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GUIDANCE NOTE

Validation of Product Shelf-life (Revision 4)

Guidance Note No. 18
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(Revision 4)

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CONTENTS

ABBREVIATIONS

ACMSF	Advisory Committee on the Microbiological Safety of Food
BS	British Standard
CCP	Critical Control Point
EU	European Union
EC	European Commission
EFSA	European Food Safety Authority
FAO	Food and Agricultural Organization of the United Nations
FIC	Food Information for Consumers
FSA	Food Standards Agency
FSAI	Food Safety Authority of Ireland
GHP	Good Hygiene Practices
GMP	Good Manufacturing Practices
HACCP	Hazard Analysis and Critical Control Point
ISO	International Organisation for Standardization
ICMSF	International Commission on Microbiological Specifications of Foods
MAP	Modified Atmosphere Packaged
VP	Vacuum Packed
WHO	World Health Organization

1. INTRODUCTION

Shelf-life is the period of time over which a food maintains its safety and/or quality under reasonably foreseeable conditions of distribution, storage and use[1-2]. The shelf-life of a food begins from the time the food is produced and/or packed.

Validating product shelf-life is obtaining and documenting any evidence that proves that the shelf-life of a food is accurate and that the food will maintain its safety and/or quality until the end of that shelf-life.

While the overarching responsibility for food safety rests with food business operators[3-5], there is no generic method to estimate and set food shelf-life. This is because many different conditions can affect product safety and quality. As such, this document outlines good practice for food business operators to estimate, set and verify the safety of food over its shelf-life.

2. SCOPE

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

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

3. LEGAL REQUIREMENTS AND RESPONSIBILITIES FOR SHELF-LIFE

General Food Law

General food safety requirements are that food must not be placed on the market if it is unsafe, i.e. injurious to health, or unfit for consumption[5].

Responsibility

Generally, the manufacturer of a food (with some exceptions) is responsible for setting and validating the shelf-life. However, this responsibility may also fall to secondary manufacturers (co-packers), re-packers, food caterers, food retail outlets etc. depending on specific circumstances[5].

Microbiological Criteria

Under Regulation (EC) No 2073/2005, food should "*not contain microorganisms their toxins and metabolites in quantities that present an unacceptable risk for human health*"[1].

Furthermore, some food business operators may be required to demonstrate that foods they manufacture comply with specified microbiological criteria throughout the foods shelf-life under reasonably foreseeable conditions of distribution, storage and use[1, 6].

Labelling

Shelf-life is defined in European legislation as the 'date of minimum durability' and means the date until which a food retains its specific properties when properly stored. The date of minimum durability provides for two different indicators of food shelf-life[2]:

- 'Use-by' date – Used for food which from a microbiological point of view, is highly perishable and therefore, likely after a short period to constitute an immediate danger to human health. After the 'use-by' date has passed, a food is deemed unsafe[1-2] and must not be sold or consumed
- 'Best-before' date – The date until which a food retains its specific properties when properly stored, i.e. quality characteristics such as appearance, odour, texture, flavour etc.

4. SETTING AND VALIDATING SHELF-LIFE OF FOOD

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

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

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

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

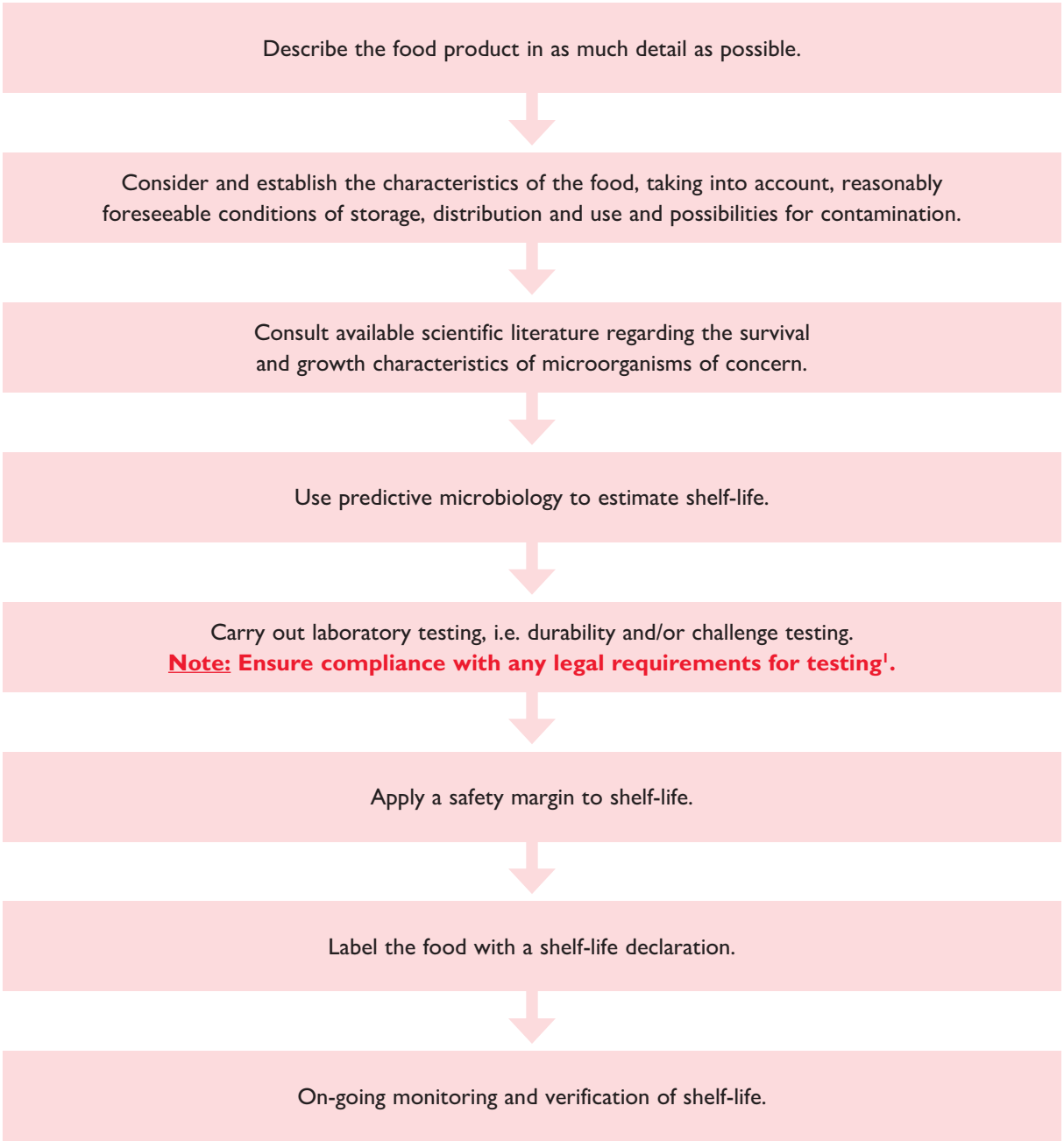
The shelf-life of food ideally should be estimated during product development and set before the food goes on sale to consumers. The estimate of shelf-life should be made at the point in the product development process where the food business operator is confident that it can consistently produce the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

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

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

For good practice, food business operators should estimate, validate and set shelf-life during product development using a shelf-life study which has the following steps as set out in Figure 1:

Figure 1. Good Practice in Estimating, Validating and Setting Shelf-life



4.1 Describe the Food

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

Ready-to-eat status of food

Food business operators should decide if the food is intended for direct human consumption without the need for cooking or other processing effective to eliminate or reduce to an acceptable level, microorganisms of concern. If this is the case, the food is considered as a ready-to eat food. Where foods are considered ready-to-eat, the food business operator should document this information and ensure it is consistent with the products labelling. A decision tree to help manufacturers and producers determine if a food is ready-to-eat is provided in FSAI Guidance Note No. 27[80].

