAP chilled foods must understand the hazards associated with non-proteolytic *C. botulinum* and take steps to appropriately manage it. Guidance on microbiological safety controls are given in the pink box for non-proteolytic *C. botulinum* which is able to grow and produce toxin at 3 °C and above. Foods stored at less than 3 °C throughout the food chain are outside the scope of this guidance.

The following guidance on *C. botulinum* applies to any VP or MAP chilled beef, lamb or pork that is further processed such as minced, cooked or mixed with any other ingredients such as herbs, spices or curing salts, and to any other VP or MAP chilled foods. Since spores of non-proteolytic *C. botulinum* are widely distributed in the environment, it should be assumed that any ingredient or food might be contaminated. It is on this basis that specific recommendations for shelf-life of VP and MAP foods are made (Advisory Committee on the Microbiological Safety of Food, 2020; Food Standards Agency, 2020). The shelf-life will begin as soon as the controlling factor(s) have been first applied. All food business operators opening and repacking VP or MAP products should establish a new product shelf-life (Food Standards Agency, 2020; Food Safety Authority of Ireland, 2009). For example, if a chilled VP or MAP product is unwrapped (e.g. for slicing or portioning), and then re-wrapped into VP or MAP, a new shelf-life should be established to the re-wrapped product which should not exceed the shelf-life given to the original product, unless appropriate controls are applied as set out in this guidance.

Control factors necessary to extend shelf-life of VP and MAP chilled food beyond 10 days:

In addition to chill temperatures (≤ 5 °C) which should be maintained throughout the food chain, the following controlling factors should be used singly or in combination to prevent growth and toxin production by non-proteolytic *C. botulinum* in chilled foods with a shelf-life of more than 10 days:

- a heat treatment of 90 °C for 10 minutes or equivalent lethality at the slowest heating point in the food [7]
- a pH of 5.0 or less throughout the food and throughout all components of complex foods
- a minimum salt level of 3.5% in the aqueous phase throughout the food and throughout all components of complex foods
- a water activity (a_w) of 0.97 or less throughout the food and throughout all components of complex foods
- a combination of controlling factors which can be shown consistently to prevent growth and toxin formation of non-proteolytic *C. botulinum* [8]

[7] In view of the evidence regarding lysozyme, it is recommended that the maximum shelf-life of foods given a heat process of 90 °C for ten minutes (or equivalent) should be limited to 42 days, unless it can be shown that lysozyme is absent from the food. Expert advice should be sought if a shelf-life in excess of 42 days is desired (Advisory Committee on the Microbiological Safety of Food, 2020).

[8] The Advisory Committee on the Microbiological Safety of Food subgroup (2020) recommended amending "heat and preservative factors" to "controlling factors" in the wording of the final bullet point in the Food Standards Agency guidance (2020) to reflect that heat is not a necessary controlling factor in all cases.

This guidance on *C. botulinum* does not apply to VP and MAP chilled fresh beef, lamb and pork, which is without added ingredients or further processing beyond cutting, packing, chilling, freezing and quick-freezing. Food business operators producing VP and MAP chilled fresh beef, lamb and pork which is outside the scope this guidance are responsible for identifying and applying a safe shelf-life in relation to non-proteolytic *C. botulinum* in line with their existing food safety management systems. Alternatively, food business operators may adopt a shelf life ≤ 13 days as recommended by the Advisory Committee on the Microbiological Safety of Food (2020). This recommendation was based on evidence gathered by the British Meat Processors Association in a risk assessment project jointly run with Meat and Livestock Australia (Peck, 2019; Peck *et al*., 2020).

