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18

GUIDANCE NOTE

Determination of Product Shelf-Life

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Guidance Note No. 18
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Abbreviations:

a_w	Water Activity
BS	British Standard
CCP	Critical Control Point
Eh	Redox Potential
EC/EU	European Commission/ European Union
FBOs	Food Business Operators
FSAI	Food Safety Authority of Ireland
GHP	Good Hygiene Practice
GMP	Good Manufacturing Practice
HACCP	Hazard Analysis Critical Control Point
ICMSF	International Commission for Microbiological Specifications in Food
INAB	Irish National Accreditation Board
ISO	International Standards Organisation
IS	Irish Standard
MAP	Modified Atmosphere Packaged
No	Number
NSAI	National Standards Authority of Ireland
RTE	Ready-to-Eat
S.I.	Statutory Instrument
SOP	Standard Operating Procedure(s)
Temp	Temperature (°C)
VTEC	Verotoxigenic *Escherichia coli*

1. BACKGROUND

The Food Safety Authority of Ireland Act, 1998 established the Food Safety Authority of Ireland (FSAI) to perform the functions assigned to it by the Act.

The FSAI believes that Guidance Notes have a major role to play in assisting the food industry and regulators in Ireland, to achieve a high degree of compliance with legislation and with good practice generally. A Guidance Note is not a substitute for legislation. However, the FSAI believes that adherence to it should make compliance easier, by providing the basis for a high degree of consistency in the application of legislation. This Guidance Note has been prepared by an industry working group in consultation with the FSAI.

2. DISCLAIMER

This document is intended to act as a guideline to legislation which requires food business operators (FBOs) to ensure the safety of their products throughout their shelf-life * ‡ [1-4]. It does not purport to be comprehensive or to be a legal interpretation or to constitute legal or other professional advice. Changes to legislation can be expected in the future that will necessitate this Guidance Note being updated.

Reference in this Guidance Note to any specific commercial products, process, service, manufacturer, or company does not constitute its endorsement or recommendation by the FSAI. Examples contained in this Guidance Note are not exhaustive and are intended for illustration purposes only. The FSAI is not responsible for the contents of any website referenced in this Guidance Note.

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* Regulation (EC) No. 852 of 2004 on the hygiene of food products will replace Directive 93/43/EEC from 1st January 2006. As a consequence the current national legislation (S.I. No. 165 of 2000) will have to be revoked by that time[1].

‡ When produced in the European Community and traded between Member States, food products intended for human consumption must currently fulfil the public health requirements laid down in 17 separate Council Directives. These Directives will continue to apply until the 1st of January 2006 when they will be replaced with Regulation (EC) No 853/2004 laying down specific hygiene rules for food of animal origin and Regulation (EC) No 852/2004 on the hygiene of foodstuffs. Directive 2004/41/EC (OJ L195, p12, 02/06/2004) will repeal these 17 existing directives and amend Directives 89/662/EEC and 92/118 EEC and Decision 95/408/EC while leaving the implementing decisions in force [2].

3. INTRODUCTION

Food products should not contain microorganisms‡, their toxins, or metabolites in quantities that present an unacceptable risk for human health [5]. 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 unsafe [3]. The shelf-life of food products is an integral part of food safety.

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 conditions [6].

In legislative terms, the term "date of minimum durability" will describe a food product's shelf-life and is the date until which a food product retains its specific properties when properly stored [4]. The date of minimum durability must be indicated by a 'best-before' date or a 'use-by' date [4].

The 'best-before' date will reflect the quality e.g. taste, aroma, appearance rather than safety of a food product. A food which is past its 'best-before' date may not necessarily be unsafe to consume but it may no longer be of optimum quality. Typically, a 'best-before' date is required on products such as canned, dried and frozen foods.

Food products which, from a microbiological point of view, are highly perishable* and are therefore likely, after a short period of time, to constitute a danger to human health must have a 'use-by' date (Section 6.2.2) [4]. The 'use-by' date will indicate the date up until which the product can be safely consumed. Therefore, unlike the 'best-before' date, the accurate determination of the 'use-by' date to ensure product safety is critical [5].

