



Food Safety
AUTHORITY OF IRELAND

18

GUIDANCE NOTE

**Validation of Product Shelf-Life
(Revision 1)**

The first part of the document discusses the importance of maintaining accurate records of all transactions. It emphasizes that every entry, no matter how small, should be recorded to ensure the integrity of the financial data. This includes not only sales and purchases but also expenses and income. The document provides a detailed list of items that should be tracked, such as inventory levels, accounts payable, and accounts receivable. It also outlines the procedures for recording these transactions, including the use of double-entry bookkeeping to ensure that the books are balanced.

The second part of the document focuses on the analysis of the financial data. It explains how to calculate key financial ratios and metrics, such as the gross profit margin, operating profit margin, and return on investment. These calculations are essential for understanding the company's financial performance and identifying areas for improvement. The document also discusses the importance of comparing the company's performance to industry benchmarks and providing a clear explanation of the reasons for any variances.

The final part of the document covers the preparation of financial statements. It provides a step-by-step guide to creating the income statement, balance sheet, and cash flow statement. It also discusses the importance of auditing the financial statements to ensure their accuracy and reliability. The document concludes with a summary of the key findings and recommendations for the future, emphasizing the need for continued monitoring and reporting of financial performance.

Guidance Note No. 18

Validation of Product Shelf-Life

(Revision 1)

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ABBREVIATIONS

| | |
|----------------------|---|
| a_w | Water Activity |
| ACMSF | Advisory Committee on the Microbiological Safety of Food |
| BS | British Standard |
| CCP | Critical Control Point |
| Eh | Redox Potential |
| EU | European Union |
| EC | European Commission |
| EFSA | European Food Safety Authority |
| FSA | Food Standards Agency |
| FSAI | Food Safety Authority of Ireland |
| GHP | Good Hygiene Practices |
| GMP | Good Manufacturing Practices |
| HACCP | Hazard Analysis Critical Control Point |
| HSE | Health Service Executive |
| ICMSF | International Commission for Microbiological Specifications in Food |
| INAB | Irish National Accreditation Board |
| ISO | International Standards Organisation |
| IS | Irish Standard |
| MAP | Modified Atmosphere Packaging |
| NSAI | National Standards Authority of Ireland |
| SI | Statutory Instrument |
| SOP | Standard Operating Procedure(s) |
| STEC | Shiga Toxin Producing Escherichia coli |
| USDA | United States Department of Agriculture |
| VTEC | Verotoxigenic Producing Escherichia coli |

I. INTRODUCTION

The primary responsibility for food safety rests with food business operators¹⁻³. Regulation (EC) No 178/2002 sets down general food safety requirements, according to which, food must not be placed on the market if it is unsafe³. Under Article 14 of Regulation (EC) No 178/2002³ “*Food shall not be placed on the market if it is unsafe. Food shall be deemed to be unsafe if it is injurious to health or unfit for consumption*”. Food products should not contain microorganisms, their toxins and metabolites in quantities that present an unacceptable risk for human health⁴.

Validationⁱ of shelf-life is important for ensuring the microbiological safety of food. In particular, shelf-life is important for those foods which are perishable, ready-to-eat and/or support the growth of pathogens such as *Listeria monocytogenes*. Under Article 3 of Regulation (EC) No 2073/2005, food business operators are obliged to ensure that the food safety criteria applicable throughout the shelf-life of the products can be met under reasonably foreseeable conditions of distribution, storage and use⁴. As necessary, the food business operators responsible for the manufacture of a product may have to conduct studies to demonstrate compliance with the food safety criteria throughout the shelf-life. 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 health⁴.

The Codex Alimentarius defines shelf-life as the period during which a food product maintains its microbiological safety and suitability at a specified storage temperature and where appropriate, specified storage and handling conditions⁵. Under current European legislation, the term ‘date of minimum durability’ describes a food product’s shelf-life and is the date until which a food product retains its specific properties when properly stored⁶. The shelf-life determines the durability date and is expressed as a ‘use-by’ or ‘best-before’ date on the product as outlined in Articles 9 and 10 of Directive 2000/13/EC⁶.

ⁱ Validation and verification are standard parts of food safety management systems such as HACCP. In relation to shelf-life validation, this means obtaining evidence that proves that the declared shelf-life is accurate and the food product is safe until the end of that shelf-life. Verification is the application of methods, procedures, tests and other evaluations, in addition to monitoring to determine compliance with the declared shelf-life.

2. PURPOSE OF THE GUIDANCE NOTE

This guidance note provides guidance for food business operators in validating the shelf-life of food products which require a 'use-by' date declaration. The guidance note also provides guidance for food business operators on the implementation of the European Commission's working document on *L. monocytogenes* shelf-life studies for ready-to-eat foods⁷, under Regulation (EC) No 2073/2005⁴. The guidance note may also be used to assist competent authorities when assessing compliance.

3. SCOPE

This guidance note outlines best practice for the validation of product shelf-life and is applicable to all food business operators manufacturing or packing food products which require a 'use-by' date. The guidance note is not applicable to food business operators manufacturing or packing food products which require a 'best-before' date. However, similar principles as outlined in this document are required to establish durability for these products.

The guidance note should be read in conjunction with current food safety and hygiene legislation¹⁻⁴, Irish standards^{8,9}, Irish guidelines¹⁰⁻¹⁴, European Union (EU) guidelines^{7,15} and industry best practice guidance¹⁶⁻²⁰. However, all food business operators must comply with the minimum legislative requirements of current relevant legislation¹⁻⁴.

4. ESTABLISHING SHELF-LIFE REQUIREMENTS

Shelf-life should be validated by a food business operator as part of a regular review of its food safety management system, e.g. Hazard Analysis Critical Control Point (HACCP) and specifically under the following circumstances⁷:

- New product development
- Absence of shelf-life studies for an existing product
- Modification of an existing product
- Modification or change of production site or production equipment
- Shelf-life studies required under Regulation (EC) No 2073/2005⁴ (Appendix I)

The food business operator is responsible for determining the shelf-life under defined conditions, which should take into account reasonably foreseen conditions of distribution, storage and use. An important part of these foreseen conditions is the storage temperature of the product during its shelf-life. Therefore, the decision on which temperature or temperatures are used in determining the shelf-life must be justified by the food business operator⁷. If an inappropriate

storage temperature is used to establish the shelf-life compared to actual temperatures during distribution and use, there may be an underestimation of microbial growth, particularly pathogens, and an overestimation of the safe shelf-life⁷.

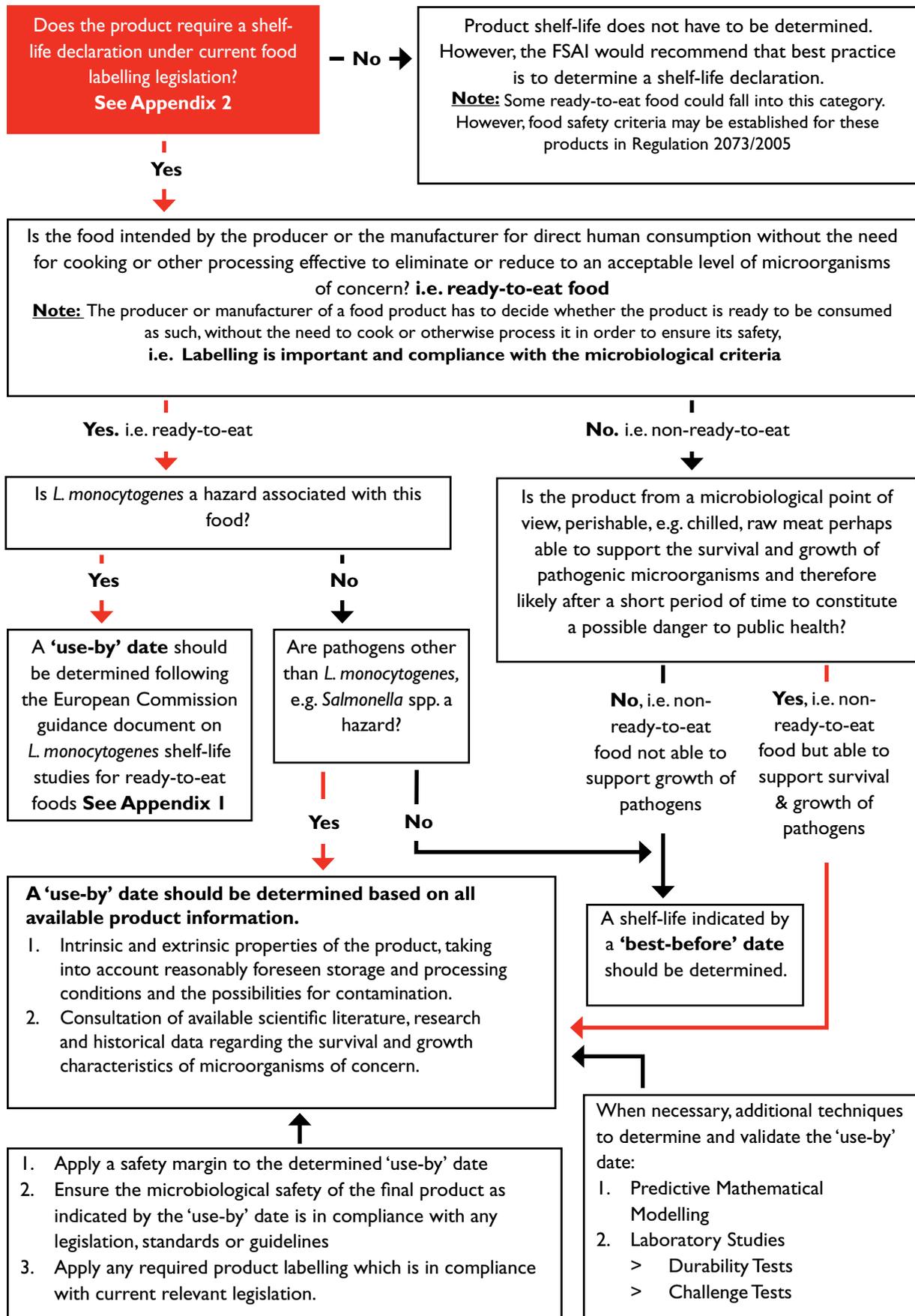
The intrinsic and extrinsic properties of the product (Section 5) that affect shelf-life may need to be identified as critical control points and controlled proactively by the food business operator. Intrinsic properties are those properties that are an inherent part of the food product such as pH and water activity. Extrinsic properties are the properties of the environment in which the food is stored such as temperature and atmosphere²¹. In practice, setting product shelf-life should be considered an integral part of any food safety management system and take account of the following⁷:

- Controls on suppliers assuring raw material quality
- Analysis of trends in results of microbiological testing of raw materials and final **products except where microbiological limits are based on the presence/absence of a pathogen, their toxins or metabolites**
- Analysis of trends in results of microbiological testing of the process environment and equipment
- Hygiene controls applied in the process environment
- Experience from the manufacture of similar products, i.e. where applicable
- Experience from use of traditional practices, i.e. where applicable
- Relevant industry guides, i.e. where applicable
- Rate of microbiological spoilage and maintenance of organoleptic quality under foreseen conditions of storage and use

The identification of the pathogens associated with raw materials and the production environment is critical for the accurate determination of a safe shelf-life. It is important to note that deviations from normal conditions, such as high levels of initial contamination in raw materials or elevated temperatures during storage or transport will impact on the safety of the product during its shelf-life.

Figure 1 outlines a best practice approach to establishing product shelf-life, providing food business operators with an indication of what considerations should be taken in determining the shelf-life, e.g. margin of safety and when additional studies such as durability and challenge tests are required to investigate the potential growth of pathogens in the product during its shelf-life. It is important to note that ongoing monitoring and verification of the shelf-life is necessary to confirm maintenance of the defined shelf-life for each product^{7,15}.