Legal criteria for certain pathogens in certain types of ready-to-eat foods are set in Commission Regulation (EC) No 2073/2005, as amended[1]. With respect to *Listeria monocytogenes*, the Regulation sets legal criteria for this pathogen in all ready-to-eat foods. The Regulation emphasises the importance for manufacturers of ready-to-eat foods which support the growth of *L. monocytogenes*, to ensure that their products comply with the criteria throughout the product's shelf-life and lists the type of studies they should conduct in order to investigate this. These studies are outlined in Appendix 1 of this document[6, 8].

Product specification

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

- Ready-to-eat status of the food
- Ingredient list and specifications for each ingredient.

  Note: Some retailers will request ingredient supplier details
- Processing parameters
- Good manufacturing and hygiene practices
- Product specific procedures based on HACCP
- Quality control parameters and measures
- Packaging details and specifications for all packaging
- Labelling considerations, e.g. shelf-life declaration
- Storage, distribution and retail display conditions
- Instructions for use of the product as applicable
- Details of microbiological and compositional specifications, including limits
- Legislative requirements

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

4.2 Establish the Characteristics of the Food

All foods have their own unique characteristics which will affect food safety and shelf-life. The characteristics of the food's entire lifecycle from choice of ingredient through processing and distribution to final consumer, will affect shelf-life.

Some characteristics prolong shelf-life while others decrease it. Describing, measuring and understanding these characteristics will allow food business operators to identify what characteristics will cause food to become unsafe and affect the shelf-life.

All foods can have their characteristics broadly divided into intrinsic and extrinsic characteristics. Intrinsic characteristics are those characteristics inherent to the composition of the food such as its ingredients and formulation. Extrinsic characteristics are those characteristics which relate to the external processing environment which impact on the food such as storage temperature and packaging[9-11]. Table 1 outlines some the more commonly identified intrinsic and extrinsic characteristics of foods.

Table 1. Intrinsic and Extrinsic Characteristics[a]

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

[a] Table adapted from[9-11]

[b] For the majority of food business operators, the most important intrinsic and extrinsic characteristics are the pH, water activity, storage temperature and packaging of the food.

[c] May also relate to intrinsic characteristics depending on the nature of the data

All microorganisms have minimum/maximum and optimal requirements for survival and growth in foods. Measuring and describing the intrinsic and extrinsic characteristics of the food will allow food business operators to determine what microorganisms may survive and grow in their food, particularly those which can cause illness, i.e. pathogens. This will allow food business operators to control the safety of food during its shelf-life by preventing or minimising survival and growth of specific pathogens.

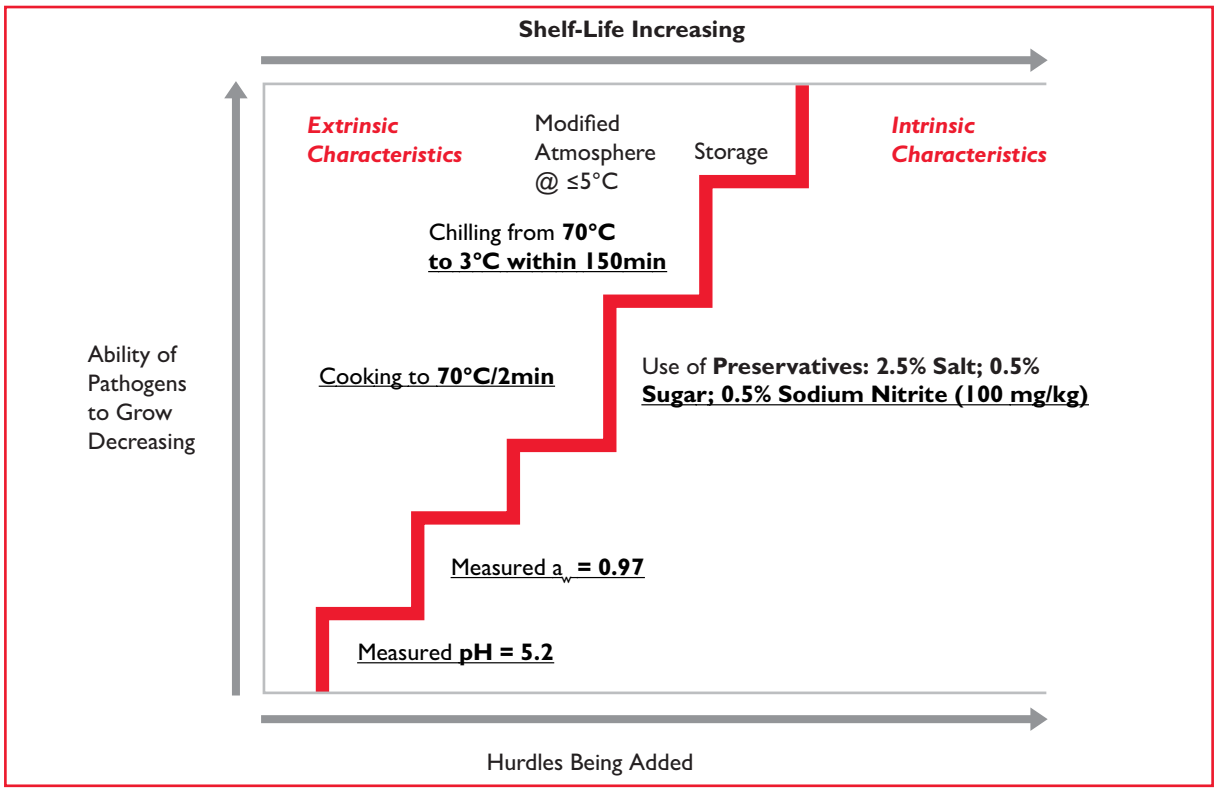
The control of product safety and shelf-life typically requires the combination of different intrinsic and extrinsic characteristics to act as hurdles to microbial growth and survival. This provides a preservation effect adequate for control of specific pathogens and shelf-life stability[12]. In relation to shelf-life, some intrinsic and extrinsic characteristics can be considered hurdles to the survival and growth of microorganisms during, and up to the end of shelf-life. A carefully

selected and monitored combination of these characteristics can retard or inhibit microbial growth in a food. For example, foods with the following characteristics are not considered to support the growth of *Listeria monocytogenes*[1]:

- pH is ≤ 4.4, or
- A_w is ≤ 0.92, or
- pH is ≤ 5.0 and the water activity is ≤ 0.94
- The food is frozen

Hurdles can be based on any number of intrinsic and extrinsic characteristics. An example of how hurdles can be used in a pre-packed, sliced cooked ham to retard or inhibit the survival and growth of pathogens such as *L. monocytogenes* and ensure product safety up to the end of shelf-life, is given in Figure 2.

Figure 2. Hurdles used to Inhibit Pathogen Survival/Growth in Cooked Ham



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

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

4.2.1 Intrinsic characteristics

pH and type of acid

The pH and acidity are very important intrinsic characteristics affecting the survival and growth of microorganisms in food. The pH is a measure of a product's acidity or alkalinity with a scale that extends from 0 to 14 with the relative strengths of acid and alkaline defined by their pH value on this scale, i.e. pH of 7 is neutral, less than 7 is acidic and greater than 7 is alkaline.

The pH scale is logarithmic, meaning that each one point change in pH is ten times more acidic or less acidic, e.g. pH 6 is ten times more acidic than pH 7. The pH range for microbial growth and survival is defined by a minimum and maximum value with an optimum pH for growth and survival. Most microorganisms grow best or optimally at or near a neutral pH of 7.