Challenge testing may be considered to establish whether a shelf-life of greater than 10 days is safe for VP or MAP chilled beef, lamb or pork that is further processed such as minced, cooked or mixed with any other ingredients such as herbs, spices or curing salts, and any other VP or MAP chilled foods, when the foods do not have any of the single specified controlling factors specified in the pink box above in combination with storage temperatures of ≤ 5 °C. An appropriate centre of expertise should be consulted to carry out challenge testing and to interpret the results. Campden BRI (2009) Guideline 11 (second edition) *'A code of practice for the manufacture of vacuum packed and modified atmosphere packed chilled foods'* provides advice on what conditions must be met in order to give such chilled VP and MAP food products a shelf-life of more than 10 days. The Food Standards Agency provides online training for their enforcement officers in VP and MAP of food products which is available on the UK Food Standards Agency website[9]. The Food Standards Agency (2020) guidance also has a decision tree to assist in determining whether the risk of *C. botulinum* in VP and MAP food products with a shelf-life of greater than 10 days is effectively controlled.

Note that the guidance provided in this appendix is specific to the risk from non-proteolytic *C. botulinum*. Food business operators must also consider all other relevant hazards that may be associated with the food products they manufacture under their food safety management system when establishing and validating a shelf-life for that food (e.g. *L. monocytogenes* is also capable of growing under VP and MAP conditions and at refrigeration temperatures).

[9] Available at http://vacuumpackingtraining.food.gov.uk/introduction/

Appendix 3 Historical data

Food business operators must satisfy the relevant competent authority that any historical data they use is sufficient to demonstrate that specific microorganisms will not survive and/or grow, or that legal limits will not be exceeded in their product during its shelf-life. In some circumstances, the competent authority will require these data to be complemented with further studies such as laboratory based microbiological analysis.

The following is a non-exhaustive list of potential sources of historical data:

- Certificates of conformance from ingredient suppliers
- Routine food business operator monitoring checks (e.g. temperatures, pH, water activity etc.)
- Laboratory testing of supplied ingredients
- Laboratory testing of finished product throughout shelf life
- Laboratory testing of water, staff hygiene and environmental samples
- Records of staff training
- Records of cleaning and sanitation procedures
- Records of complaints
- Implementation of recognised quality management systems.

Depending on its nature and source, historical data held by a food business operator are also helpful in verifying the safety and shelf-life of foods for the following reasons (Chilled Food Association & British Retail Consortium, 2010):

- It indicates the levels of pathogens and other microorganisms in the production environment, ingredients and existing foods, under the food business operator's current practices of GHP, GMP and procedures based on HACCP
- It indicates levels of selected pathogens in existing foods and can be used to assess potential growth of pathogens in similar foods with comparable intrinsic and extrinsic characteristics manufactured under similar conditions
- Data collected over a period of time on an on-going basis can help to verify the food business operator's commitment and capacity to produce safe foods. It enables food business operators to analyse the data they have collected in order to identify trends (i.e. trend analysis).

Examples of where historical data might be used in relation to pathogens such as *L. monocytogenes* include:

- Where levels of *L. monocytogenes* in ready-to-eat food at the end of shelf-life are consistently low or absent and no results have been obtained which exceed the legal limits (European Commission, 2005). These data could be used in combination with data from environmental sampling and quality of ingredients to give the food business operator confidence that such ready-to-eat foods will not pose a risk to public health. The level of confidence increases with the amount of data available. The more product units that are tested, the more reliable the historical data become (European Union Reference Laboratory for *Listeria monocytogenes*, 2012a, 2013).
- Historical data on levels of *L. monocytogenes* in existing ready-to-eat foods at the start and end of shelf-life can be used to help verify product shelf-life under reasonably foreseeable conditions of processing, storage, distribution and use.

However, food business operators should be aware that historical data from microbial testing for pathogens that consistently fails to detect the target pathogen, does not confirm the absence of the pathogen in the food (International Commission on Microbiological Specifications for Foods, 2017).

Each microbiological sampling plan used has an expected performance that can be defined as a given confidence in a certain detection or enumeration limit (e.g. 95% confidence that the product contains less than 1 bacterium in 10g of product). Software tools have been developed to calculate this performance (International Commission on Microbiological Specifications for Foods, 2018).