Figure 1. Best Practice Approach to Establishing Product Shelf-Life



4.1 Products Requiring a Shelf-Life Declaration

Food producers or manufacturers of pre-packaged foods are required under labelling legislation to include a shelf-life declaration, i.e. date of minimum durability in the form of a 'best-before' or 'use-by' date (Figure 1)⁶. However, some food products are exempt from carrying a shelf-life declaration due to the conditions in which they are sold, while others have a specific derogation to the labelling legislation (Appendix 2)⁶. As such, these food products are not required to carry a shelf-life declaration⁶. However, where applicable, compliance with relevant food safety criteria throughout product shelf-life is required under Regulation 2073/2005⁴. **It is recommended that best practice should be the inclusion of a shelf-life declaration on the labels of all foods whether exempt or derogated under labelling legislation**⁶. Additional information on the general labelling requirements for shelf-life is outlined in Section 2.1.5.5 of the Food Safety Authority of Ireland's (FSAI) *The Labelling of Food in Ireland, 2007*²².

4.2 Required Declaration of Shelf-Life

A crucial decision in considering shelf-life is whether a food product requires a 'best-before' or 'use-by' date as a declaration of shelf-life (Figure 1).

4.2.1 'Use-by' date

Food products which are microbiologically perishable, e.g. chilled ready-to-eat foods and may consequently, after a short period of time, pose a risk to public health⁶ will generally have their shelf-life indicated by a 'use-by' date (Figure 1). Food products which are typically consumed or intended to be consumed without further preparation, i.e. ready-to-eat foods, or after treatment, unlikely to be sufficient to destroy pathogens and toxins or metabolites which may be present will also have their shelf-life indicated by a 'use-by' date, excluding eggs.

The 'use-by' date will indicate the date up until which the product can be safely consumed (Appendix 2). Therefore, the accurate determination of the 'use-by' date is crucial for food safety. As such, when food business operators are establishing the shelf-life of food products requiring a 'use-by' date, consideration should be given to all intrinsic and extrinsic properties which could affect product safety and shelf-life (Section 5). In the case of ready-to-eat foods, the producer or manufacturer of a food product 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 (Figure 1)⁴.

4.2.2 'Best-before' date

The 'best-before' date typically reflects the quality rather than safety of a food product. A 'best-before' date is normally required on products such as ambient/shelf stable, canned, dried and frozen foods (Appendix 2). Products of this nature are more prone to chemical deterioration, e.g. staling, rancidity, texture changes, flavour loss etc., or microbial spoilage rather than pathogenic growth and consequently unlikely, after a short period of time, to pose a risk to public health (Figure 1).

Food products which receive processing, e.g. heating, drying, freezing, irradiation etc., sufficient to eliminate or retard growth of pathogens which may be present may also have their shelf-life indicated by a 'best-before' date. As a 'best-before' date typically reflects quality characteristics rather than food safety, a food which is past its 'best-before' date may not be unsafe to consume but may not be of optimum quality. Therefore, unlike the 'use-by' date, the accurate determination of a 'best-before' date is not crucial for food safety.

4.3 Ready-to-Eat Foods

Food business operators, with the exception of primary producers, are required to maintain and implement documented procedures in a food safety management system based on HACCP principles^{1,2}. Documentation of these procedures should include a description of the product under consideration, and this description should include the ready-to-eat status of the foodstuff. The ready-to-eat status is fundamental to the subsequent hazard analysis and hazard management controls and procedures (Section 5.12).

A ready-to-eat food is defined under Commission Regulation 2073/2005⁴ as '*a food intended by the producer or the manufacturer for direct human consumption without the need for cooking or other processing effective to eliminate or reduce to an acceptable level microorganisms of concern*'. In other words, it is the responsibility of the producer or manufacturer to determine if the food is ready-to-eat or non ready-to-eat. If the producer or manufacturer determines that the food can be consumed by the consumer without cooking or further processing to ensure food safety, the food can be classified as ready-to-eat. **Otherwise it is a non ready-to-eat food.**

Where foodstuffs are described as ready-to-eat, compliance with the criteria for *L. monocytogenes* laid down in Table I, Annex I of Commission Regulation (EC) No 2073/2005⁴, is mandatory. Criteria are established for three categories of ready-to-eat food in Commission Regulation (EC) No 2073/2005⁴. Food business operators must determine which category their ready-to-eat food falls into and thereby which criterion is applicable to their foodstuff. Further detail on criterion for *L. monocytogenes* in ready-to-eat foods is given in the FSAI guidance note on Commission Regulation (EC) No 2073/2005 on microbiological criteria for foodstuffs²³.

The 'use-by' date for a ready-to-eat product should be determined using the European Commission's guidance document on *L. monocytogenes* shelf-life studies for ready-to-eat' (Appendix I). Where appropriate, reference should also be given to the EU technical guidance document on shelf-life studies for *L. monocytogenes* in ready-to-eat foods¹⁵.

In relation to microbiological criteria, Regulation (EC) No 852/2004¹ requires food business operators to comply with microbiological criteria in Regulation (EC) No 2073/2005⁴ for certain combinations of microorganisms and foodstuffs. Currently, the microbiological criteria legislation⁴ does not contain a criterion for all foodborne pathogens in all food. **However, the absence of a microbiological criterion in the Regulation does not suggest/imply insignificance in relation to food safety**, e.g. a criterion is not established in the Regulation for pathogenic microorganisms such as *Campylobacter* spp. or *Verotoxigenic Escherichia coli* (VTEC) in ready-to-eat foods. Likewise, where a food safety criterion is established for a pathogen such as *L. monocytogenes* in ready-to-eat foods, other pathogens may also be of concern even if they are not specified in the legislation⁴.

Regulation (EC) No 178/2002³ which lays down the general principles for all food legislation requires that food business operators do not place unsafe food on the market. It is important the food business operators consider all microbiological hazards when establishing product shelf-life as they have a legal obligation to produce safe food¹³ (Section 8.2.5).

4.3.1 Cooking and reheating instructions

It is recommended that best practice should be the inclusion of a ready-to-eat statement on all pre-packaged food, if it is a ready-to-eat food. In the case of loose food, this information could be provided to the consumer through the display cabinet or printed on a label when purchasing the food. This information is particularly important for foodstuffs where ambiguity may arise over the ready-to-eat status. Furthermore, where foodstuffs are described as not a ready-to-eat, instructions for use, e.g. cooking instructions, should also be provided. This is a legal requirement:

- Article 6 of Commission Regulation (EC) No 2073/2005 on Microbiological Criteria for Foodstuffs⁴ applies to minced meat, meat preparations and meat products intended to be eaten cooked (applies to all species other than poultry). It states that these commodities must be clearly labelled by the manufacturer to inform the consumer of the need for thorough cooking prior to consumption⁴. This applies whether the food is placed on the market pre-packaged or loose

- Notwithstanding the above, pre-packaged food must comply with Directive 2000/13/EC (relating to the labelling, presentation and advertising of foodstuffs)⁶. Under Article 3.1 of the Directive 2000/13/EC⁶ it states that “*instructions for use are required when it would be impossible to make appropriate use of the foodstuff in the absence of such instructions*”. Article 11 of Directive 2000/13/EC⁶ requires that “*instructions for use of a foodstuff shall be indicated in such a way as to enable appropriate use to be made thereof*”, e.g. where cooking is required then cooking instructions must be provided. If the product is frozen, the cooking instructions should indicate if cooking should be from frozen or thawed prior to cooking

Where cooking or reheating instructions are included, they should be validated by the producer or manufacturer to ensure the pathogen(s) of concern will be destroyed and the product is safe to consume³. This validation study should take into consideration whether the products will be cooked/reheated from frozen or thawed prior to cooking. These instructions, e.g. cook from frozen or thaw prior to consumption should also be included on the label. Further information on instructions for use, storage and handling of food products is outlined in Appendix 2.

5. ESTABLISHING THE INTRINSIC AND EXTRINSIC PROPERTIES

All microorganisms will have minimum requirements for survival and growth in foods. Establishing product characteristics such as pH, water activity (a_w), storage temperature, salt concentration etc (Table 1) will allow food business operators to determine what microorganisms, including pathogens, may survive and grow in their food products. Product characteristics are sometimes referred to as intrinsic and extrinsic properties. Key considerations which should be taken by food business operators when establishing product characteristics are as follows:

- Establish product characteristics under the normal conditions of production, packaging and storage
- Establish product characteristics with an understanding of the products production, physical structure and formulation. Some products may have variable characteristics throughout the food due to their production, e.g. immersion cured meats and cheeses, multi-component products, e.g. ready meals, or physical structure/formulation, e.g. emulsified products such as sauces and condiments, margarines and butter. In all cases, it is important that food business operators establish the product characteristics **which are most favourable** to pathogen growth within the food throughout its entire shelf-life
- If food business operators do not have sufficient technical expertise/resources to establish product characteristics, it is recommended that relevant technical advice is sought from suitably qualified and trained personnel to ensure product characteristics are correctly determined. However, it is not recommended that food business operators rely solely on industry guides and practices to justify validity of determined shelf-lives
- Laboratories used by food business operators in establishing product characteristics should be accredited to the ISO 17025 standard for the test methods they apply, with the required expertise for conducting shelf-life studies

Establishing product characteristics as outlined in Table 1, with the above considerations, will allow food business operators to determine whether pathogens will grow or survive in a food product. This information may also allow the food business operator to reformulate products to prevent or minimise the survival or growth of specific pathogens, e.g. under Regulation (EC) No 2073/2005, foods are not considered to support the growth of *L. monocytogenes* if ⁴:

- pH is ≤ 4.4 , or
- Water activity (a_w) is ≤ 0.92 , or
- pH is ≤ 5.0 with the a_w being ≤ 0.94

Table 1. Food Properties Influencing Microbial Growth^a

| Intrinsic Properties | Extrinsic Properties |
|--|---|
| Microbiological quality & history of raw materials | Good manufacturing & hygiene practices |
| Food formulation & composition | Food safety management system, e.g. HACCP |
| Food assembly & structure | Food processing |
| pH | Storage temperature |
| Type of acid present | Gas atmosphere |
| Water activity (a_w) | Relative humidity |
| Redox potential | Packaging |
| Biological structures | Distribution chain |
| Nutritional content & availability | Consumer practices |
| Antimicrobial substances | |
| Microflora - natural occurring or added | |

^a Table adapted from^{21,24}

Advice on the choice of methodology to measure the properties of food products such as pH, a_w , Eh and temperature (Table 1) and the appropriate equipment should be sought from manufacturers and suppliers. However, in all cases, measuring/monitoring instruments should have a defined accuracy and be initially calibrated (prior to use) and re-calibrated at specified intervals (as per manufacturer's instructions) against measurement standards traceable to an Irish or international measurement standard.

5.1 Margin of Safety

While the accuracy and reproducibility of shelf-life will be affected by the properties of a food (Table 1), 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. Therefore, it is strongly recommended that a margin of safety is applied to reduce the average shelf-life and that this is reflected in the labelled 'use-by' date.

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 properties of foods, e.g. pH or temperature during storage,

should be taken into consideration when applying the margin of safety. Applying a margin of safety will reduce the shelf-life of a food product to a ready-to-eat interval than the determined shelf-life. However, this allows the food business operator to take account of reasonably foreseeable conditions of use which may affect product safety and shelf-life.

5.2 Microbiological Quality and History of Raw Materials

Variation in the microbiological quality of raw materials and ingredients can affect the safety and subsequent shelf-life of food products. It should be assumed that any raw material or ingredient entering a food business operator is a potential source of microbiological contamination (see Section 5.7). Therefore, the starting point for producing safe food products with a desired shelf-life is the use of raw materials and ingredients which comply with legislative requirements for food safety and hygiene, particularly microbiological criteria where applicable⁴. In the absence of specific criteria set in legislation, raw materials and ingredients should comply with relevant Irish standards^{8,9}, Irish guidelines¹⁰⁻¹⁴ or industry best practice guidance¹⁶⁻²⁰.