Typically, pH is measured using hand-held pH meters but also in larger industrial operation, in-line pH measurement of food is sometimes used. It is recommended that pH is measured according to ISO 2917:1999 or other applicable method [13].

Typically, pH is measured on macerated food and is therefore an average value. In multi-component foods, e.g. ready meals, sandwiches etc. each component of the food may have a different pH value. It may be necessary to measure the pH of each component separately (as far as possible) in order to assess if any component can support pathogenic growth. Taking coleslaw as an example, mayonnaise has a low pH which may not support the growth of *L. monocytogenes*, but cabbage (with a higher pH) could.

It may also be necessary to measure the pH of foods over their shelf-life as pH can vary with time due to microbial activity, product composition or formulation. Some foods may be more prone to pH change than others including vegetables, fresh meats, poultry, fermented meats and some mould/smear ripened cheeses. The pH of multi-component products may also vary within the food due to diffusion and mixing limitations.

In some foods, there may also be a range of different pH which could allow growth of pathogens which otherwise would not grow at the measured pH value, e.g. foods containing meat, fats or oils can be difficult to acidify uniformly and food business operators should take extra care with these foods[14].

The type of acid used in food will also have an influence on microbial survival and growth. Organic acids such as acetic, sorbic, propionic and benzoic typically cause disruption of the microbial cell membrane. Acetic acid, i.e. vinegar at levels greater than 0.1%, inhibits the growth of some foodborne pathogens and is used extensively in sauces and pickles, typically in combination with mild pasteurisation heat treatments. Sorbic and benzoic acids are more typically used to control yeast and mould in the beverage industry[9-10].

Where pH is a controlling characteristic for food safety and shelf-life, it should be routinely monitored, ideally for each production batch[9-10, 14]. Table 2 outlines the approximate pH of some common foods.

Table 2. Approximate pH of Common Foods [a-b]

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

[a] All values given in Table 2 are approximations only. Laboratory analysis of a food is required in order to determine an accurate pH measurement. [b] Table adapted from [9-10, 15]

Water activity

Water activity (A_w) is a measure of the amount of free or available water within a food. The A_w of most foods ranges from 0.2 for very dry foods to 0.99 for moist fresh foods (Table 3).

Table 3. Approximate Water Activity Values for some Foods [a-d]

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

[a] Values taken at 20°C

[b] A_w has a scale from zero, i.e. 0% water available to one, i.e. 100% water available

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

d Table adapted from [9-10, 15, 17-18, 20]

It's important not to confuse the A_w with the moisture content of foods. While some high moisture foods may have high A_w this is not always the case, e.g. jams have high moisture contents but the moisture is bound to the sugar in the jam and unavailable for microbial growth, giving jams a low A_w.

Foods with a low A_w cannot support microbial growth because microorganisms need water for growth. Pathogenic and spoilage bacteria do not grow in food with an A_w < 0.85, but some yeast and mould can grow at A_w as low as ≤ 0.60 [9-10, 20]. The A_w of a food can be altered by processing such as drying, concentrating or freezing or by the addition of ingredients such as salt and sugar [17-18].

Sugar and particularly salt are used to preserve foods by decreasing the A_w by either binding free water and making it unavailable for microbial growth, e.g. sugar in jams or by exerting osmotic pressure directly on microorganisms, e.g. salt used in brine for some cured meats.

Typically, the concentration of salt in the aqueous or water phase of a food, i.e. water phase salt content (WPS) affects the A_w of the food. The WPS (g/100mls) can be calculated using the following formula:

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

The WPS can also be used to estimate the A_w if direct measurements for A_w are not taken using the following formula:

Water Activity = [1- (WPS ×0.0052471)]- (0.00012206 × WPS^2) [19]

The standard method for determining A_w is ISO 21807:2004[16]. Most individual foods will have a homogenous A_w therefore, homogenisation with a blender is not required. In many cases, homogenisation is not recommended as the sample material can become hot, losing water and thereby making the A_w measurement not representative of the food been examined.

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

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

Like pH, the A_w of a food can change with time due to microbial activity, product composition and formulation [9-10]. However, where A_w is a controlling characteristic for food safety and shelf-life, it should be routinely monitored, ideally for each production batch [9-10, 14].

Redox Potential

The redox potential (E_h) of a food determines which type of microorganisms will grow in it, depending on whether they require oxygen for growth (aerobic) or not (anaerobic).

The redox potential is measured in millivolts (mV) because when electrons move they create an electric current, which can be measured[9]. When the redox potential is measured, it should be referenced with the pH of the food, as redox potential is dependent on the pH of the food.

Routine measurement of the redox potential in foods is quite simple and normally taken at a pH 7.0[10]. However, difficulties may arise in taking accurate, reproducible measurements and in accounting for differences in the redox potential throughout a food product[9-10]. Microorganisms can be broadly classified into the following groups based on their requirements for oxygen and redox potential of the food (measured in mV)[9-10]:

- Aerobes require oxygen for growth and can grow at a redox potential between +300 to +500 mV
- Facultative anaerobes grow with or without oxygen and can grow at a redox potential between +300 to -100 mV
- Anaerobes require no oxygen for growth and can grow at a redox potential between +100 to ≤ -250 mV
- Microaerophilic require limited oxygen for growth and can grow at a redox potential between +100 to ≤ -250 mV[21]

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

The redox potential is particularly important in ensuring the safety of products such as ambient-stable meat products e.g. salamis, fermented and dried meats [22]. However, as with pH and water activity, the redox potential of foods can be variable.

It is recommended that food business operators do not use redox potential measurements solely to assess product safety due to the high variability of the redox potential and the often low accuracy in its measurement. Table 4 outlines the approximate redox potential of some common foods.

Table 4. Approximate Redox Potential of common Foods[a]

Food	Redox Potential
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] Food business operators should note that some foods packaged in aerobic conditions may have an anaerobic internal environment. Table adapted from[9-10, 15, 21-22]

Natural barriers

Some foods will have natural barriers or coverings that provide different levels of protection from external contamination. These barriers include shells, skins and membranes commonly found on foods such as nuts, eggs, vegetables/fruit and fish. The effectiveness of these barriers to prevent contamination of foods will vary considerably, and in some cases, may actually facilitate microbial growth, particularly if the natural covering is damaged during harvesting, e.g. hen's eggs are typically sterile but heavily contaminated on the shell so any damage to the shell can allow microorganisms to enter[10].

It is recommended that when food business operators remove natural barriers from foods, an appropriate method to reduce microorganisms, e.g. washing, filtration, trimming etc., is used[9-10].

Nutrient availability

All microorganisms have basic nutritional requirements for growth and maintenance of basic metabolic functions, e.g. protein, fat, sugars, minerals, vitamins etc. These requirements vary depending on the microorganism. Therefore, the nutrient content and availability of nutrients in a food will influence microbial growth. Typically, bacteria have the highest nutritional requirements for growth followed by yeasts and moulds[9-10]. However, viruses and protozoa do not grow in food.

Antimicrobial substances

Some foods will contain antimicrobial substances which retard or prevent the growth of microorganisms. There is a wide variety of antimicrobial substances with varying levels of antimicrobial activity. Some antimicrobial substances are found naturally in foods[9], e.g. allicin in garlic and onions and lysozyme in eggs and milk. Some antimicrobial are also created during food processing, e.g. production of phenols during smoking or bacteriocins during fermentation[10]. Other antimicrobials can be added to foods, i.e. food additives to the extend shelf-life and/or inhibit pathogens[23].