Shelf-life means either the period corresponding to the period preceding the 'use-by' date or the 'best-before' date [4].

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‡ Microorganisms are bacteria, yeasts, moulds and viruses and include, but are not limited to, species having public health significance (i.e. capable of causing illness or disease). Pathogenic microorganisms are those microorganisms that are of public health significance. Spoilage microorganisms are those microorganisms that subject food to decay and/or decomposition and/or indicate that a food is contaminated or adulterated [7].

* A perishable food is a food product which is subject to rapid decay, spoilage and/or growth of pathogenic microorganisms with or without production of toxins or metabolites in quantities that may present an unacceptable risk for human health [7-8].

In the EU, microbiological criteria have been laid down for specific foods. These criteria are applicable at the site of food production as well as in the framework of import control and Intra-Community trade. Currently, within the EU, microbiological criteria of specific foods are covered under seven individual Commission Decisions (i.e. 2001/471/EC) and Council Directives (i.e. 94/65/EC; 93/51/EEC; 92/46/EEC; 91/492/EEC; 89/437/EEC and 80/777/EEC). A number of other Directives including enabling provisions, which provide the possibility to set microbiological criteria in accordance with the comitology procedure, notably Council Directive No. 93/43/EEC also apply.

From January 1st 2006, the above individual legislation relating to microbiological criteria will be revoked and replaced with a single European Commission Regulation on Microbiological Criteria for Foodstuffs*[5]. Compliance with this new regulation shall mean obtaining satisfactory or acceptable results when testing against the values set for the criteria, through the taking and analysis of samples [5]. In addition, microbiological criteria for bovine raw milk and raw milk from other species, is outlined under Regulation (EC) No. 853 of 2004 [2].

* Microbiological criteria are tools that can be used in assessing the safety and quality of food products. The use of microbiological criteria should form an integral part of the implementation of HACCP-based procedures and other hygiene control measures [5].

4. SCOPE AND LIMITATIONS OF THIS GUIDANCE NOTE

1. The primary responsibility for food safety rests with FBOs [1-2].
2. Unless otherwise indicated, from this point forward, the shelf-life will refer to the 'use-by' date of a food product.
3. This Guidance Note should be read in conjunction with current food safety and hygiene legislation [1-5], relevant Irish standards [9-13], Irish guidelines [14-19] or industry best practice guidance [20-21].
4. This Guidance Note is advisory in nature and outlines agreed best practice to be used by FBOs to determine product shelf-life.
5. Where legislative requirements for microbiological criteria of specific food products exists, it shall take precedent over all other standards, guidelines etc., and should be used to determine the end of product shelf-life [5].
6. The Guidance Note does not provide a shelf-life testing protocol or procedure(s) which can be applied to every food product.
7. All FBOs must comply with the minimum legislative requirements of all current and future legislation [1-5].

5. RECOMMENDATIONS

1. FBOs **must** comply with their minimum legislative requirements.
2. Where a FBO has insufficient resources to determine shelf-life or has an alternative procedure(s) not outlined in this Guidance Note, it is strongly recommended that advice from a competent body is sought.
3. The safety and shelf-life of food products are primarily ensured by a preventive approach, such as implementation of good hygiene practices (GHP), good manufacturing practices (GMP) and application of procedures based on hazard analysis and critical control point (HACCP) principles [1].
4. FBOs should develop and implement supplier control to ensure the microbiological safety of raw materials and ingredients used in food processing [1-2].
5. Where legislation exists for the microbiological criteria of food products it shall take precedent over all other standards, guidelines etc., and may be used to determine the end of product shelf-life and in validation and verification of shelf-life, HACCP procedures and other food safety and hygiene control measures [5].
6. FBOs should develop their own protocols and standard operating procedures (SOPs) to allow consistent and accurate determination of product shelf-life.
7. FBOs should determine and describe the intrinsic and extrinsic properties of the food products they produce or pack, under all reasonably foreseeable conditions of processing, packaging, distribution, storage and use.
8. FBOs should not rely on individual intrinsic or extrinsic properties solely to assess product safety and shelf-life.
9. A margin of safety should be determined and applied to the shelf-life by the FBO producing and/or packing a food product under reasonably foreseeable conditions of processing, packaging, distribution, storage and use.
10. FBOs should only use laboratories with relevant expertise and accreditation to a recognised standard for shelf-life evaluation of food products.
11. FBOs should obtain detailed reports on product shelf-life rather than just provision of microbiological data from laboratories they use.
12. Challenge testing of food products should be avoided where possible, and only carried out by external laboratories with relevant expertise and accreditation to a recognised standard. FBOs should not perform their own on-site challenge testing.