In some cases, the microbiology quality of raw materials and ingredients will be set in a specification by the food business operator or a customer. In this case, the specification must meet minimum legal requirements where applicable. Often, a food business operator will have a written supplier approval procedure which means that raw materials/ingredients are only sourced from an approved supplier.

All water and ice used as an ingredient and for preparation of food must be of drinking water standard²⁵. Where water (intended to be used as an ingredient) entering premises is not of potable quality, or where quality is unreliable, appropriate treatment should be applied by the food business operator to the water before use^{1,25,26}. Under EU food law¹, where there is a reference to drinking water, it is usually defined as water which meets the standards of the drinking water legislation²⁵.

5.3 Food Formulation, Composition, Structure and Assembly

The formulation of a food product from constituent ingredients influences properties such as pH and a_w for example, and as such, a microorganism's ability to survive and grow. Some constituent ingredients can also retard or eliminate microbial growth due to specific antimicrobial properties.

Some food products may have a heterogeneous or non-uniform internal structure and may therefore have intrinsic properties which are variable within the structure of the food. As a consequence, micro-environments may form within the food products which have different intrinsic properties to the food product as a whole. Micro-environments can be problematic if the general intrinsic properties of a product appear to prevent or retard the growth of target pathogens, when in fact there are areas within the product which could support growth. Table 2 gives examples of formulation and compositional issues which may affect the safety and shelf-life.

Table 2. Examples of Food Formulation and Compositional Issues that affect Shelf-Life

| Situation | Example of Issue |
|---|--|
| An ingredient is removed or an incorrect quantity of ingredient is added to the product | In producing a cooked ham, a food business operator removes sodium nitrite from the curing solution resulting in a product with increased susceptibility to pathogenic growth and a reduced shelf-life. |
| An ingredient is replaced with an alternative 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 adequacy of the thermal process this new puree formulation receives has not been determined and spores of <i>Clostridium botulinum</i> survive the thermal process resulting in contamination of the new sugar-free hazelnut yogurt. |
| Ingredients from two different suppliers have different microbiological quality | A food business operator's regular raw chicken supplier is unable to meet an order. The food business operator orders from a competitor. However, the microbiological quality of this new supply is inferior to the regular suppliers, resulting in a reduction in final product shelf-life. |
| Ingredients of differing microbiologically quality are combined together | A pre-prepared, packaged ham and cheese sandwich is prepared with a good quality cheddar cheese. However, cooked ham which has passed its 'use-by' date is also used resulting in a reduction in final product shelf-life. |
| 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 shelf-life. |

5.4 pH and Type of Acid

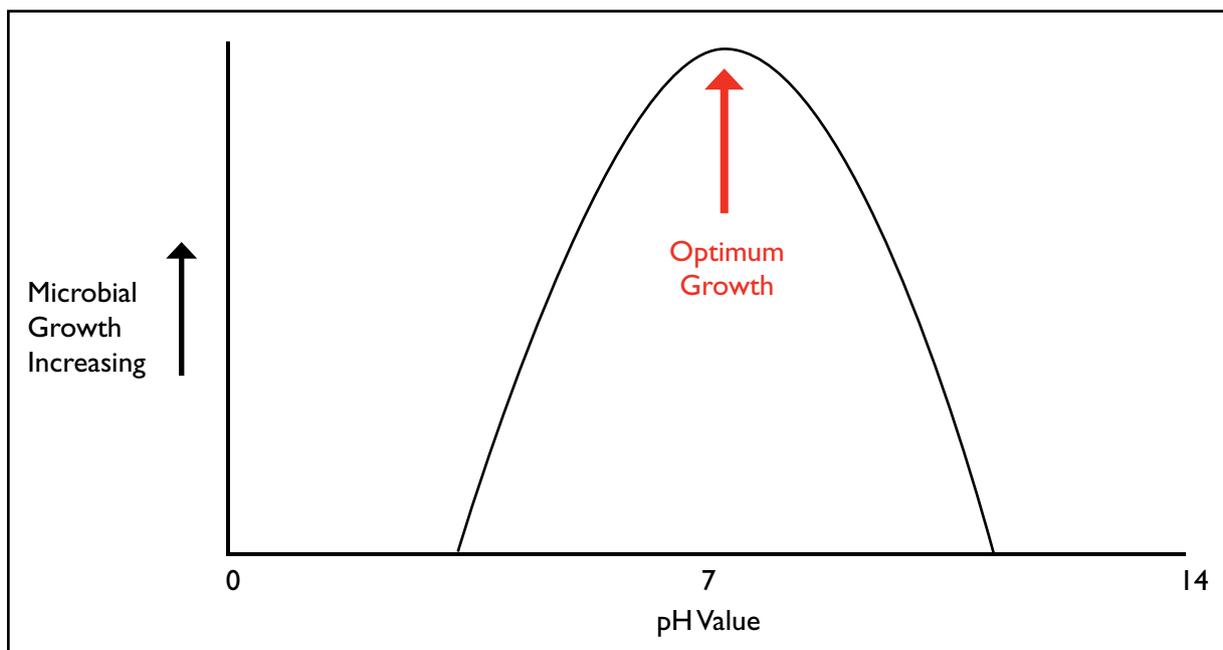
Acidity is an important factor affecting the growth and survival of microorganisms in food. The pH is a measure of a product's acidity and will vary between food products. The pH scale extends from 0 to 14 with the relative strengths of acid and alkaline defined by their pH value on this scale. A pH of 7 is neutral while a pH above 7 is alkaline and a pH below 7 is acidic. The pH scale is logarithmic, therefore each pH unit has 10 times more acidity as the scale moves down from 14 to 0, e.g. pH 6 is 10 times more acidic than pH 7.

Most food products will naturally contain acids and depending on the type and concentration of acid, they can be designated high, intermediate or low acid foods as outlined below²¹:

- High acid, i.e. **pH less than 3.5**
- Intermediate acid, i.e. pH 3.5 to 4.5
- Low acid, i.e. **pH greater than 4.5**

A food's ability to support the growth and survival of pathogens is influenced by its pH. The pH of food products may vary with time due to microbial activity and product composition or formulation. Specific food products may be more prone to pH change than others including vegetables, fresh meats, poultry and mould/smear ripened cheeses. The pH range for microbial growth and survival is defined by a minimum and maximum value with an ideal pH for optimum growth and survival. Most microorganisms grow best at or near a neutral pH, i.e. pH = 7.0 (Figure 2).

Figure 2. Effect of pH on Microbial Growth^a



^a Similar graphs can be used to illustrate other product characteristics such as water activity and storage temperature

At a processing level, some food products will have pH values which prevent or retard the growth of pathogens. A pH of 4.6 is important in food processing because in foods with pH less than 4.6, *Clostridium botulinum* will not produce toxins and is the basis for commercial sterilisation in low and intermediate acid foods.

Typically, foods with high to intermediate acid levels are easier and safer to process than low acid foods which can require the application of more complex processing techniques. However, in all cases, if the pH changes during product shelf-life and pathogens are present, the safety of the product is at risk. It is important to note that pH is typically measured on macerated food and is therefore an average. In some food products, micro-environment pH can change within the food allowing growth of pathogens which otherwise would not grow due to the average measured pH. As such, control of pH and the application of a margin of safety (Section 5.1) are required for these food products. The average pH of some common food products is given in Table 3.

Table 3. Average pH of Selected Foods^{a-e}

| Food | Approx pH Range |
|-----------------------------------|-----------------|
| 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 juice | 2.0 - 2.2 |

^a The pH of foods is inherently variable and all values in Table 3 are approximate values.

^b The pH of some multi-component foods may vary within the product due to diffusion and mixing limitations. If pH is the controlling factor for safety, it should be monitored for every production batch¹⁹. A batch is defined as “a clearly identified unique volume of product consisting of one or more saleable units sharing a common process, common ingredients, packaging and services”⁴.

^c Acidified foods containing meat, fats or oils can be difficult to acidify uniformly and food business operators should take extra care with these foods¹⁹.

^d Typically, pH is measured on macerated food and is therefore an average. Micro-environment pH can change within a food

^e Routine pH measurement of food products is common in all sectors of the food industry, particularly using hand-held pH meters. It is recommended that the determination of pH should be performed according to EN ISO 2917:1999²⁷ or other applicable method. On a larger industrial scale, in-line pH measurement is beginning to become more common place.

Table adapted from ^{21,28,29}

The type of acid used in food will also have an influence on microbial growth. Organic acids such as acetic, sorbic, propionic and benzoic typically cause disruption of the microbial cell membrane. Acetic acid at levels greater than 0.1% inhibits the growth of most foodborne pathogens and is used extensively in many sauces and pickles, typically in combination with mild pasteurisation heat treatments. Sorbic and benzoic acids are more typically used to control yeast and mould in the beverage industry (Section 5.9). Organic acids, while antimicrobial in nature, are also extensively used in the food industry to control product pH²¹.

5.5 Water Activity

Water activity (a_w) is a term referring to the free or available water within a food which is not bound to food molecules. As such, free water can support the growth of microorganisms. Water activity has a scale ranging from zero, i.e. 0% water available, to one, i.e. 100% water available. Food products can be designated high, intermediate or low a_w foods as outlined below²¹:

- High a_w , i.e. **greater than 0.92**
- Intermediate a_w , i.e. **0.85 to 0.92**
- Low a_w , i.e. **less than 0.85**

It is important to note that a_w is not the same as the moisture content of foods. While some high moisture foods will have a higher a_w than dry foods, this is not always the case. Some foods may have similar moisture contents but very different water activities, e.g. jams have high moisture contents, however, the moisture is bound to the sugar in the jam and unavailable for microbial growth, giving jams a low a_w . High sugar and salt concentrations are used to preserve foods by decreasing the a_w by either binding free water making it unavailable for microbial growth, e.g. jams or by exerting osmotic pressure directly on microorganisms, e.g. salt used in brine for some cured meats.

Like pH, the a_w of foods will help determine what the lower limit for microbial growth will be in that food³⁰. In dried and low moisture foods, the control of a_w is an important part of their preservation. Ingredients such as salt and sugars and processing techniques such as drying, curing and cooking used in the production of foods, will influence the a_w and therefore, the growth of specific pathogens and subsequent shelf-life.

As with pH (Figure 2), the growth range of microorganisms will be defined by minimum, maximum and optimum values of a_w . Most microorganisms cannot grow at less than a_w of 0.60 with the majority growing at an a_w greater than 0.90³¹. Typically, bacteria require a higher a_w to grow than moulds or yeasts. Most foodborne pathogenic bacteria require a_w greater than 0.91 to grow. *Cl. botulinum* requires a minimum a_w of 0.94 for growth and toxin production. However, *Staphylococcus aureus* has been found to grow at a_w of 0.83³².

Most spoilage bacteria do not grow below a_w of 0.91, while spoilage moulds can grow as low as a_w 0.80. Some halophilic, i.e. salt-loving, spoilage bacteria can grow as low as a_w 0.75. However, xerophilic, i.e. dry-loving moulds, and osmophilic yeasts, i.e. microorganisms which live in high osmotic pressures, can grow at a_w between 0.61 – 0.65, respectively²¹. The average a_w of some common food products is given in Table 4.

Table 4. Average Water Activity of Selected Foods^{a-e}

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

^a The a_w of foods is inherently variable and all values in Table 4 are approximate.

^b The a_w of some multi-component foods may vary within the product. If a_w is the controlling factor for safety, it should be monitored for every production batch¹⁹.

^c Typically, a_w is measured on macerated food and is therefore an average. Micro-environment a_w can change within a food.