Food additives

Regulation (EC) No 1333/2008 harmonises the use of food additives in foods in the EU and defines food additives as follows[23]:

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

This definition of food additives[23] includes the use of food additives in foods covered by Directive 2009/39/EC[24] 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.

Microflora

All foods naturally contain different types and concentrations of microorganisms, i.e. natural microflora. In some foods, microorganisms are added for processing and technological reasons such as lactic acid bacteria which are added to milk to make cheese and yogurt.

In the case of natural microflora, the types and concentrations of microorganisms in food can vary widely. The presence of certain microorganisms in foods, e.g. lactic acid bacteria, may also retard or prevent the growth of pathogens. They can do this by outgrowing the pathogens, consuming available nutrients and/or producing substances in the food which retard or prevent growth of pathogens, i.e. a process known as competitive inhibition.

Microbiological quality of ingredients

The microbiological quality of ingredients will affect the safety and shelf-life of foods. Food business operators should assume that all ingredients are a potential source of microbiological contamination. Therefore, the starting point for producing safe food products with a desired shelf-life is the use of ingredients which comply with legislative requirements for food safety and hygiene, particularly microbiological criteria where applicable[1].

In the absence of specific criteria set in legislation, ingredients should comply with relevant Irish standards[25-26], Irish guidelines[27-31] or industry best practice guidance[14, 32-35].

It is recommended that the microbiological quality of ingredients is set out in a specification agreed between the food business operator and the supplier. In this case, the specification must meet minimum legal requirements where applicable[5]. Good practice for food business operators is to have a written supplier approval procedure which means that ingredients are only sourced from a supplier previously approved by the food business operator.

All water and ice used as an ingredient and for preparation of food must be of drinking water standard[36]. Where water (intended to be used as an ingredient or for preparing food) entering premises is not of potable quality or where quality is unreliable, e.g. from a private well, appropriate treatment should be applied by the food business operator to the water to ensure it is of potable quality before use[3, 35-36, 91].

Under EU food law[3] where there is a reference to drinking water, it is usually defined as water which meets the standards of the drinking water legislation[36].

Food formulation, composition, structure and assembly

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

Table 5 gives examples of some food formulation, compositional, structure and assembly issues which may affect food safety and shelf-life.

Table 5. Some Examples of Food Formulation, Compositional, Structure and Assembly Issues

Situation	Example of Issue
Manufacturing Error An ingredient is removed or an incorrect quantity of ingredient is added to the product	In producing a cooked ham, a food business operator doesn't add the correct concentration of salt to the curing solution, resulting in a product with increased susceptibility to pathogenic growth and a reduced shelf-life.
Product Development Error Ingredients within a product are in close proximity to each other, causing migration of some components, e.g. water, fats, out of the product	A cheese-based sauce separates on standing as no emulsifier is present which results in a reduced product safety and a shorter shelf-life.
Quality of Ingredients Ingredients from two different suppliers have different microbiological quality	A supplier of raw chicken is unable to meet an order. The food business operator orders the chicken from another supplier without supplier approval. However, the microbiological quality of this new chicken is inferior to the regular suppliers resulting in a reduction in final product shelf-life.
Quality of Ingredients Ingredients of differing microbiological quality are combined together	A pre-packaged ham and cheese sandwich is prepared with a sliced, pre-packaged cheddar cheese. However, the cooked ham is sliced by the food business operator on a poorly cleaned slicing machine increasing the food safety risks and reducing the shelf-life of the product.
Reformulating and Producing Variants of Products An ingredient is replaced with an alternate ingredient	A food business operator wants to develop a sugar-free version of its standard hazelnut flavoured yogurt. A new canned hazelnut puree sweetened with an artificial sweetener is supplied. However, the thermal process applied to the new puree formulation does not destroy spores of *Clostridium botulinum*. In addition, the aspartame-sweetened puree has a higher A_w than the original sucrose-sweetened puree, which permits outgrowth of spores and formation of toxin in the puree and/or the new sugar-free hazelnut yogurt.

4.2.2 Extrinsic characteristics

Temperature

The safety and shelf-life of most foods but in particular foods which require refrigeration, is very dependent on temperature[11]. Microorganisms' ability to grow at different temperatures is broad and includes those microorganisms which are[9]:

- Psychrotrophic, i.e. optimum temperature 20°C to 30°C, but many can survive and grow at or below 5°C
- Mesophilic, i.e. optimum temperature 30°C to 40°C, but many can survive and grow between 20°C to 40°C
- Thermophilic, i.e. optimum temperature 55°C to 65°C, but many can survive and grow at 45°C but not less than 30°C

The control of temperature during all stages of food manufacture, storage, distribution and use should be carefully considered, measured and documented by food business operators as it can significantly affect shelf-life. In particular, food business operators should consider if foods may be subject to temperature abuse during storage, distribution and use, e.g. research has shown that domestic refrigerators often operate at a higher temperature than 5°C[38-43]. Recommended temperatures for distribution, catering and retail in Ireland are ≤ 5°C[25-26].

Gas atmosphere

The gas atmosphere and its composition which surround a food will affect shelf-life. Typically, the gas atmosphere and its composition are altered using modified atmosphere packaging (MAP), i.e. gas flushing[44] or vacuum packing (VP) to extend shelf-life[14, 34, 45].

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

The extension of shelf-life through the use of MAP or VP generally requires the control of temperature and other characteristics of the food such as pH. In addition, the specific concentrations of gases, the packaging and equipment used can all affect food safety[14]. For example, the permeability of packaging and actively respiring fruit and vegetables can affect the composition of gases in the pack during shelf-life which in turn, can affect microbial growth and product safety.

Under current legislation, foods which have their shelf-life extended by means of packaging gases must be labelled "packaged in a protective atmosphere"[2].

It is also recommended that the labelling carries a clear statement that the shelf-life is no longer valid once food packaging is opened. MAP and VP packaged food should also carry instructions for use that include how soon the food must be consumed after the pack is opened and the storage temperature for the opened product.

Specific information related to the safety and shelf-life of foods with respect to non-proteolytic *Clostridium botulinum* is given in Appendix 2. However, it is strongly recommended that food business operators seek relevant expert advice before using MAP or VP for the first time. The FSAI has also produced a factsheet on the retail display of poultry from opened gas flushed packs[44].

Relative humidity

Relative humidity is the concentration of moisture in the atmosphere surrounding a food. Typically, there is an exchange of moisture between a food and its atmosphere which continues until the food is in equilibrium with the surrounding atmosphere. As such, the relative humidity can affect the water activity of foods and this should be taken into consideration by food business operators[9-10]. Some foods are expected to be dry, e.g. cereals, some moist, e.g. cooked meats, and others will be very wet, e.g. chilled chicken soup. If dry products like cereals are held at high humidity, the water activity will increase.

The relative humidity is also associated with the storage and distribution temperature of foods. Typically, for lower storage temperatures, a higher relative humidity is required to ensure that product characteristics are maintained[46].

Packaging

Packaging will help to control both the gas atmosphere and relative humidity of foods. However, food business operators should be aware that packaging will have differing properties such as its gas and water vapour permeability, which will affect food safety and shelf-life.

For foods packaged in impermeable packaging, the relative humidity of the storage environment is unlikely to be important in influencing shelf-life. However, if shelf-life of the food is limited by moisture gain/loss or if the food is packaged in moisture sensitive packaging, control of relative humidity should be a consideration in setting and validating shelf-life.

The choice and use of packaging often requires specialised equipment, materials and trained personnel. The FSAI has also produced a factsheet on food contact materials[47].

Food business operators should seek expert advice from an appropriate packaging supplier before using a specific packaging technology to ensure the safety of their food and compliance with legislation[1-5, 48].