13. Predictive mathematical modelling techniques should only be used by trained, experienced personnel with an understanding of the limitations of use. Consultation with a competent body is recommended before use of this technique.

14. FBOs should be able to furnish data (where necessary) which supports any declared shelf-life given for a food product they produce and/or pack.

15. FBOs should not alter or change a determined product shelf-life. If the shelf-life is altered, the FBOs should be able to furnish adequate scientific data specific to the product to support this change.

16. All records should be held by FBOs for at least six months after the shelf-life of food products has expired.

17. For best practice, products which legally don't require the inclusion of a date of minimum durability should have a date of minimum durability included on their labels.

6. DETERMINATION OF PRODUCT SHELF-LIFE*

6.1 Introduction

For a food product to be microbiologically safe and commercially viable, a FBO must produce a product which has a consistently reproducible and acceptable microbiological safety. Part of this consistency is a reproducible and accurately determined shelf-life. The shelf-life of most perishable food products is based on the survival and growth of spoilage microorganisms‡ but can also include pathogenic survival and growth (with or without production of toxins or metabolites). Therefore, an inaccurately determined shelf-life has the potential to endanger consumer health [1-5].

Food business operators can exert significant control over product safety and shelf-life through careful selection of raw materials/ingredients, the processing they receive and how they are packaged and stored. Poor hygiene practices will result in contamination of products. The shelf-life of food products will be affected by the microbiological quality of the raw materials/ingredients, product formulation, processing stages, packaging and the subsequent temperatures employed during transport, storage, retail display, catering and domestic use. All of these stages must be considered prior to and during determination of product shelf-life.

The determination of product shelf-life typically begins at the product development stage. Food product development involves the initial product concept, through to sample production and finally, a finished product produced on a commercial scale for consumer purchase and use. However, irrespective of the stage a food product is at in its development, it is important to ensure that shelf-life is considered at each stage and determined accurately using all available data.

* As stated in Section 4, unless otherwise indicated in this Guidance Note, the shelf-life of a food product will refer to the 'use-by' date or vice versa.

‡ Spoilage is a term used to describe detrimental changes in a food product's texture, colour, odour or flavour to the point where it is unpleasant or unsuitable for human consumption. Spoilage microorganisms are responsible for some detrimental quality changes in food products. Microbial spoilage of food often involves the degradation of protein, carbohydrates, and fats by microorganisms or their enzymes. Food spoilage occurs at varying rates depending on the microorganisms present, type of food product, and methods of preservation used on the food product. Spoilage microorganisms can include bacteria, moulds and yeasts. Spoilage can also be caused by chemical and physical changes in the food.

Food business operators should develop protocols and SOPs to allow consistent and accurate determination of product shelf-life. It is not possible to outline a specific testing protocol for every food product, raw material or ingredient in this Guidance Note. Therefore, best practice for accurate and consistent determination of product shelf-life is outlined. Accurate and consistent shelf-life determination will require some or all of the following:

1. Access to suitable equipment/facilities e.g. microbiological testing facilities
2. Access to appropriate/relevant data e.g. published literature
3. Access to qualified personnel e.g. microbiologist, production managers etc.
4. Standardised procedures/methods for testing e.g. International Standards Organisation (ISO) methods, British Standards (BS), accredited methods.

6.2 Shelf-Life Determination

Food business operators responsible for the manufacture of food products should conduct studies to investigate compliance of food products with microbiological criteria throughout product shelf-life (Section 3) [5]. In particular, this applies to ready-to-eat (RTE) foods* that are able to support the growth of *Listeria monocytogenes* and other pathogens. The studies should include:

1. The determination of the intrinsic and extrinsic properties of the product, taking into account the storage and processing conditions, the possibilities for contamination and the foreseen shelf-life
2. The consultation of available scientific literature and research data regarding the survival and growth characteristics of microorganisms of concern.