^d Values taken at 20°C.

^e It is recommended that the determination of a_w should be performed according to EN ISO 21807:1994³³ or other applicable method. Due to the nature of a_w testing, it may be necessary to approach a specialised laboratory to do a_w measurements and to interpret the data¹⁹.

Table adapted from ^{21,28-31}

5.6 Redox Potential

The redox or oxidation/reduction potential of a food is the ease by which a food can gain or lose electrons and determines whether microorganisms require oxygen for growth, i.e. aerobic, or not, i.e. anaerobic and is measured in millivolts (mV)²¹. When electrons move they create an electric current which can be measured. If a food product loses electrons, it is described as being oxidised. Oxidised environments provide aerobic conditions for microbial growth. If a food product gains electrons, it is said to be reduced. Reduced environments provide anaerobic conditions for microbial growth²¹. Microorganisms display different degrees of sensitivity to the redox potential but can be broadly classified into the following groups based on their Eh²⁸:

- Aerobes, i.e. **+500 to +300 mV**
- Facultative Anaerobes, i.e. **+300 to -100 mV**
- Anaerobes, i.e. **+100 to less than or equal to -250 mV**

The redox potential of food is influenced by its chemical composition, processing and storage conditions, i.e. 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 in modified atmospheres or vacuum packs. The redox potential is particularly important in ensuring the safety of products such as ambient-stable meat products, e.g. salamis, fermented and dried meats³⁴.

However, 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 limitations in its measurement, e.g. low accuracy. The average redox potential of some common food products is given in Table 5.

Table 5. Average Redox Potential of Selected Foods ^{a-b}

| Food | Approx mV Range |
|--------------------------------------|-----------------|
| Fruit/Plant foods, e.g. fruit juices | +300 to +400 |
| Minced meats, e.g. minced beef | + 200 |
| Whole or solid meats, e.g. steak | -200 |
| Cheeses | -20 to -200 |
| Canned foods | -130 to -550 |

a The redox potential of foods is variable and all values in Table 5 are approximate.

b When the redox potential is measured, it should be described with the pH of the food product, as redox potential is dependent on the pH of the substrate. Routine measurement of redox potential in food products is quite simplistic. However, difficulties may arise in taking accurate, reproducible measurements and in accounting for differences in the redox potential throughout a food product ²⁸.

Table adapted from ^{21,28}

5.7 Biological Structures

Some raw materials/ingredients will have natural barriers or coverings that protect the food within from external contamination by microorganisms. These barriers include shells, skins and membranes commonly found on foods such as nuts, eggs, vegetables/fruit, meat and fish. The effectiveness of these biological structures in preventing contamination of food products will vary considerably, and in some cases, can facilitate microbial growth. When biological structures are removed, food business operators should consider the use of an appropriate method, e.g. washing, filtration, trimming etc. to reduce microbial loadings and improve microbiological quality of the raw materials before use (see Section 5.2).

5.8 Nutrition Content and Availability

All microorganisms require nutrients, e.g. protein, fat, sugars, minerals and vitamins for growth and maintenance of basic metabolic functions. The concentration and type of nutrients required will vary depending on the microorganism. Therefore, the specific nutrition content and availability of those nutrients in a food will influence microbial growth. Typically, bacteria have the highest nutritional requirements for growth followed by yeasts and moulds^{21,28}.

5.9 Antimicrobial Substances

Some foods will contain antimicrobial substances which retard, prevent or eliminate 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 foods²¹, e.g. Allicin in garlic and onions and Lysozyme in eggs and milk, while others are artificially added as food additives, e.g. nitrite in processed meats.

5.9.1 Food additives

Regulation (EC) No 1333/2008 harmonises the use of food additives in foods in the EU and defines food additives as “*substances not normally consumed as a food in itself and not normally used as a characteristic ingredient of food, whether or not it has nutritive value, the intentional addition of which to food for a technological purpose in the manufacture, processing, preparation, treatment, packaging, transport or storage of such food results, or may be reasonably expected to result, in it or its by-products becoming directly or indirectly a component of such foods*”³⁵. This definition of food additives³⁵ includes the use of food additives in foods covered by Directive 2009/39/EC³⁶ 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.

5.9.2 Salt (sodium chloride)

Salt or sodium chloride is one of the most common substances added to food for its antimicrobial properties. Typically, the percentage of salt in the aqueous phase of a food product is the controlling factor where salt is used as a preservative in that food. The percentage of salt in the aqueous phase, i.e. an aqueous solution, is one in which the solvent is water can be calculated from the grams of salt present per/100g and the moisture content per/100g product using the following calculation:

$$\% \text{ Salt Aqueous Phase} = \frac{\% \text{ Salt} \times 100}{\% \text{ Salt} + \% \text{ Moisture}}$$

5.10 Microflora

All food products contain varying numbers and types of microorganisms and in some foods microorganisms are deliberately added, e.g. lactic acid bacteria added to milk to make cheese. In the case of natural microflora, the composition can vary widely. The presence of certain microorganisms in foods, e.g. lactic acid bacteria in natural yogurt may retard or prevent the growth of pathogens. Some spoilage microorganisms may outgrow pathogens, consume available nutrients and predominate in the food by a process known as competitive inhibition. In addition, microorganisms may also excrete antimicrobial substances (Section 5.9) which may retard or prevent the growth of pathogens.

5.11 Good Manufacturing and Hygiene Practices

Measures to control microorganisms in foods must be complemented by measures to minimise the risk of recontamination from the food processing environment. Good manufacturing practices (GMP) and good hygiene practices (GHP) and the development and implementation of a food safety management system based on the principles of HACCP (Section 5.12) are fundamental for ensuring and maintaining the continued safety and shelf-life of foods. All food business operators, including primary producers, are legally obliged to implement GHP^{1,2}.

5.12 Food Safety Management System

A food safety management system based on the principles of HACCP^{1,2,11} is a structured systematic approach to food safety, which involves identifying potential hazards and planning for their monitoring and control. Once a valid shelf-life has been determined, the extrinsic and intrinsic factors of the food that have been identified during the validation process must be systematically controlled during manufacture and distribution. The important extrinsic and intrinsic factors of the food can be identified as critical control points, assigned critical limits and monitored in keeping with the principles of HACCP. In this way, procedures based on the principles of HACCP, applied logically and systematically will reduce or prevent contamination of food products and ensure that the validated shelf-life is consistently achieved.

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 principles¹. The FSAI has produced extensive guidance on applying HACCP principles^{11,37,38}.

5.13 Food Processing

The processing involved in the manufacture of foods varies in its complexity but is typically designed to maintain and improve food safety. Processing techniques such as heat treatment may extend the shelf-life of foods by destroying or reducing numbers of microorganisms. Other processing techniques such as curing, drying or vacuum packaging 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 will also result in the formation of antimicrobial substances in foods including the following processes (Section 5.9):

- Smoking, e.g. fish and meat products
- Fermentation, e.g. meat products
- Condensation reactions between sugars and amino acids, i.e. Maillard reaction during heating of certain foods

As such, a food business operator should consider how the various stages in production may affect the survival and growth of microorganisms and thus final product shelf-life, e.g. by applying HACCP principles. However, food business operators should seek advice from a competent body and/or an appropriate equipment manufacturer before implementing or altering any food processing technique.

5.13.1 Heat treatments

Typically, heat treatments are mild and will not destroy all microorganisms, their spores or toxins, but rather will eliminate or reduce numbers of specific target organisms. However, as a general guide, a heat treatment should be sufficient to ensure heat penetration at the centre or thickest part of a food to reduce the number of target pathogens by 6 log cycles, e.g. 1 million per gram to 1 per gram.

To design and implement a safe heat process requires food business operators to have a good general understanding of the mathematics behind heat processing, along with an understanding of the effects of heat processing on pathogens, i.e. thermal destruction. In addition, the food business operator should have a general understanding of the factors affecting heat resistance of pathogens and the factors affecting heating and chilling processes¹⁴.

5.13.2 Decimal reduction time (D-value)

Most foodborne vegetative pathogens are not particularly heat resistant and are easily killed by pasteurisation and normal cooking temperatures. However, variations in heat resistance have been observed in many pathogens in different foods where product characteristics such as the level of fat, water, protein, carbohydrates, salt, pH and competitive microorganisms have been shown to have an effect.

As such, for every target microorganism under the specific conditions of a food product, there is a specific time required at a particular temperature to ensure destruction of 90% of all viable, i.e. vegetative cells and/or spores present. This time, i.e. in minutes or seconds is referred to as the decimal reduction time or D-value. A 90% reduction is also referred to as a 1 Log_{10} cycle reduction or a ten-fold reduction¹⁴. Typically, a time/temperature combination of greater than or equal to 70°C for two minutes at the centre or thickest point of the food or equivalent should ensure a 10⁶, i.e. D-6 reduction of viable *L. monocytogenes* cells, the most heat resistant vegetative pathogen^{14,39}.

The FSAI has produced guidance on cook-chill systems in the food service sector¹³ and the industrial processing of heat-chill foods¹⁴.

5.14 Storage Temperature

The shelf-life of many foods is dependent on storage temperature²⁴. In relation to microorganism's ability to grow at certain temperatures, there are three broad categories of growth range²¹:

- Psychrotrophic microorganisms have an optimum temperature range of 20°C to 30°C, but many can survive and grow at or below 5°C. Foodborne pathogens which will grow at or below 5°C include *L. monocytogenes*, *Yersinia enterocolitica* and non-proteolytic *Clostridium botulinum*
- Mesophilic microorganisms have an optimum temperature range of 30°C to 40°C, but many can survive and grow between 20°C to 40°C. Many foodborne pathogens are mesophiles including *Salmonella* species, VTEC and *Staphylococcus aureus*
- Thermophilic microorganisms have an optimum temperature range between 55°C to 65°C, but many can survive and grow well at 45°C but not less than 30°C. Some foodborne pathogens are thermophiles such as *Clostridium perfringens*

Typically, the storage temperature for food products should be specified for safety and/or quality reasons and/or shelf-life. It is important to note that some foods don't require temperature control for food safety reasons. To specify a storage temperature, the food business operator should accurately determine the following:

- Will the recommended storage temperature increase, slow or stop microbial growth?
- Will pathogens grow at the recommended storage temperature and if so, which pathogens?
- Will the product be subject to temperature abuse during storage, distribution and display?

Where a food business operator decides that additional shelf-life studies, e.g. challenge testing or durability studies are required, but where the storage temperatures are unknown for the product, the food business operator may define a storage temperature for the shelf-life studies. However, the food business operator must justify which temperatures are used for the shelf-life study, taking into account data from temperatures during distribution and storage by consumers, where available^{7,15}. The EU *Technical Guidance Document on Shelf-Life Studies for Listeria monocytogenes in Ready-to-Eat Foods* suggests temperatures for challenge and durability studies if these data are not available¹⁵.

5.15 Gas Atmosphere

The gas atmosphere composition surrounding a food will have an effect on the survival and growth of microorganisms. Some food business operators will use modified atmosphere packaging (MAP), gas flushing⁴⁰ or vacuum packing to alter the gas atmosphere composition surrounding the food and extend the shelf-life^{18,19,41}. However, the extension of product shelf-life through the use of MAP or vacuum packing often requires the additional control of other product characteristics such as pH and storage temperature (Table 1). In addition, the specific concentrations of gases, the packaging (Section 5.17) and equipment¹⁸ used in the product must be carefully controlled to ensure product safety. Where not available, food business operators should seek advice from a competent body before using MAP or vacuum packing.