Food processing

The variety and nature of food processing varies enormously depending on the food being manufactured. But typically, processing is designed to improve food palatability, safety and shelf-life. Common technology such as heat treatment, i.e. cooking, pasteurisation etc. will improve food safety and extend shelf-life by destroying dangerous pathogens and reducing numbers of other microorganisms.

Typically, heat treatments are mild and will not destroy all microorganisms, their spores or toxins, but rather will destroy or reduce numbers of specific microorganisms. To design and implement a safe heat treatment process requires food business operators to have an understanding of the mathematics behind heat processing and the associated effects, i.e. thermal destruction of the process on microorganisms, particularly of pathogens[31, 49].

Most foodborne pathogens are not particularly heat resistant and are easily destroyed by normal cooking temperatures. However, variations in heat resistance have been observed in many pathogens and the intrinsic characteristics of the food such as salt and fat concentration, pH and presence of competitive microorganisms etc. have also been shown to have an effect.

As a general guide for food safety, heat treatments should be sufficient to ensure heat penetration at the centre or thickest part of a food and reduce the number of target pathogens by 6 log cycles, i.e. a six-fold reduction in pathogen numbers, e.g. from 1 million per gram to 1 per gram.

Typically, when a temperature of 75°C or an equivalent temperature/time combination is achieved at the centre or thickest point of the food, this should ensure a 6 log cycle reduction of viable *Listeria monocytogenes* cells, generally considered the most heat resistant vegetative pathogen[30-31, 49].

The FSAI has produced detailed guidance on cook-chill systems in the food service sector[30] and the industrial processing of heat-chill foods[31].

Other processing technologies such as high pressure processing[90], smoking, fermentation, curing, drying, chilling, freezing etc. may alter the intrinsic or extrinsic properties of the food to retard or select for the growth of specific microorganisms. Some forms of food processing such as natural smoking may also result in the formation of antimicrobial substances in foods which can retard microbial growth.

Storage, distribution and use

How a food is stored, distributed and used by consumers will affect food safety and shelf-life. It is important that food business operators consider all reasonably foreseeable conditions of storage, distribution and use when setting and validating shelf-life. An important part of reasonably foreseeable conditions of storage, distribution and use is temperature[50-53].

In many circumstances, food will experience temperature variation, e.g. due to season of the year or abuse during storage, distribution and use which can significantly affect food safety and shelf-life. Therefore, in setting and validating shelf-life, the decision on which temperature or temperatures are appropriate for the food must be carefully considered by the food business operator[6]. If an inappropriate storage temperature, e.g. recommended temperatures for distribution, catering and retail in Ireland are ≤ 5°C, is used in setting the shelf-life compared to actual temperatures during storage, distribution and use, there may be an underestimation of microbial growth, particularly pathogens, and an overestimation of a safe food shelf-life[6, 25-26].

Consumer practices during purchase, storage and use of foods are predominately outside the control of the food business operator. Scientific studies of consumer practices and performance of domestic refrigerators both in Ireland and abroad have shown a relatively poor understanding of basic food hygiene and food safety, particularly temperature control among consumers[50-56]. Many domestic refrigerators in Ireland have been shown to operate at high temperatures around 10°C which can significantly affect the safety and shelf-life of food products[51-53].

As such, food business operators should take particular account of consumer practices in setting and validating food shelf-life and as required, specify clear storage instructions for consumers on food labels[50]. Current legislation requires pre-packaged foods to be labelled with instructions for use where it would be difficult to make appropriate use of the food in the absence of such instructions[2].

Good manufacturing and hygiene practices

Measures to control microorganisms in foods must be complimented by measures to minimise the risk of contamination or recontamination from the food processing environment. Good manufacturing practices (GMP) and hygiene practices (GHP) and the development and implementation of procedures based on HACCP are fundamental in maintaining food safety and setting and validating food shelf-life. All food business operators, including primary producers, are legally obliged to implement GHP[3-4].

Historical data

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

Procedures based on HACCP (Food safety management system)

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[3]. The FSAI has produced extensive guidance on procedures based on HACCP[28, 58-59].

Procedures based on HACCP[3-4, 28] provide a structured systematic approach to food safety, which involves identifying potential hazards and planning for their monitoring and control.

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

4.2.3 Consultation of scientific literature

When the intrinsic and extrinsic characteristics of the food have been established, this information can be used to compare the product with existing data on the survival and growth of pathogens in scientific literature.

Data on food safety, pathogens, manufacturing, shelf-life etc. are available from scientific journals, books, industry guides, third level institutes etc. Additionally, the FSAI and other competent authorities, e.g. Department of Agriculture Food and the Marine (DAFM), the Health Service Executive (HSE) as well as professional and international institutions, have resources and data available.

Table 6 outlines some of the key growth characteristics of common foodborne pathogens compiled from recent scientific literature. These data can be used by food business operators as a guide to determining what pathogens might be an issue for their food.

Table 6. Growth Characteristics of Common Foodborne Bacterial Pathogens[a-b]

Pathogen	Temp (°C)	pH	Water Activity (A_w)	(%) Salt[l]	Gas Atmos-phere	Some Commonly Associated Foods
	Min (Optimum) Max *Allowing Growth*		**Min** *Allowing Growth*	**Max** *Allowing Growth*	*Allowing Growth*	
Salmonella spp.[c]	5 (35-43) 47	3.8 (7-7.5) 9.5	0.94	4	Facultative	Eggs, meats, unpasteurised dairy products, sprouting seeds, fruit, vegetables, chocolate, infant formula, herbs, spices etc.
Clostridium botulinum (Proteolytic)	10 (35-40) 42	< 4.6 (7) 8	> 0.94	10	Anaerobic	Foods which are canned, vacuum packed, modified atmosphere packed, jarred, i.e. low oxygen environments
Clostridium botulinum[d] *(Non-Proteolytic)*	3 (28-30) 35	< 5.0 (7) 8	> 0.97	5	Anaerobic	
Staphylococcus aureus	10 (40-45) 48	4 (7-8) 9.6	0.83[e]	10	Facultative	Eggs, poultry, meats, dairy products, confectionary, salads, sandwiches, etc.
Campylobacter spp.	32 (42-43) 45	4.9 (6.5-7.5) 9	> 0.98	1.5	Micro-aerophilic	Poultry meat, unpasteurised milk and dairy products
Yersinia enterocolitica	-1.3 (25-37) 42	4.2 (7.2) 9.6	0.94	7	Facultative	Fresh meats (pork in particular) and unpasteurised milk and dairy products
Listeria monocytogenes[f]	-1.5 (30-37) 45	4.2 (7) 9.5	0.90	12	Facultative	Chilled, ready-to-eat foods
Clostridium perfringens[g]	10 (43-47) 50	5.5 (7.2) 9	0.93	6	Anaerobic	Cooked meats, gravy, stocks, soup
Shiga toxin (STEC) or Verocytotoxin (VTEC) producing Escherichia coli[h]	6.5 (30-40) 45	3.6 (6-7) 9	0.95	> 6.5	Facultative	Meat, poultry, unpasteurised dairy products and apple juice, sprouted seeds, salad vegetables, untreated drinking water etc.
Bacillus cereus[i]	4 (30-40) 55	4.3 (6-7) 9.3	0.93	7.5	Facultative	Cooked rice, spices, neonatal liquid formulas

Pathogen	Temp (°C)	pH	Water Activity (A_w)	(%) Salt[l]	Gas Atmos-phere	Some Commonly Associated Foods
	Min (Optimum) Max *Allowing Growth*		Min *Allowing Growth*	Max *Allowing Growth*	*Allowing Growth*	
Vibrio parahaemolyticus	5 (37) 43	4.8 (7.8-8.6) 11	0.94	8	Facultative	Fish and shellfish
Cronobacter spp.[j]	5.5 (39.4) 45	3.89 (5-9) No Data	0.2[k]	9.1	Facultative	Dried infant formula, infant feeds, follow-on formula

[a] Table adapted from[1, 6, 8-10, 14-15, 18, 20, 32, 34-35, 45, 49, 60-75, , 88-89]

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

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

[d] See Appendix 2 for further information

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

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

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

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

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

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

[k] Can survive in infant formula at this A_w

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

4.3 Predictive Microbiology

Predictive microbiology uses mathematical models (built with data from laboratory testing) and computer software to graphically describe the responses of microorganisms to intrinsic or extrinsic characteristics[6].