Appendix 4 Labelling and food information for customers

Regulation No (EU) 1169/2011 on the provision of food information to consumers (FIC) is often referred to as the (FIC) Regulation (European Union, 2011). The FIC Regulation sets out the requirements for the provision of food information to the consumer as well as setting out the requirements with regard to the provision of nutrition information on foodstuffs (European Union, 2011; Food Safety Authority of Ireland, 2021d).

In relation to shelf-life, when a food business operator has estimated and set the shelf-life, it is important that this information is provided in accordance with the FIC Regulation (European Union, 2011). In the legislation, shelf-life is referred to as the date of minimum durability (i.e. best before date) and means *"the date until which the food retains its specific properties when properly stored".* In the case of foods which from a microbiological point of view, are highly perishable and are therefore, likely after a short period, to constitute an immediate danger to human health, the date of minimum durability must be replaced by the 'use by' date. Under the FIC Regulation, once the 'use by' date has passed, a food is deemed to be unsafe in accordance with Article 14(2) to (5) of Regulation (EC) No 178/2002 (European Commission, 2002).

The FIC Regulation requires an indication of the date of freezing, or the date of first freezing, for frozen meat, frozen meat preparations and frozen unprocessed fishery products. These meats and fishery products must indicate the date of freezing, or the date of first freezing, in cases where the product has been frozen more than once. This indication must be as follows (European Union, 2011):

- It must be preceded by the words 'Frozen on …'; and accompanied by the date itself or a reference to where the date is given on the labelling
- The date must consist of the day, the month and the year, in that order and in un-coded form.

Under the FIC Regulation, a number of products are exempt from the requirement to indicate a date of minimum durability (i.e. shelf-life) and these are listed in Annex X to the Regulation (European Union, 2011). For business to business sales, where the prepacked food is intended for the final consumer but marketed at a stage prior to sale to the final consumer, or where the food is intended for supply to mass caterers for preparation, processing, splitting or cutting up, food information can be provided on the commercial documents referring to the food, where it can be guaranteed that the documents either accompany the food, or were sent before, or at the same time as the delivery. However, the following pieces of information must appear on the external

packaging in which the prepacked foods are presented for marketing:

- Name of the food
- Date of minimum durability (i.e. best before date) or the use by date
- Any special storage conditions and/or conditions of use
- The name and business name and address of the food business operator

For business to business sales where the food is not intended for the final consumer or mass caterers, the food business operator supplying the food must ensure that those other food business operators are provided with sufficient information to enable them, where appropriate, to meet their provision of food information requirements.

Additionally, where foods are offered for sale to the final consumer or to mass caterers without pre-packaging, or where foods are packed on the sales premises at the consumer's request or pre-packed for direct sale, they do not require a date of minimum durability ('best before') or 'use by' date declaration (European Union, 2011). However, even if a shelf-life does not have to be labelled under the FIC regulation, the food business operator needs to know what the safe shelf-life is to ensure they do not put unsafe food on the market. Under Article 8 of the FIC Regulation, food business operators, within the businesses under their control, shall ensure that information relating to non-prepacked food intended for the final consumer or for supply to mass caterers shall be transmitted to the food business operator receiving the food in order to enable, when required, the provision of mandatory food information to the final consumer (European Union, 2011).

FSAI guidance

Further information and eLearning modules on the general principles and obligations for food business operators regarding the provision of food information to consumers under Regulation No (EU) 1169/2011, as amended, are available (See: Food Safety Authority of Ireland's eLearning resources, pp. 52).

EFSA guidance

The European Food Safety Authority Panel on Biological Hazards has published guidance to assist food businesses in deciding which type of date marking should be labelled on food product (European Food Safety Authority Panel on Biological Hazards**,** 2020) and additional guidance on food information relating to storage conditions and/or time limits for consumption after opening a food package and thawing of frozen foods (European Food Safety Authority Panel on Biological Hazards, 2021).

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