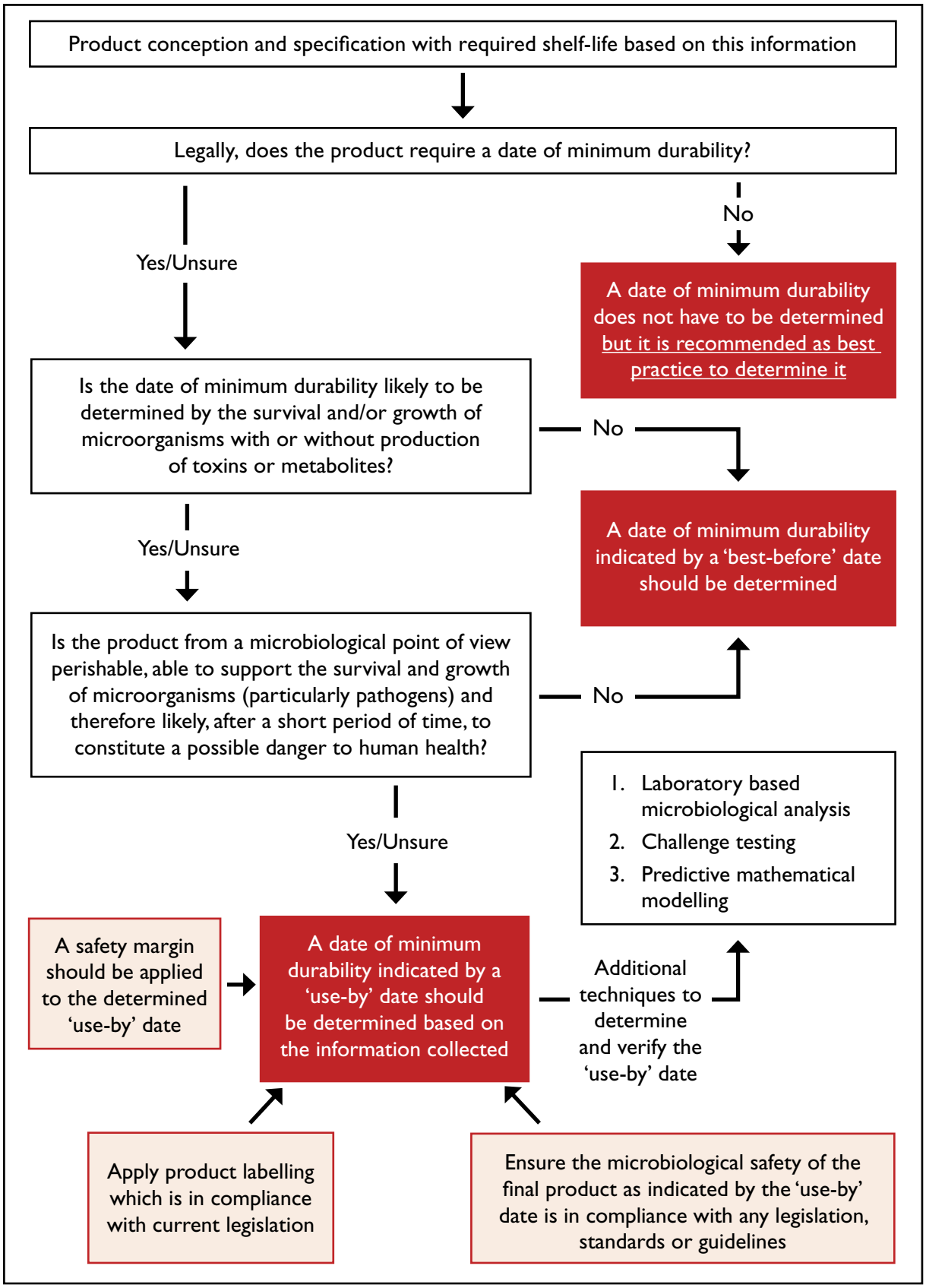
When necessary, on the basis of these studies, FBOs should conduct additional studies which may include [5]:

1. Laboratory based microbiological sampling and analysis
2. Predictive mathematical modelling
3. Challenge tests to investigate the ability of microorganisms of concern to grow or survive in the food product under reasonably foreseeable conditions of distribution and storage.