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

However, predictive microbiological models do not replace laboratory analysis or the training and judgement of an experienced food microbiologist. Food business operators should never rely solely on any predictive microbiological model to determine the safety of food or its shelf-life.

Data generated from predictive microbiological models should only be used as a guide to the response of microorganism(s) to a particular set of characteristics and should be verified by a durability study or challenge test. This is particularly pertinent when the conditions in the food are near the boundaries of the models parameters. Consultation with a competent body is strongly recommended before their use.

Predictive microbiological models are normally developed assuming that microbial responses are consistent[32]. While predictive models can provide a cost effective means to minimise microbiological testing in determining shelf-life, there may be occasions when the model's predictions may not be accurate, due to inconsistent microbial responses and variations in the growth media. Research has indicated that this is often why some predictive microbiological models fail to accurately predict the survival, growth or inactivation of pathogens in food products[76].

Initiatives to develop and improve microbiological modelling programs have been ongoing in the United States, the United Kingdom, Denmark, France, Australia and other countries for a number of years. These programs have resulted in the development of a wide range of microbiological modelling software packages becoming available[77].

4.4 Laboratory Testing

The next step in a shelf-life study is often the planning and design of laboratory testing of the food. In this regard, microbiological tests are predominately used to make the critical decisions regarding food safety and shelf-life.

Microbiological tests are also used to estimate food quality over the shelf-life and are often carried out in conjunction with tests to establish safety. However, the quality aspects of shelf-life are not discussed here.

Two types of laboratory testing, durability studies and challenge testing can be used in relation to shelf-life.

4.4.1 Durability studies

Most food business operators will carry a durability study which determines the growth of microorganisms in the food as manufactured, under reasonably foreseeable conditions of distribution, storage and use. Before beginning a durability study, it should be properly designed and planned.

If the durability study is specifically for *L. monocytogenes* in foods, the EC guidance should be followed (Appendix 1)[6, 8]. In all other cases, food business operators should follow the twelve good practice steps outlined below:

1. **Confirm the samples to be tested**

   Samples of food should, where possible, represent the worst case formulation processed under worst case processing conditions once the food business operator has established process and product variability. In so doing, the results of durability testing will be valid for the commercial product.

2. **Establish the study duration**

   Initially, the durability study should run up to and beyond the target shelf-life required by the food business operator. For example, if the target shelf-life is 28 days, testing could last 28 days plus seven days. If, after this time, the qualifying microbiological criteria are still being met, the testing may be continued until they are exceeded.

   Under some circumstances, a product may exceed its qualifying criteria before its target shelf-life. At this point, testing should stop and the food business operator accepts the estimated shelf-life or continue with product development and further testing until the desired shelf-life is achieved.

3. **Establish the study conditions**

   To estimate, set and validate the shelf-life requires laboratory testing to be carried out under realistic conditions which mirror reasonably, foreseeable conditions of storage, distribution and use, i.e. in particular storage temperature.

   Foods should be stored at temperatures which reflect normal practice, even if these temperatures are different to the recommended temperatures. For example, consumers are advised to store chilled foods at ≤5°C, but this is not always achieved. If the actual storage temperatures are unknown for a food product, the food business operator may use its own storage temperatures for the duration of the study. However, the food business operator must consider temperature abuse and justify which temperatures are used, taking into account available data from temperatures during transport and storage by consumers[6, 8].

It is generally recommended that the storage time is divided into three stages, i.e. distribution, retails display and consumer storage with two thirds of the time at 7°C (representative of the 95th percentile of the chill chain in Ireland) and one third at 12°C (representative of the 95th percentile of domestic refrigeration temperatures in Ireland). Therefore, if a stored sample is tested after three days it should have been subjected to two days at 7°C and one day at 12°C before testing. Then, if the next stored sample is tested after six days it should have been subjected to four days storage at 7°C and two days storage at 12°C before testing and so on for the remaining storage samples and times.

4. Establish the frequency of testing

The frequency of testing during the durability study should be based on experience with similar foods and the established characteristics of the food. For example, perishable food with a target shelf-life of seven days may require testing at daily intervals while less perishable foods may only require twice weekly or weekly testing intervals.

5. Establish the number of samples to be tested

At each interval in the durability study where testing takes place, it is important that a sufficient number of sample replicates are tested to account for product variability. This is because the distribution of microorganisms in foods is typically not uniform.

The size of the food business operator's production batch will help determine the number of samples required. The International Commission on Microbiological Specifications of Food (ICMSF) has produced extensive guidance on microbiological sampling plans which can be used by food business operators in determining product safety and shelf-life[78]. Software tools are also available from the WHO/FAO and a European funded study called Baseline.

In the absence of a specified sample number, it is recommended that at least three replicate samples from three separate production batches are tested at each interval during the durability study. This will help to ensure that the samples tested are representative of the food during its production. However, the larger the number of replicates tested per interval, the greater the degree of confidence a food business operator can have in the estimated shelf-life.

6. Choose the testing laboratory

Although not a legal requirement, the FSAI strongly recommends that food business operators only use laboratories which are accredited to conduct the specific test in that food. The Irish National Accreditation Board (INAB) is the national body with responsibility for accreditation of laboratories, i.e. private and public in Ireland. Accreditation is the formal recognition of a laboratory's competence to conduct testing in compliance with the international standard ISO 17025. Compliance with this standard requires laboratories to demonstrate competence, impartiality and integrity. A list of accredited laboratories and the specific tests for which they are accredited is available on the INAB website.

7. Establish the tests to be performed

Due to the wide variety of foods, it is impossible to accurately describe all the microbiological tests that may be used in a durability study. The type of pathogen(s) which could be expected to be present in the food will depend on the intrinsic and extrinsic characteristics of the food. As such, food business operators should be aware that it's not always necessary to test for all pathogens in all foods (Table 4). However, pathogens of concern should have already been identified by the food business operator through hazard analysis conducted as part of its procedures based on HACCP.

Food business operators should also note that they must comply with any requirements of legislation on the microbiological criteria of food products, e.g. there is a legal microbiological criterion for *L. monocytogenes* in ready-to-eat foods (Appendix 1)[1].

The decision to carry out specific microbiological tests should only be made by a trained food microbiologist or in consultation with a competent body. Consultation with a competent body is recommended where a food business operator has insufficient resources to decide which microbiological tests may be required to determine product safety and shelf-life.

The results of microbiological tests are dependent on the analytical method used, and therefore, a given reference method should be associated with each microbiological test performed[1]. It is recommended that all microbiological tests are carried out using a recognised reference method, e.g. ISO, EN, BS.

If testing against legal microbiological criteria set out in Regulation (EC) No 2073/2005, the method for analysis is specified[1]. If the food business operator wishes to use an alternative method, this method must be validated against the reference method. If the alternative method is a proprietary (rapid) method, it must be certified by a third party in accordance with the protocol set out in EN/ISO standard 16140 or other internationally accepted similar protocols[1].