Vacuum packing involves the removal of air from the package leaving a small, i.e. residual, air content. MAP or gas flushing involves the removal of air from the packaging and its substitution with another gas or mixture of gases such as oxygen, carbon dioxide or nitrogen. Nitrogen is typically a filler gas while oxygen maintains the sensory characteristics of the product. Carbon dioxide is typically inhibitory to moulds, yeasts and aerobic bacteria. When pH and storage temperatures are low, higher concentrations of carbon dioxide will provide higher inhibitory effects.

Under current legislation, food products which have their shelf-life extended by means of packaging gases, e.g. MAP, should not be sold, presented or advertised nor should free samples be provided unless the labelling of the food product indicates that the shelf-life has been extended by means of packaging gases (Appendix 2)⁴.

Food business operators should be aware that packaging permeability can affect the composition of gases in the pack during shelf-life which in turn, affects the microbiological growth. It is also recommended that the labelling carries a clear statement that the 'use-by' date on MAP and vacuum packed food is no longer applicable once the pack is opened. MAP and vacuum packaged food should also carry instruction for use that include how soon the food must be consumed after the pack is opened and the storage temperature.

The Food Standards Agency (FSA) in the United Kingdom has published guidance summarising the advice of the Advisory Committee on the Microbiological Safety of Food (ACMSF) on the safety and shelf-life of vacuum packed and MAP chilled foods with respect to non-proteolytic *Cl. botulinum*¹⁹. There were 2 key ACMSF recommendations that related to the safety of vacuum packed food products. Firstly, for products with a shelf-life of greater than 10 days, in addition to chill temperatures, the following control factors should be used singly or in combination to prevent growth of non-proteolytic *Clostridium botulinum*¹⁹:

- Heat treatment of 90°C for 10 minutes or equivalent
- pH of 5 or less
- Minimum salt level of 3.5% (in the aqueous phase)
- a_w of 0.97 or less
- Combination of heat and preservative factors shown to prevent growth

Secondly, in the absence of demonstrated safety factors, shelf-life must be restricted to less than 10 days and the product must be stored at 8°C or below¹⁹. Campden BRI, has also published *A code of practice for the manufacture of vacuum packed and modified atmosphere packed chilled food* was published in 1996 and it was updated in 2009⁸. The FSA provides online training for enforcement officers in vacuum packed and MAP of food products which is available on their website.

Large quantities of pre-packaged, chilled, vacuum packed/MAP, raw meats are sold in Ireland and when correctly stored, have not been associated with foodborne botulism. The majority of these products on the Irish market have shelf-life greater than 10 days without receiving any of the control measures specified by the FSA/ACMSF/Camden BRI^{19,42} as outlined above⁴¹. Based on these facts, current industrial practices in Ireland would appear to have a high degree of safety⁴¹. However, it is clear that if present, non-proteolytic *Cl. botulinum* can form toxin in less than 10 days, at less than 8°C⁴¹. That toxin formation has not occurred in correctly stored pre-packaged, chilled, vacuum packed/MAP, raw meats sold in Ireland and internationally must be due to presence of one or more unknown controlling factors⁴¹.

The FSAI recommends that the UK FSA/ACMSF approach¹⁹ for products with a shelf-life of greater than 10 days is followed. However, in the case of chilled vacuum pack/MAP raw meats sold as whole joints or cuts, current industrial practice is acceptable.

The FSAI recommends that if vacuum packed/MAP products are opened by food business operators for portioning or when vacuum packed/MAP ingredients are used as components of other products and then repackaged as vacuum packed/MAP products, the shelf-life should not be extended beyond the original vacuum packed/MAP product shelf-life⁴¹, unless the food business operator can satisfy the competent authority that the declared shelf-life is valid. Food business operators should adopt procedures to prevent cross contamination during opening and repacking of these products.

The FSAI recommends that caution is always exercised by food business operators when modifying current industrial practices, such as, extending shelf-life beyond those currently used, and in the research and development of new products⁴¹.

5.16 Relative Humidity

Relative humidity is the concentration of moisture in the atmosphere surrounding a food product whether packaged or not. It is calculated as a percentage of the humidity required to completely saturate the atmosphere, i.e. saturation humidity. Typically, there will be an exchange of moisture between a food and its atmosphere which continues until the food reaches equilibrium with the surrounding atmosphere.

Relative humidity can affect the a_w (Section 5.5) of food products²¹. If a specific a_w is required to control microbial survival or growth in a food, it is important that the product is stored in an environment where the relative humidity prevents the a_w of the product changing. In determining the appropriate storage and packaging conditions for a food product, it is important to note that relative humidity is associated with storage temperature (Section 5.14). Typically, for lower storage temperatures, a higher relative humidity is required⁴³. Some food products 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 and moulds may grow with subsequent spoilage of the product.

5.17 Packaging

Many packaging systems such as MAP and vacuum packing (Section 5.15) control the gas atmosphere composition surrounding a food product and extend shelf-life. However, different packaging will have different properties such as gas and water vapour permeability, and understanding these properties is important for product safety and shelf-life, e.g. in foods packaged in impermeable packaging, the relative humidity (Section 5.16) of the storage environment is unlikely to be important in influencing shelf-life. However, if shelf-life of the product is limited by moisture gain/loss or if the food is packaged in moisture sensitive packaging, control of relative humidity should be a consideration in validation of product shelf-life.

The choice and use of packaging may require specialised equipment, packaging materials and trained personnel. Food business operators should seek advice from a competent body and/or an appropriate equipment manufacturer before using a specific packaging technology for the first time and to ensure their compliance with legislation^{1-4,6,44}.

5.18 Distribution Chain

How a food is handled and stored as it passes through the distribution chain will affect shelf-life. In some circumstances, food may experience temperature abuse during storage, distribution and retail display which will affect product shelf-life. As such, food business operators should consider, under all reasonably foreseeable conditions, the effects of the distribution chain on product shelf-life, e.g. temperature abuse. Research has shown that the average temperature in domestic refrigerators is around 10°C⁴⁵. Consequently, the shelf-life of chilled foods should take this reality into consideration irrespective of the labelled storage temperature.

5.19 Consumer Practices

Consumer practices during purchase, storage and use of foods are predominately outside the control of the food business operator. A recent scientific study of consumer practices in Ireland has shown a relatively poor understanding of basic food hygiene and food safety, particularly temperature control⁴⁵. Many domestic refrigerators may not operate at appropriate temperatures⁴⁵ which can affect the safety and shelf-life of food products. A food business operator should take account of poor consumer practices in determination of product shelf-life.

As required, a food business operator should specify storage temperatures on the labelling of food products⁴⁶. General food labelling legislation⁶ requires pre-packaged foods to be labelled with instructions for use to enable members of the public make appropriate use of the food (see Appendix 2). Commission Regulation 2073/2005 on microbiological criteria for foodstuffs⁴ also has labelling requirements for minced meat, meat preparations and meat products intended to be eaten cooked (Section 4.3.1).

5.20 Hurdle Technology and Shelf-Life Stability

Hurdle technology is a concept of achieving control of product safety by combining different food properties or preservation techniques. This provides a preservation effect adequate for control of specific pathogens and shelf-life stability⁴⁷.

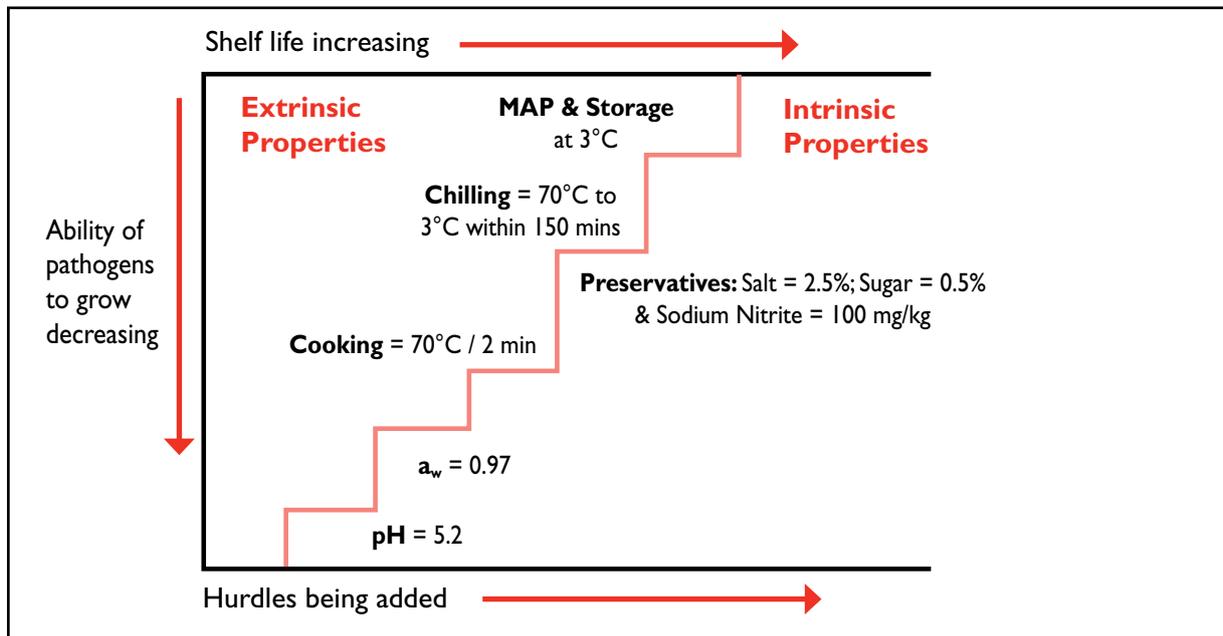
In relation to shelf-life, each food property is considered a hurdle to the survival and growth of microorganisms during and up to the end of shelf-life. A carefully selected combination of food properties will retard or inhibit microbial growth in a food product (Table 1).

Hurdle technology can be based on any number of food properties, e.g. pH, a_w , storage temperature, gas atmosphere⁴⁷ and food preservation techniques, typically classified as follows:

- Removal, limitation or prevention of contamination, e.g. **GHP, GMP, HACCP**
- Slowing or stopping of microbial growth, e.g. **pH, a_w , Eh etc.**
- Inactivation of microorganisms, e.g. **thermal processing, etc.**

An example of hurdle technology is given in Figure 3. A pre-packaged, sliced, cooked ham has its safety and shelf-life preserved by using a combination of mild preservation factors and processing techniques to inhibit the survival and growth of target pathogens, e.g. *L. monocytogenes* and ensure product safety up to a determined shelf-life.

Figure 3. Hurdle Technology in Cooked Sliced Ham^a



^a Not all hurdles are proportional in terms of the effect they have on the ability of pathogens to survive and grow. Therefore, specific steps in the graph may have a greater, e.g. cooking or lesser, e.g. chilling effect. In the above example, cooking has the greatest effect on the ability of pathogens to survive and grow.

The hurdle concept allows a food business operator to address safety and shelf-life concerns they may have with a specific food product. It also allows the food business operator to address consumer demands for convenient foods that are minimally processed by manipulating and applying a number of mild preservation steps, i.e. intrinsic and extrinsic properties, to the product (Table 1). As further steps are added, it becomes more difficult for microorganisms to survive and grow in the food product (Figure 3).

In all products, the exact combination of hurdles required for inhibiting survival and growth of microorganisms is dependent on the properties of a specific food product and what the food business operator requires from the product in terms of safety and shelf-life⁴⁷. Many different hurdles are available for use in food processing and preservation (Table 1). However, the use of hurdle technology is heavily dependent on a detailed knowledge of the effects of various food properties individually and in combination as well as on factors or processes which may impact on these effects. While each hurdle on its own may not be sufficient to eliminate or reduce a hazard to an acceptable level, in combination they may, and where that is the case, each hurdle should be identified and controlled as a critical control point.

6. CONSULTATION OF SCIENTIFIC LITERATURE AND HISTORICAL DATA

6.1 Scientific Literature

A wide resource of data on foodborne pathogens and shelf-life is available from the scientific journals, books, industry guides and third level institutes. In addition, the FSAI and other competent authorities, e.g. Dept of Agriculture, Marine and Food, the Health Service Executive (HSE) as well as professional and international institutions have resources and data available.