The above mentioned studies should take into account the inherent variability linked to food products, the microorganisms in question and the processing and storage conditions. Figure 1 outlines the decision tree (i.e. best practice) for determining the shelf-life of food products.

* Ready-to-eat foods are foods intended by the FBO for direct human consumption without the need for cooking or other preparation, effective to eliminate or reduce to acceptable levels microorganisms of concern [5].

Figure 1. Determination of Product Shelf-Life



6.2.1 Product conception and specification

Before a food product is produced, it should be described as accurately as possible in the form of a product specification. The initial specification for the proposed product should be drafted by the FBO to initially evaluate the product characteristics and safety. At a minimum, this specification should include the following:

1. Proposed product description
2. Proposed product ingredient listing
3. Proposed nutritional characteristics (i.e. as applicable)
4. Proposed processing, packaging, storage and distribution characteristics
5. Proposed HACCP plan and any available risk assessment data
6. Proposed end consumer
7. Any legislative requirements e.g. microbiological, chemical, nutritional, packaging, labelling etc. and/or customer requirements
8. Desired shelf-life required in meeting safety, quality and marketing specifications.

In addition, any data which are available and can be related to the proposed product, should be considered at this stage. FBOs should ask these questions about the proposed product to help collect these data which will be helpful in determining the shelf-life:

1. Is the proposed product similar to any products already produced?
2. Is there any product(s) on the market already with similar characteristics such as ingredient listing, packaging etc.?
3. Are there any available data or published guidance which are related to the shelf-life of the proposed product?
4. Can any of these data be used to help determine the product shelf-life?

6.2.2 Does the product require a date of minimum durability?

Using the initial product specification (Section 6.2.1), FBOs should evaluate whether the proposed product will require a date of minimum durability e.g. 'best-before' date or 'use-by' date [4]. FBOs are required under the current general food labelling legislation, to include a date of minimum durability on the label of most food products [4]. However, specific food products are exempt from carrying a date of minimum durability declaration due to the conditions in which they are sold, such as unpackaged vegetables (Appendix 1) [4].

Other food products have a specific derogation to the general labelling regulations. As such, these food products also do not require a label which indicates the date of minimum durability (Appendix 1) [4]. In both cases (i.e. products exempt or with a specific derogation), it is recommended that best practice should be the inclusion of a date of minimum

durability on the labels of all these food products. These recommendations are particularly pertinent to products which would be prepared and packed on retail premises with or without the request of the consumer (Appendix 1). Instructions for use of food products are compulsory on the product labelling when it would be impossible to make appropriate use of the food product in the absence of such instructions (Appendix 1) [4, 15].

6.2.2.1 '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 uncoded chronological form [4].

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 packaging) [15].

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 declared [15].

6.2.2.2 'Best-before' date

Certain perishable food products, e.g. margarine, butter may not support the growth of pathogens and as such do not require a 'use-by' date (Section 6.2.2.1) but rather a 'best-before' date. Raw shell eggs and frozen food products also require a 'best-before' date.

Unlike food products with a 'use-by' date, there is no legal requirement against packaged foods being offered for sale on or after their 'best-before' date provided that the food is still of acceptable safety and quality. When a FBO sells food past its 'best-before' date, it should indicate to the customer that the food is past its 'best-before' date [4]. An exception to this is shell eggs which must be sold at least seven days before their 'best-before' date [40]. The date declared depends on whether the product has a short shelf-life or a long shelf-life [4]:

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

6.2.3 Is the date of minimum durability influenced by microbial survival and growth?

Food products which are typically consumed or intended to be consumed without preparation, or after treatment unlikely to be sufficient to destroy microorganisms and toxins or metabolites which may be present, will have their date of minimum durability determined by the survival and growth of microorganisms.