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

The FSAI has produced guidance on selecting an external consultant[79], microbiological tests and associated microbiological criteria for foods[27, 80] and factsheets which outline alternative proprietary methods and best practice for testing foods when assessing compliance with Regulation (EC) No 2073/2005[81-83].

8. Perform and document the durability study

Ensure all samples are stored under agreed storage conditions and tests are performed on the appropriate samples at the appropriate time intervals.

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

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

The results of durability studies reflect the natural contamination of food products. However, food business operators should be aware that 'absence' results are not proof that the batch of food from which the samples came is not contaminated, due to the low probability of detecting pathogens in a contaminated batch, the low number of microbial cells initially present and their uneven distribution in the food.

The interpretation of the test results should only be made by a trained food microbiologist in consultation with the testing laboratory. Consultation with a competent body is also recommended in some cases. However, the results from microbiological analysis should be first compared to any applicable legislation requirements[1] then any relevant standards and guidelines.

At a point during the durability study, testing will begin to display results which are close to or no longer meet legislative requirements and/or agreed test parameters. Using these results and other data recorded, e.g. intrinsic and extrinsic characteristics; the food business operator must assign an appropriate shelf-life which ensures food safety. If results appear unsatisfactory or inconsistent, further testing may be required. In some cases, if the estimated or target shelf-life determined during product development is not achieved in the durability study, the product may have to be redeveloped or modified.

Ultimately, the safety of foods should be ensured by a preventative approach incorporating product and process design, application of GHP and GMP and procedures based on HACCP. It is now widely accepted that food product testing alone cannot guarantee the safety of foods. However, testing for specific microorganisms is a useful tool in setting the shelf-life and its ongoing verification.

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

10. Applying a margin of safety

While the accuracy and reproducibility of shelf-life will be affected by the characteristics of the food, it is unrealistic to expect the shelf-life of foods to be consistently accurate and reproducible under all circumstances. In addition, the shelf-life will never be an absolute value that terminates at an exact time and date. Rather, there will be a distribution of times and dates around an average shelf-life.

As such, it is strongly recommended that a margin of safety is applied to the shelf-life of the food. The margin of safety should be determined and applied by the food business operator after examining all reasonably foreseeable conditions of processing, storage, distribution and use.

It is not possible to define exact margins of safety for food products as it will vary between products. However, possible variations in the characteristics of foods, e.g. pH or storage temperature, should be taken into consideration when applying the margin of safety.

Applying a margin of safety will reduce the shelf-life of the food to a shorter time interval. However, this allows the food business operator to take account of reasonably foreseeable conditions of use which may affect product safety and shelf-life. The rationale behind an applied margin of safety should be documented by the food business operator and the food product specification and labelling finalised.

11. Labelling of shelf-life

Foods which are microbiologically perishable and may consequently, after a short period of time, pose a risk to public health, will generally have their shelf-life indicated by a 'use-by' date[1-2]. Foods 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.

The 'use-by' date will indicate the date up until which the product can be safely consumed. In the case of ready-to-eat foods, the manufacturer of a food has to decide whether the product is ready to be consumed as such, without the need to cook or otherwise process it in order to ensure its safety[1]. Further details on labelling requirements for shelf-life are given in Appendix 4.

12. On-going monitoring and verification

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

4.4.2 Challenge testing

When a new food product with a unique set of intrinsic and extrinsic characteristics is developed by a food business operator, data on the effect of the intrinsic and extrinsic characteristics on specific pathogens may not be available in the scientific literature. Accordingly, it may be necessary to evaluate the safety of the food using challenge testing.

Challenge testing determines if a pathogen(s) can grow and/or survive in the food and if so, how fast it will grow, i.e. growth potential. Challenge testing will also establish and validate the safety of foods over a set shelf-life.

In a challenge test, a food is inoculated with several strains of a known pathogen or non-pathogenic microorganism with similar characteristics, at a specific inoculation level. It is recommended to use at least three strains with known growth characteristics of which two should preferably be isolates from similar foods and one should preferably be a human isolate. The food is then stored under reasonably foreseeable conditions of distribution and use by the laboratory and the survival and growth of the inoculated microorganisms is measured.

In the majority of cases, food business operators will not require challenge testing of their foods. But for those foods which may require challenge testing, it is important to note that challenge testing is highly specialised, complex, expensive and generally food product exclusive.

Guidance on challenge testing of foods for *L. monocytogenes* has been published by the EC[8]. The ISO is currently in the process of producing an international standard for conducting challenge studies in food and feed. This guidance is expected in 2018.

Consultation with a competent body or an appropriately experienced laboratory is strongly recommended before deciding to use challenge testing.

APPENDIX 1.
SHELF-LIFE STUDIES FOR *L. MONOCYTOGENES* IN READY-TO-EAT FOODS UNDER REGULATION (EC) NO 2073/2005 ON MICROBIOLOGICAL CRITERIA FOR FOODSTUFFS

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

The EU has established legal microbiological criteria for *L. monocytogenes* in all ready-to-eat foods in Regulation (EC) No 2073/2005[1]. 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[1]. In particular, this applies to ready-to-eat foods that are able to support the growth of *L. monocytogenes* and that may pose a *L. monocytogenes* risk for public health[6].

The specific food safety criteria for *L. monocytogenes* in read foods are laid down in Annex I of the Regulation[1]. 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[1]. When testing against food safety criteria provides unsatisfactory results, the product or batch of the foodstuffs shall be withdrawn or recalled from the market. Furthermore, corrective actions at the production plant according to procedures based on HACCP shall be taken[6].

Annex II of the Regulation[1] describes the types of shelf-life studies that the food business operator can conduct in order to investigate compliance with the criteria throughout the shelf-life. These shelf-life studies shall always include:

- Specifications of physico-chemical characteristics of the product (such as pH, A_w, salt content, concentration of preservatives and the type of packaging system) 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 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 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

Each one of these tools has advantages and disadvantages and when necessary, different tools can be combined. Food business operators may collaborate with each other and seek advice from various food laboratories, e.g. research institutes or reference laboratories when they conduct these shelf-life studies.

Further detail on *L. monocytogenes* in ready-to-eat foods is given in FSAI Guidance Note No. 27 on Regulation (EC) No 2073/2005[80].

Food requiring shelf-life studies under Regulation 2073/2005

A wide range of products may require shelf-life studies to investigate compliance with the criteria for *L. monocytogenes* throughout their shelf-life. As such, it is difficult to provide an exhaustive list of all foods. Table 7 provides some examples of products falling under the food safety criteria for *L. monocytogenes* in the Regulation[1].