Foodborne pathogens have minimum, optimum and maximum requirements for growth and survival in foods based on the foods intrinsic and extrinsic properties. Typically, the growth rate of pathogens will decrease as the upper or lower limits of growth are approached (Figure 2). However, it is important to note that pathogens may out grow the limits reported in scientific literature. When a food business operator has established the properties of their food (Section 5) and the conditions under which that food is produced, packaged and stored, this information can be used to compare the product with existing data on the survival and growth of pathogens in scientific literature. Further information on the growth characteristics of common foodborne pathogens is outlined in Appendix 3.

6.2 Historical Data

Historical data are an important component of records which all food business operators keep as a part of ongoing business. Some of these data are recorded as part of legal obligations under food safety legislation and other data may come from a food business operator's own quality procedures held as part of the food business operator's ongoing quality control procedures. Final product testing is often carried out on the day of production and at the end of product shelf-life to verify the correct operation of the production and HACCP based systems and the validity of the product's shelf-life, respectively. Historical data are helpful in determining the shelf-life of foods for the following reasons²⁰:

- They indicate levels of selected pathogens found in the production environment, raw materials and existing foods, under the food business operators current practices of GHP, GMP and food safety management system
- They indicate levels of selected pathogens in existing foods at the start/end of shelf-life and can be used to assess potential growth of pathogens in similar foods with comparable intrinsic/extrinsic properties manufactured under similar conditions
- Historical data on levels of *L. monocytogenes* in existing ready-to-eat foods at the start/end of shelf-life are used to verify product durability and confirm that a determined shelf-life is accurate under reasonably foreseeable conditions of processing, storage, distribution and use

- Historical data, generated over a period of time for comparable foods, and which continue to be generated on an on-going basis by the food business operator, can be used for trend analysis, e.g. 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 limits⁵, such data can be used in combination with data from environmental sampling and on quality of raw materials, 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 become⁷

It is important to note that the food business operator must satisfy the competent authority that their historical data are sufficient to demonstrate that pathogens such as *L. monocytogenes* will not grow or 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, e.g. durability studies or challenge tests.

7. PREDICTIVE MATHEMATICAL MODELLING

Laboratory based durability studies (Section 8) are typically used to make the critical decisions regarding food safety and product shelf-life. However, predictive mathematical modelling utilises mathematical models built with data from laboratory testing and computer software to mathematically describe the responses of microorganisms to specific intrinsic and extrinsic properties.

Data to build predictive mathematical models are normally derived from experiments carried out under laboratory conditions. In most cases, these experiments are performed using laboratory media rather than actual food products. Before use, the models must be validated against data on the survival and growth of microorganisms in actual food products. Cumulative databases are built up from microbial responses, and procedures to interpret and interact with the database in a mathematical model are then developed, i.e. predictive food microbiology⁷.

Predictive mathematical models are normally developed assuming that microbial responses are consistent⁶. 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 shown that this is often why some predictive mathematical models do not accurately predict the survival and growth of pathogens in food products⁴⁸.

Predictive mathematical models are useful when the shelf-life has been determined, but the product is then subject to a minor process or formulation change. A predictive model can then be used to initially establish if the change will have any effect on the safety and shelf-life of the product, e.g. will *L. monocytogenes* grow in cooked ham if the salt concentration is decreased from 5% to 3%. Predictive mathematical models are also particularly useful in the early stages of product development to give an estimation of the shelf-life.

Predictive mathematical models only provide accurate information when interpreted by trained microbiologists with appropriate skills and experience. Where a food business operator does not have sufficient skills or expertise to use predictive mathematical models it should seek external advice.

Some widely recognised and commonly used, freely available models are listed below, although this is not intended to be an exhaustive list⁷:

- Growth Predictor & Perfringens Predictor- Freely available from the Institute of Food Research, UK at <http://www.ifr.ac.uk/safety/growthpredictor/>
- Pathogen Modelling Programme - Freely available from the United States Department of Agriculture, Agriculture Research Service at <http://portal.arserrc.gov/>

Further information on predictive microbiology is also available on the FSAI website at http://www.fsai.ie/food_businesses/topics_of_interest/predictive_micro.html

Other predictive modeling software is also commercially availableⁱⁱ.

ⁱⁱ The FSAI takes no responsibility for the content or availability of other websites. All referenced websites last accessed August 5th 2011.

8. LABORATORY STUDIES

Two types of laboratory study are normally conducted in relation to shelf-life, challenge testing and durability studies. Although not a legal requirement, the FSAI strongly recommends that food business operators using external services for laboratory studies of food products only use laboratories which are accredited to conduct the analytical method for the required food matrix. The Irish National Accreditation Board (INAB) is the national body with responsibility for accreditation of laboratories, i.e. private and public, established 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 INAB accredited laboratories is available on their websiteⁱⁱⁱ.

8.1 Challenge Testing

Microbiological challenge testing is a laboratory study to determine the behaviour of a particular microorganism in a foodstuff. It determines if the organism is able to grow in the foodstuffs and if so, how fast it will grow. Challenge testing will also establish and validate the safety of foods at a determined shelf-life. In a challenge test, a food product is inoculated, i.e. spiked, with a known pathogen or non-pathogenic microorganism with similar characteristics, at a specific inoculation level. The food product is then treated under reasonably foreseeable conditions of distribution, storage and use by the food business operator and the survival and growth of the inoculated microorganisms is measured.

Typically, challenge testing is used to establish potential risks for the survival, growth and/or production of toxins by specific foodborne pathogens. Challenge testing may be required for food products where important controlling factors, e.g. pH, a_w , storage temperature, for pathogens have not been described by the food business operator. In addition, if no safety data are available for the product or a closely related product, challenge testing may also be required.

Challenge testing must always be used with caution. Consultation with a competent body is strongly recommended before its use. It is strongly recommended that food business operators only perform challenge testing if they have appropriate facilities, understanding, training and experience with these microbiological techniques. Preferably, external laboratories with appropriate accreditation and experience should be used if challenge testing is required¹⁶. In practice, challenge testing will only be required if all other methods of assessing the safety of a food product, i.e. intrinsic and extrinsic properties, durability studies, predictive microbiology etc have been exhausted. Guidance on challenge testing of foods for *L. monocytogenes* has been published by the EC ^{7,15}.

ⁱⁱⁱ See: <http://www.inab.ie/directoryofaccreditedbodies/laboratoryaccreditationtesting/>

8.2 Durability Studies

A durability study is a laboratory study which determines the growth of a particular organism in a naturally contaminated food under reasonably foreseeable conditions of distribution, storage and use. In some cases, it will be necessary for food business operators to carry out durability studies to determine and/or validate product shelf-life. The analysis should be specific for pathogens which can grow or survive (Appendix 3) in the product based on the determined intrinsic and extrinsic properties of the food (Table 1). Guidance on durability studies of foods for *L. monocytogenes* has been published by the EC ^{7,15}.

Durability studies are in many cases, more realistic than challenge tests as the contamination is naturally occurring. However, results can be difficult to interpret due to the low probability of testing a contaminated unit, the low number of microbial cells initially present and their uneven distribution in the food. Ultimately, the safety of food products should be ensured by a preventative approach incorporating product and process design, application of GHP and GMP (Section 5.11) and a food safety management system based on HACCP principles (Section 5.12). Microbiological criteria⁴ where applicable, must be used in validation and verification of the food safety management system and other hygiene control measures.

Furthermore, food business operators should request the analysis of specific product properties such as pH and a_w rather than just provision of microbiological data from laboratories they use. Food business operators using external consultants should only select consultants with relevant expertise in food safety and shelf-life determination and validation. The FSAI has produced guidance on how to select an external consultant⁴⁹.

Some of the more common questions which arise in relation to the design and implementation of durability studies are outlined in the following sections, 8.2.1 – 8.2.9:

8.2.1 What type of samples should be tested?

Traditionally, samples for durability studies would be representative of the final commercial product taken on the day of production. Food business operators should also consider final products which are worst case formulated once they have established process variability. In so doing, the results of durability testing will be more representative of the average values for the commercial product on the market.

Food business operators are reminded of the need to operate a food safety management system based on HACCP principles, and not to rely solely on end-product testing⁵⁰. It is now widely accepted that end-product testing alone cannot guarantee the safety of foods, due to reasons relating to sampling, methodology and uneven distribution of microorganisms in foods. However, end-product testing for specific microorganisms on the day of production and at the end of shelf-life is a useful tool to verify durability and the effective functioning of the HACCP system²⁰.

8.2.2 How long should sample testing last?

Initially, shelf-life testing should last as long as the target 'use-by' date and/or the predetermined date set by the food business operator, e.g. if a product has a target shelf-life of 7 days, i.e. 7 days after the day of manufacture, testing should last a minimum of 8 days. Microbiological analysis should be performed during this period. If, after this time, the qualifying criteria are still being met, e.g. microbiological criteria for *L. monocytogenes*[†], the shelf-life testing may be continued until they are exceeded. Under some circumstances, a product may exceed its qualifying criteria before its target 'use-by' date. At this point, shelf-life testing should stop and the food business operator should either give the product the determined shelf-life or continue with product development and further testing until the desired shelf-life is achieved. However, it is recommended that food business operators apply a margin of safety to a determined shelf-life (Section 5.1).

8.2.3 At what frequency should samples be tested?

The frequency of sample testing during the shelf-life study should be based on experience with similar foods and the established properties of the food product (Table 1). The nature of food products will largely determine the frequency of sample testing, e.g. perishable food products, e.g. target shelf-life of 5-7 days, may require testing at daily intervals while less perishable foods may only require twice weekly or weekly testing intervals.

8.2.4 How many sample replicates should be tested?

At each sample interval during shelf-life determination, 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 food products is typically not uniform. In the absence of specified sample numbers, it is recommended that at least three replicate samples are tested at each sample interval. This is to ensure that the samples tested are representative of the food product, i.e. production lot, batch etc. The larger the number of replicates tested per interval, the greater the degree of confidence a food business operator can have in a determined shelf-life.

The size of the production batch will also determine the number of samples to be taken. However, if specific microbiological criteria exist in legislation[†], the appropriate sampling plan should be implemented at each measurement point. The International Commission on Microbiological Specifications for Foods (ICMSF)^{iv} has produced extensive guidance on microbiological sampling plans which can be used by a food business operator in determining product safety and shelf-life, including the recently published *Microorganisms in Foods 8 - Use of Data for Assessing Process Control and Product Quality*⁶⁹.

^{iv} For further information please see the website of International Commission on Microbiological Specifications for Foods: <http://www.icmsf.iit.edu/main/home.html>

8.2.5 What microbiological tests are required?

Due to the wide variety of food products, it is impossible to accurately describe all the microbiological tests that may be used to determine shelf-life. However, at a minimum, the food business operator must comply with the requirements of the legislation on the microbiological criteria of food products^{1,4}. Competent bodies may also produce guidance on microbiological tests and associated microbiological criteria for food products^{10,51}. 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 (Section 4.3).

The FSAI has produced a factsheet⁵² which outlines best practice for testing foods when assessing compliance with the microbiological criteria specified in Commission Regulation (EC) No 2073/2005⁴.

8.2.6 Do microbiological tests have to be to specific standards?

Microbiological test results are dependent on the analytical method used, and therefore a given reference method should be associated with each microbiological test performed⁴. It is recommended that all microbiological tests are to a recognised standard, e.g. ISO, EN, BS. However, food business operators should have the possibility to use analytical methods other than the reference methods, in particular, more rapid methods, as long as the use of these alternative methods provides equivalent results and has been validated against the reference method⁴.

Under the microbiological criteria regulation⁴, the use of alternative analytical methods is acceptable when the methods are validated against the reference method listed in Annex I of the regulation and if a proprietary method is used, it is certified by a third party in accordance with the protocol set out in EN/ISO standard 16140 or other internationally accepted similar protocols⁴. If the food business operator wishes to use analytical methods other than those validated and certified as described in the Regulation, the methods shall be validated according to internationally accepted protocols and their use authorised by the competent authority⁴. The FSAI has produced factsheets which list alternative proprietary methods applicable when testing foodstuffs against food and process safety ^{53,54} microbiological criteria specified in Commission Regulation (EC) No 2073/2005⁴.

8.2.7 How should food products be stored during analysis?

To determine an accurate shelf-life, microbiological data should be collected while food products are kept under all reasonably foreseeable conditions of storage, distribution and use. Products should not be stored at temperatures which don't reflect normal practice even if these storage temperatures are not the recommended temperatures. If the actual storage temperatures are unknown for a food product, the food business operator may use its own storage temperatures for the shelf-life studies. However, the food business operator must justify which temperatures are used for the shelf-life tests, taking into account the data from temperatures during distribution and storage by consumers, where available^{7,15}. The EU *Technical Guidance Document on Shelf-Life Studies for Listeria monocytogenes in Ready-to-Eat Foods* suggests temperatures for challenge and durability studies if these data aren't available¹⁵.

8.2.8 How do I interpret microbiological data?

The interpretation of data is only reliable if analysis has been designed and implemented correctly, e.g. correct sampling plan. The data collected from microbiological analysis should be compared to relevant microbiological criteria legislation, standards and guidelines. If the shelf-life is determined during product development and this indicates that the shelf-life is unacceptable for the product's target market, that product may have to be redeveloped or modified. The FSAI has produced a guidance note on Regulation 2073/2005 which outlines in detail all of the issues surrounding interpretation of microbiological data²³.

8.2.9 What records and documentation should be kept?

It is recommended that food business operators document procedures, data and records relevant to the establishment and validation of the product shelf-life. These data can be used as validation of a determined shelf-life. Details of all methods, procedures and correspondence during determination should also be recorded and maintained. It is essential that the documentation is readily available to allow the food business operator to demonstrate to the satisfaction of the appropriate competent authority, that product shelf-life has been accurately determined and validated.

9. SUMMARY OF REQUIREMENTS FOR ESTABLISHING SHELF-LIFE

Establishing product shelf-life is a complex area (Figure 1) as outlined in the previous sections. However, the main points which relate to its establishment are provided below:

- The food business operator who manufactures the food product is responsible for determining the shelf-life under defined conditions which should take into account reasonably foreseen conditions of distribution, storage and use
- The safety of foods should be ensured by food business operators using a preventative approach with the implementation of GMP, GHP and a food safety management system based on the principles of HACCP
- In practice, setting product shelf-life should be considered an integral part of a food business operator's food safety management system and should be validated by food business operators as part of a regular review of its food safety management system
- The food business operator should, as part of their GMP, GHP and HACCP principles, ensure compliance with the current Commission Regulation (EC) No 2073/2005 on microbiological criteria⁴ and is applicable to food business operators at all stages of the food chain. However, depending on the stage of the food chain, food business operators may need to comply with only process hygiene criteria or food safety criteria or both
- Shelf-life studies are particularly important for food which supports the growth of pathogens such as *L. monocytogenes* in ready-to-eat foods
- The intrinsic and extrinsic properties of the food product should be established by the food business operator so it can determine what microorganisms, including pathogens, may survive and grow
- The food business operator should decide if the product requires a 'use-by' date or 'best-before' date
- The intrinsic and extrinsic properties of the food product that affect shelf-life may need to be identified as critical control points and controlled proactively by the food business operator
- The food business operator should consult available scientific literature and research data regarding the survival and growth of microorganisms including pathogens which may survive and grow
- The food business operator should consult historical data collected as part of its on-going business, e.g. environmental monitoring records, cooking records, traceability etc. Trend analysis of these data may also, where appropriate, be used

- If consultation by the food business operator of available scientific literature and research data regarding the survival and growth of microorganisms does not provide sufficient data to support a shelf-life, further studies should be conducted, which may include:
 - Predictive Mathematical Modelling
 - Challenge Testing
 - Durability Studies
- Having established and validated a product's shelf-life, the food business operator should apply a safety margin to the shelf-life
- Ensure the microbiological safety of the final product as indicated by the 'use-by' date is in compliance with any legislation, standards or guidelines
- Apply any required product labelling which is in compliance with current relevant legislation
- The product shelf-life should be validated by food business operators as part of a regular review of its food safety management system
- Ensure that all documentation relating to the establishment and validation of food product shelf-life is available to relevant competent authorities as evidence to support accuracy of the shelf-life. This documentation can include, but is not limited to, the following:
 - Product specification outlining the physical, chemical and microbiological characteristics of the product
 - Details of any relevant quality control/assurance results for manufactured batches of the product.
 - Details of recommended storage conditions for the product during its shelf-life
 - HACCP plan
 - Details of any laboratory based analysis including durability and/or challenge tests carried out
 - Scope of accreditation in relation to laboratory
 - Details of any predictive mathematical modelling carried out

APPENDIX I. 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 0°C, and as such can grow in refrigerated foods. It is able to 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 and modified atmosphere packaged foods.

The EU has established microbiological food safety criteria for *L. monocytogenes* in ready-to-eat foods in Regulation (EC) No 2073/2005⁴. 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. 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 health⁷.

The specific food safety criteria for *L. monocytogenes* in ready-to-eat foods are laid down in Annex I of the Regulation⁴. Annex I of 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. 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 the HACCP plan shall be taken⁷.

Annex II of the Regulation⁴ describes the shelf-life studies that the food business operator shall conduct as necessary 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) taking into account the processing steps and conditions, storage and the possibilities for contamination and the foreseen shelf-life

and

- Consultation of the available scientific literature and research data regarding the survival and growth characteristics. 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 take into account the inherent variability linked to the product and the processing and storage conditions. These studies may include:

- Predictive microbiological (mathematical) modelling (Section 9) established for the food in question, using critical survival or growth characteristics for the microorganisms of concern in the product

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 (Section 8) or adequate historical data

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 (Section 10)⁴

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 the FSAI guidance note on Commission Regulation (EC) No 2073/2005 on microbiological criteria for foodstuffs²³.

APPENDIX 2. LABELLING

When a food business operator has established the shelf-life of a food product, it is important that the product is correctly labelled in compliance with current food labelling legislation⁶.

'Use-by' Date

In the case of a 'use-by' date, the words 'use-by' must be followed by the date itself, e.g. use by 7 June or a reference to where the date is given on the labelling, e.g. for 'use-by' date: see lid. The date shall consist of the day, the month, e.g. use by 7 June and possibly the year, e.g. use by 7 June 2005 in that order and in an un-coded chronological form⁶.

The 'use-by' date must be printed on the food itself and/or its packaging. A product with a 'use-by' date can be used up to midnight on the date shown, e.g. use by 7 June 2005. Where a product has several component/wrappers or sleeves in its packaging which will be discarded, the 'use-by' date should appear on the packaging that the product will be sold in to the consumer, i.e. outer packaging²².

A 'use-by' date only applies to food products in the state in which they are purchased, e.g. chilled product should be sold chilled and not frozen. Some food products will require treatment before consumption, such as raw meat. In such cases, the 'use-by' date means prepare, e.g. cook by the date declared²².

It is a legal requirement that a 'use-by' date is included on the label of all packaged poultry and also that the 'use-by' date is displayed next to loose poultry⁴⁰.

'Best-before' Date

The date declared depends on whether the product has a short shelf-life or a long shelf-life⁶:

- Foods that will not keep for more than 3 months, an indication of the day and month are sufficient, e.g. best-before: 23rd January
- Foods that will keep for more than 3 months but not more than 18 months, an indication of the month and year are sufficient, e.g. best-before end: March 2001
- Foods that will keep for more than 18 months, an indication of the year is sufficient, e.g. best-before end: 2002

Selling Products past their 'Use-by' or 'Best-before' Dates

Under current labelling legislation⁶ there is no specific legal requirement against packaged foods being offered for sale on or after their 'use-by' or 'best-before' date provided that the food is still of acceptable safety and quality. When a food business operator, such as a retailer, sells food to consumers past its 'use-by' or 'best-before' date, it should make the consumer aware that the food is past its declared shelf-life. In such cases, the retailer is solely liable for the safety of the food that is sold after its 'use-by' date. An exception to this is shell eggs which must be sold at least 7 days before their 'best-before' date⁵⁵.

Responsibility of food business operators to sell only safe food is outlined under Regulation 178/2002³. However, the FSAI recommended best-practice is that foods past their 'use-by' date should not be placed on the market. Nevertheless, there are no legal provisions to make it an offence under labelling legislation⁶ to offer such products for sale. The only labelling offences regarding 'use-by' are in regard to:

- Misleading the consumer, **e.g. hiding/changing the 'use-by' date**
- Placing no date/incorrect date/'best-before' date on a food which should be labelled with a 'use-by' date

Labelling Exemptions

The following foods are specifically exempt from carrying a date of minimum durability declaration⁶:

- Fresh fruit and vegetables including potatoes which have not been peeled, cut, treated or processed (except for sprouting seeds and similar products such as bean sprouts which do require a date of minimum durability)
- Wines, liqueur wines, sparkling wines, aromatised wines and similar products obtained from fruits other than grapes, and beverages falling within CN codes^y 2206 00 91, 2206 0093 and 2206 00 99 and manufactured grapes or grape musts
- Beverages with greater than 10% volume of alcohol
- Soft drinks, fruit juices, fruit nectars and alcoholic beverages in individual containers greater than 5 litres intended to supply mass caterers only
- Bakery products which are normally consumed within 24 hours of manufacture such as baguettes and cream buns
- Vinegar (including wine vinegar)

^y The CN (Combined Nomenclature) Code is the tariff classification system used by customs for goods within the EU. It is an eight-digit Community Code where there is no customs duty on goods within the EU. It is based on the internationally recognised Harmonised System, which has a standard world-wide six-digit code.

- Cooking salt (mineral and herbal salts are not included)
- Solid sugar (sucrose). This exemption does not apply to fructose or sweeteners or mixtures of sugars
- Confectionery products consisting of mostly flavoured or coloured sugars such as hard sweets. Toffee, wine-gums and fruit jellies are not exempt
- Chewing gums or similar products
- Individual portions of ice-cream

Labelling Derogations

The following foods have a specific derogation from the general labelling regulations and therefore, do not require a label which indicates the date of minimum durability⁶:

- Pre-packaged foods that are packaged for retail sale on the premises from which they are sold need only indicate the name of the food on the label, e.g. where rashers are packaged and sold to the consumer on the same premises, the indication 'rashers' on the label is sufficient
- Pre-packaged flour confectionery for sale on the premises from which they are produced, by the person producing the flour confectionary need only indicate the name of the food on the label, e.g. a pre-packaged Madeira Cake baked on the premises from which it is sold, need only indicate 'Madeira Cake' on the label
- Foods for sale to consumers or mass caterers without pre-packaging need only indicate the name of the food either on the label or displayed on a notice near the food. This notice and the information displayed on it must be visible, legible, indelible and not obscured in any way, e.g. ham slices at a deli counter
- Foods packed on the premises at the request of the consumer, e.g. sandwiches made up at the consumer's request need only indicate the name of the food either on the label or displayed on a notice near the food. Similarly, this notice and the information displayed on it must be visible, legible, indelible and not obscured in any way
- Individually wrapped fancy confectionery not enclosed in any other packaging and intended for sale as a single item need only indicate the name of the product and the name and address of the manufacturer, packer or seller on the label. Fancy confectionery is taken to mean a product in the form of a figure, an animal, egg etc. or in any other fancy form
- Sugar confectionery products, chocolate and cocoa products less than 50 grams in net weight are exempt from carrying a label indicating net weight/quantity. However, all remaining labelling requirements including date of minimum durability will apply

Other Date Marks

Some food business operators will label food products with other terms such as sell-by, expires on, use-before, eat-by, display-until, best if consumed by or prepare-by, followed by an appropriate date. These types of date mark are sometimes used by suppliers for stock control purposes. From a public safety point of view it is strongly recommended that only the 'use-by' date or 'best-before' date are used in food labelling and packaging to prevent confusion. The aforementioned optional commercial dates are not an alternative to the statutory 'use-by' or 'best-before' dates.