Table 7. Foods falling under the Food Safety Criteria for *L. monocytogenes*[a]

Food Category	Examples of Foods
1.1 Ready-to-eat foods intended for infants and ready-to-eat foods for special medical purposes	**Ready-to-eat foods considered food category 1.1 include:** • Infant formula and follow-on formula • Prepared recipes, cooked and sterilised, sold in cans, jars, pouches etc. • Rusk biscuits used directly or after adding liquid • Desserts and drinks based on dairy or soy protein • Fruit, vegetable and herbal drinks containing controlled amounts of sugar • Ready-to eat dietary food for special medical purposes[b]
1.2 Ready-to-eat foods **able** to support the growth of *L. monocytogenes*, other than those intended for infants and for special medical purposes	**Ready-to-eat foods are considered food category 1.2 if they do not fall into food category 1.1, or the food business operator cannot demonstrate they fall into food category 1.3 and include:** • Soft cheese, pate, smoked salmon • Pre-packed (sliced) cooked meats and salads • Ready-to-eat food with a shelf-life of five days or greater
1.3 Ready-to-eat foods **unable** to support the growth of *L. monocytogenes*, other than those intended for infants and for special medical purposes	**Ready-to-eat food is considered food category 3 if:** • Products with pH ≤ 4.4 or A_w ≤ 0.92 • Products with pH ≤ 5.0 and A_w ≤ 0.94 • If it's a frozen food • If its growth potential is ≤ 0.5 Log_{10} cfu/g[8] • If its shelf-life is less than five days, i.e. total shelf-life from day 0 (day of production)[c] • Other ready-to-eat food if the food business operator can provide scientific justification for their decision

[a] See footnotes (4) to (8) in Chapter 1: Food Safety Criteria of the Regulation for further information[1]. Further detail on *L. monocytogenes* in ready-to-eat foods is given in FSAI Guidance Note No. 27[80]

[b] Some dietary foods for special medical purposes are intended specifically for use by infants. If a food which is intended to be used by infants is deemed to be a food for special medical purposes, it must also comply with the legislative rules for dietary foods for special medical purposes[84-85].

[c] The food must comply with the limit of 100cfu/g throughout the shelf-life. Although not specifically stated in the Regulation 2073/2005[1], the European Commission has indicated to the FSAI that as such, the food business operator may have to conduct some shelf-life studies to demonstrate this compliance.

APPENDIX 2.
SAFETY AND SHELF-LIFE OF FOODS WITH RESPECT TO *CLOSTRIDIUM BOTULINUM*

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 VP and MAP chilled foods with respect to non-proteolytic *Cl. botulinum*[14].

There were two key ACMSF recommendations that related to the safety of VP food products:

1. In the absence of demonstrated safety factors, a maximum ten day shelf-life is recommended for VP/MAP foods stored at 3 to ≤ 8°C, if other controls are not used[14]. At temperatures less than 3°C, the growth of non-proteolytic *Cl. botulinum* does not occur[14]
2. For products with a shelf-life of greater than ten days, the following control factors should be used in combination with chilled storage at less than 3°C to prevent growth of non-proteolytic *Cl. botulinum*[14]:
   - Heat treatment of 90°C for ten minutes or equivalent lethality at the slowest heating point in the food (ideally be in a sealed pack)
   - pH of five or less throughout the food and throughout all components of complex foods
   - Minimum salt level of 3.5% (in the aqueous phase) throughout the food and throughout all components of complex foods
   - A_w of 0.97 or less throughout the food and throughout all components of complex foods
   - A combination of heat and preservation factors which can be shown to consistently prevent growth and toxin production by non-proteolytic *Cl. botulinum*

Campden BRI, has also published *'A code of practice for the manufacture of vacuum packed and modified atmosphere packed chilled foods'* in 1996[34] and updated in 2009[86]. The FSA provides online training for their enforcement officers in VP and MAP of food products which is available on the FSA website.

Large quantities of pre-packaged chilled VP/MAP raw meats are sold in Ireland and have not been associated with foodborne botulism. The majority of these products on the Irish market have shelf-life greater than ten days without receiving any of the control measures specified by the FSA/ACMSF/Campden BRI as outlined above[14, 45, 86].

Based on these facts, current industrial practices in Ireland would appear to have a high degree of safety[45]. However, it is clear that if present, non-proteolytic *Cl. botulinum* can form toxin in less than ten days, at less than 8°C[45]. That toxin formation has not occurred in correctly stored pre-packaged chilled VP/MAP raw meats sold in Ireland and internationally, must be due to presence of one or more unknown controlling factors[45].

The FSAI recommends the following in relation to the safety and shelf-life of foods with respect to *Clostridium botulinum*[14, 45]:

- The UK FSA/ACMSF approach for products with a shelf-life of greater than ten days is followed. However, in the case of chilled VP/MAP raw meats sold as whole joints or cuts, current industrial practice is acceptable
- All food business operators opening and repacking VP or MAP products should establish a new product shelf-life[44]
- 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 products

APPENDIX 3. HISTORICAL DATA

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

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

- Certificates of conformance from ingredient suppliers
- Routine food business operator monitoring checks, e.g. temperatures, pH, water activity etc.
- Laboratory testing of other foods produced by the food business operator generated over a period of time and which continue to be generated on an on-going basis (ideally similar foods with comparable intrinsic/extrinsic characteristics produced under identical conditions)
- Laboratory testing of water, staff hygiene and environmental samples
- Records of staff training
- Records of cleaning and sanitation procedures
- Implementation of recognised quality management systems

Depending on its nature and source, historical data held by a food business operator are also helpful in verifying the safety and shelf-life of foods for the following reasons[35]:

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

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

- Where levels of *L. monocytogenes* in ready-to-eat food at the end of shelf-life are consistently low or absent and no results have been obtained which exceed the legal limits[1]. These data could be used in combination with data from environmental sampling and quality of ingredients to give the food business operator confidence that such ready-to-eat foods will not pose a risk to public health. The level of confidence increases with the amount of data available. The more product units that are tested, the more reliable the historical data become[6].
- Historical data on levels of *L. monocytogenes* in existing ready-to-eat foods at the start/ end of shelf-life can be used to help verify product shelf-life under reasonably foreseeable conditions of processing, storage, distribution and use.

However, food business operators should be aware that historical data from microbial testing for pathogens that consistently fails to detect the target pathogen, does not confirm the absence of the pathogen in the food.

Each microbiological sampling plan used has an expected performance that can be defined as a given confidence in a certain detection limit, e.g. 95% confidence that the product contains less than 1 bacterium in 10g of product. Tools have been developed to calculate this performance, e.g. International Commission on Microbiological Specifications of Foods (ICMSF) software tools[57].

APPENDIX 4. LABELLING AND FOOD INFORMATION FOR CUSTOMERS

Regulation No (EU) 1169/2011 on the provision of food information to consumers is often referred to as the (FIC) Regulation[2, 87]. The FIC Regulation sets out the requirements for the provision of food information to the consumer as well as setting out the requirements with regard to the provision of nutrition information on foodstuffs[2, 87].

In relation to shelf-life, when a food business operator has estimated and set the shelf-life, it is important that this information is provided in accordance with the FIC Regulation[2]. In the legislation, shelf-life is referred to as the date of minimum durability and means

"the date until which the food retains its specific properties when properly stored".

In the case of foods which from a microbiological point of view, are highly perishable and are therefore, likely after a short period, to constitute an immediate danger to human health, the date of minimum durability must be replaced by the 'use-by' date. Under the FIC Regulation, once the 'use-by' date has passed, a food is deemed to be unsafe in accordance with Article 14(2) to (5) of Regulation (EC) No 178/2002[5].

The FIC Regulation requires an indication of the date of freezing or the date of first freezing for frozen meat, frozen meat preparations and frozen unprocessed fishery products[2]. These meats/ fishery products must indicate the date of freezing or the date of first freezing in cases where the product has been frozen more than once. This indication must be as follows[2]:

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

Under the FIC Regulation, a number of products are exempt from the requirement to indicate a date of minimum durability, i.e. shelf-life and these are listed in Annex X to the Regulation[2].

Additionally, where foods are offered for sale to the final consumer or to mass caterers without pre-packaging, or where foods are packed on the sales premises at the consumer's request or pre-packed for direct sale, they do not require a date of minimum durability or 'use-by' date declaration[2].

However, even if a shelf-life does not have to be labelled under the FIC regulation, the food business operator needs to know what the safe shelf-life is to ensure they don't put unsafe food on the market. As such, the FSAI recommends that all foods indicate a date of minimum durability, i.e. shelf-life, on the product label or packaging.

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