Instructions for Use

General food labelling legislation⁶ requires pre-packaged foods to be labelled with instructions for use to enable members of the public to make appropriate use of the food. Raw meats requiring specific cooking before consumption must be labelled with appropriate cooking instructions.

The food business operator responsible for the production and/or packaging of a food product must determine whether that product is ready-to-eat or requires cooking, reheating or other proprietary preparation before consumption to ensure its safety and compliance with relevant legislation (Section 4.3). Under Article 6 of Regulation 2073/2005⁴ there are requirements for clear labelling in relation to the risks of *Salmonella* to be provided by manufacturers (Section 4.3.1).

The instructions for use of food products are compulsory on product labelling when it would be impossible to make appropriate use of that food product in the absence of such instructions^{6,22}, e.g. minced meat, minced meat products and meat preparations like sausages packaged for retail sale should be labelled with safe cooking and handling instructions. It is also recommended that the label is also used to inform members of the public of the potential risks associated with these products. This is already carried out voluntarily by many retailers in Ireland, e.g. such a label could contain the following information:

“This raw product may contain dangerous bacteria. It must be thoroughly cooked before eating. Do not allow this raw food to come in contact with ready-to-eat foods. Thoroughly wash all surfaces that come in contact with this raw product”.

Non-intact tenderised beef roast joints and steaks, i.e. there are two main types of products, Blade/Needle Tenderised Cuts and Reformed/Rolled Roasts etc which are typically tied together with twine should also be appropriately labelled and instructions given that these products should be cooked to well done state and not consumed rare⁵⁶.

Processors of raw meat, poultry and fish should be aware of the possible effects of the packaging method on their product and take this into account when composing cooking instructions for their product label, e.g. a 2004 study found that, nearly 100% of beef patties formed from

ground beef and packed in high-oxygen-packaging, i.e. 80% oxygen and 20% carbon dioxide, regardless of time in display, were prematurely brown when cooked to a temperature of 71.1°C by comparison with vacuum-packaged samples⁵⁷. This effect of storage conditions on meat colour could pose a food safety problem if a caterer or member of the public was to rely on colour alone to ensure a beef burger was cooked safely⁵⁶.

Storage and Handling Instructions

The particulars of the 'use-by' date must be followed on the product label by a description of the storage conditions which must be observed for the food product⁶. Storage instructions should be simple, clear and legible and, if strict storage temperatures are required to maintain product safety and shelf-life, a maximum storage temperature, e.g. store at 5°C, should be indicated. If a food product is suitable for freezing, a star marking panel may be included on the label²². The 'use-by' date applies to unopened food. A food business operator should provide handling instructions for the food product once opened, e.g. once opened store in the refrigerator for 2 days only. In addition, other options for storage of products (if applicable) must be labelled²².

Temperature Controls

The storage temperature for food products before, during and after processing will directly influence the safety and shelf-life of the product. Regulation (EC) No 853 of 2004 and related EC implementing regulations lists the current legislative requirements in relation to temperature control of food products².

APPENDIX 3. GROWTH CHARACTERISTICS OF COMMON FOODBORNE PATHOGENS

Table A3.1 outlines some of the key growth characteristics of common foodborne pathogens and can be used by food business operators as a guide to determining what pathogens could survive and grow in their food. However, other factors or combinations of factors may also be relevant and subject to scientific justification.

Table A3.1. Approximate Growth Boundaries for Common Foodborne Pathogens^{a-d}

| Foodborne Pathogen | Temp (°C) | pH ^e | a _w ^f | Salt ^g (%) | Aerobic/ Anaerobic ^{h-i} | Commonly Associated or Implicated Foods ^j |
|--|------------------------------|-----------------|------------------------------|-----------------------|-----------------------------------|--|
| | Min/opt/max | Min/opt/max | Min/opt/max | Max | | |
| <i>Salmonella</i> species ^k | 5.2 ^l /35-43/46.2 | 3.8/7-7.5/9.5 | 0.94/0.99/>0.99 | 4 | Facultative | Eggs, poultry, meats, dairy and others, sprouting seeds |
| <i>Clostridium botulinum</i> Group 1 (Proteolytic) | 10-12/35-40/40-42 | < 4.6/7/8 | < 0.94/ ND/ND | 10 | Anaerobic | Canned, vacuum packed, MAP, jarred |
| <i>Clostridium botulinum</i> Group 2 (Non-proteolytic) | 3-4/28-30/34-35 | < 5.0/7/8 | < 0.97/ ND/ND | 5 | Anaerobic | Canned, vacuum packed, MAP, jarred |
| <i>Staphylococcus aureus</i> (Enterotoxin Formation) | 10/40-45/48 | 4/7-8/9.6 | 0.85/0.98/>0.99 ^m | 10 | Facultative | Eggs, poultry, meats, dairy, confectionery & others |
| <i>Campylobacter</i> spp. | 32/42-43/45 | 4.9/6.5-7.5/9 | >0.987/0.997/ ND | 1.5 | Microaerophilic | Poultry, meat & milk |
| <i>Yersinia enterocolitica</i> | -1.3/25-37/42 | 4.2/7.2/9.6 | 0.94/ ND/ND | 7 | Facultative | Fresh meats & milk |
| <i>Listeria monocytogenes</i> ^{n-o} | -1.5/30-37/45 | 4.2/7/9.5 | 0.90/0.97/>0.99 | 12 | Facultative | Chilled, ready-to-eat food & long shelf-life foods |
| <i>Clostridium perfringens</i> ^p | 10-12/43-47/50 | 5.5-5.8/7.2/8-9 | 0.93/0.95-0.96/0.97 | 6 | Anaerobic | Cooked meat, cooked uncured meat, associated gravy & stocks, casseroles and pea soup |
| <i>Escherichia coli</i> ^{q-r} | 6.5/30-40/45 | 3.6/6-7/9 | 0.95/0.995/ ND | ≥ 6.5 | Facultative | Meat, poultry, milk & vegetable products, sprouting seeds, e.g. bean, fenugreek, mustard & rucola, drinking water, unpasteurised apple juice |

| Foodborne Pathogen | Temp (°C) | pH ^e | a _w ^f | Salt ^g (%) | Aerobic/ Anaerobic ^{h,i} | Commonly Associated or Implicated Foods ^j |
|--|-------------|-----------------|-----------------------------|-----------------------|-----------------------------------|--|
| | Min/opt/max | Min/opt/max | Min/opt/max | Max | | |
| <i>Bacillus cereus</i> ^s | 4/30-40/55 | 5/7/8.8 | 0.93/ND/ND | 7.5 | Facultative | Cooked rice & spices |
| <i>Vibrio parahaemolyticus</i> | 5/37/43 | 4.8/7.8-8.6/11 | 0.94/0.981/0.996 | 8 | Facultative | Fish & seafood products |
| <i>Cronobacter</i> spp. ^{k,t} | 6/37-43/45 | ND/ND/ND | ND/ND/ND ^u | ND | Facultative | Infant formula ^v , fermented bread, ready-to-eat fruit & vegetables & some cheese |

^a Adapted from 4,7,15,18-21,29,31,32,39,41,51,56,58-64

^b All values are approximate with growth boundaries given under optimal conditions. Growth criteria will vary according to strain, temperature, type of acid, solute and other intrinsic/extrinsic parameters. Variability in measurement of these parameters must be allowed for by the food business operator by incorporating a margin of error.

^c Further information on foodborne pathogens, including D-values, is available on the FSAI website: http://www.fsai.ie/resources_and_publications/factsheets.html

^d Many foodborne pathogens will survive without growth at much higher or lower values than that required for growth.

^e Inhibition can be dependent on type of acid (acidulant) present.

^f The minimum a_w for growth is generally determined by 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.

^g Salt expressed as percentage sodium chloride in the aqueous phase of the food.

^h Aerobic - requires oxygen for growth; Anaerobic - requires the absence of oxygen for growth; Facultative - grows either with or without oxygen; Microaerophilic - requires limited levels of oxygen for growth.

ⁱ Aerobically processed foods may have an anaerobic internal environment and as such present a risk of growth of anaerobic organisms.

^j Non-exhaustive list.

^k Commission Regulation (EC) No 2073/2005 lays down food safety criteria for *Salmonella* species and *Enterobacter sakazakii* (now known as *Cronobacter* species) in dried infant formula and dried dietary foods for special medical purposes intended for infants below 6 months of age.

^l Most serotypes fail to grow at < 7°C.

^m Under aerobic conditions (Anaerobic 0.92 - >0.99).

ⁿ 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.

^o While values for *L. monocytogenes* in Table A3.1 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.

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

- ^q All humans and animals carry *E. coli* in their intestines as part of their normal gut flora and these microorganisms are usually harmless. However, there are several types of *E. coli* strains that may cause gastrointestinal illness in humans. These strain types can be divided into several pathogroups: Enteropathogenic (EPEC), Enterotoxigenic (ETEC), Enteroinvasive (EIEC), Enterohaemorrhagic (EHEC) and Enteroaggregative (EAEC). Some *E. coli* strains are capable of producing toxins which are very similar to toxins that are produced by *Shigella dysenteriae*. These strains are referred to as STEC (Shiga toxin-producing) or also VTEC (Verocytotoxin-producing *E. coli*). *E. coli* O157:H7 is the dominant STEC serotype in humans in many parts of the world. However, multiple reports have shown that other STEC, including serogroups O26, O111, O103, and O118, frequently cause sporadic cases in humans and have been implicated in numerous outbreaks. The most recent outbreak, centred in Germany in 2011, was caused by *E. coli* O104:H4 and resulted in over 40 deaths and several thousand infections. The most likely link between food and the infections were sprouts grown from fenugreek seeds exported to Germany from Egypt. Sprouted seeds, also known as bean sprouts or sprouts are generally ready-to-eat products although some types like mung bean sprouts are more normally cooked. Because of their ready-to-eat status, sprouts represent a high risk category of food for which control measures are necessary to reduce the risk to human health. The *E. coli* O104:H4 strain from the recent outbreak in Germany seems to share virulence characteristics of STEC and EAEC strains. STEC strains usually have an animal reservoir, while EAEC have a human reservoir⁶⁵⁻⁶⁸.
- ^r 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.
- ^s No emetic toxin formation at temperature below 10°C.
- ^t *Cronobacter spp.* (*Enterobacter sakazakii* & related organisms) are Gram negative, non-spore forming bacterium belonging to the *Enterobacteriaceae* family. This bacterium has been implicated in outbreaks causing meningitis and enteritis, especially in infants.
- ^u *Cronobacter spp.* (*Enterobacter sakazakii* & related organisms) is resistant to desiccation over a wide range of a_w (0.25-0.86). Over 12 months storage the pathogen survived better in dried formula and cereal at low a_w (0.25–0.30) than at high a_w (0.69–0.82).
- ^v Commission Regulation (EC) No 2073/2005 lays down a process hygiene criterion for *Enterobacteriaceae* in dried infant formula and dried dietary foods for special medical purposes intended for infants below 6 months of age (Category 2.2.9) and dried follow-on formula (Category 2.2.10).

ND = No data available/found.

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