All microorganisms will have specific minimum requirements for survival and growth such as temperature, water and availability of nutrients. If minimum requirements are not available, then microorganisms may not survive or grow. These requirements for survival and growth may be referred to as the intrinsic and extrinsic properties [22]. Intrinsic properties are those properties that are an inherent part of the food product e.g. pH and water content. Extrinsic properties are the properties of the environment in which the food is stored [22] e.g. temperature and relative humidity.

It is important that FBOs determine the intrinsic and extrinsic properties of the food products they produce or pack, under all reasonably foreseeable conditions of processing, storage and use*.

6.2.4 Intrinsic and extrinsic properties

The survival and growth of most microorganisms is directly or indirectly influenced by the intrinsic and extrinsic properties of food products. Hence, the shelf-life of food products is also significantly influenced by these properties.

By determining the intrinsic and extrinsic properties of food products, FBOs can manipulate their products e.g. changes in processing techniques or raw materials/ingredients etc to improve product safety and achieve a desired shelf-life (Section 6.2.7). However, understanding the effect these properties have on the survival and growth of microorganisms, is important for manipulation of the properties, product safety and accurate determination of product shelf-life.

Table 1 outlines the commonly encountered intrinsic and extrinsic properties of food products.The major intrinsic (Sections 6.2.5.1–6.2.5.9) and extrinsic (Sections 6.2.6.1–6.2.6.9) properties are further discussed in detail below. Emphasis is placed on the effects the properties have on the survival and growth of microorganisms, particularly pathogens in food products.

* A FBO should always allow for circumstances which may affect the shelf-life such as temperature abuse during storage.

Table 1 Intrinsic and Extrinsic Properties of Food Products [1]

Intrinsic	Extrinsic
Microbiological quality of raw materials	Good manufacturing and hygiene practices
Raw materials history	Hazard Analysis Critical Control Point
Food formulation and composition	Food processing
Food assembly and structure	Storage temperature
pH	Gas atmosphere
Type of acid present	Relative humidity
Water activity (a_w)	Packaging
Redox potential (Eh)	Retail practices
Biological structures	Consumer practices
Oxygen availability	
Nutritional content and availability	
Antimicrobial constituents	
Natural or artificial microflora of the food	

[1] Table adapted from [22-23]

6.2.5 Determining the intrinsic properties

6.2.5.1 Microbiological quality of raw materials and ingredients

Variation in the microbiology quality of raw materials will affect the safety of food products and the shelf-life. It should be assumed that any raw material entering a food business is a potential source of microbiological contamination. 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 [5]. In the absence of legislation, raw materials and ingredients should comply with relevant Irish standards [9-13], Irish guidelines [14-19], or industry best practice guidance [20-21].

Food business operators should have a written supplier approval procedure and raw materials/ ingredients should only be sourced from approved suppliers. All water (including ice) used as an ingredient and for preparation of food must be of potable quality [24]. 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 to the water before use* [24-25].

* Directive 2000/60/EC of the European Parliament and of the Council of 23 October 2000 establishing a framework for Community action in the field of water policy Official Journal L 327, 22/12/2000 P. 0001 – 0073 will repeal (European Communities Quality of Surface Water Intended for the Abstraction of Drinking Water, Regulations, S.I. No. 294 of 1989) on the 22/12/2007.

6.2.5.2 Product formulation, composition, structure and assembly

Product formulation, composition, structure and assembly can be important in determining and maintaining the shelf-life of food products. Many food products will not have a uniform (i.e. homogeneous) internal structure. Therefore, the intrinsic properties (Table 1) of the food product may be variable within the structure of the food. As a consequence, micro-environments may form within the food product.

Micro environments may have different intrinsic properties to the food product as a whole. This can be problematic if the intrinsic properties within these micro-environments allow the growth of microorganisms, particularly pathogens if, as a whole, the product's intrinsic properties do not allow microbial survival and growth. Appendix 2 outlines some examples of product formulation and composition issues which could affect shelf-life.

6.2.5.3 pH

The pH is a measure‡ of a product's acidity or alkalinity and will vary between food products. Food products can be broadly classified into [22]:

1. High acid (pH < 3.5)
2. Intermediate acid (pH 3.5 to 4.5)
3. Low acid (pH > 4.5).

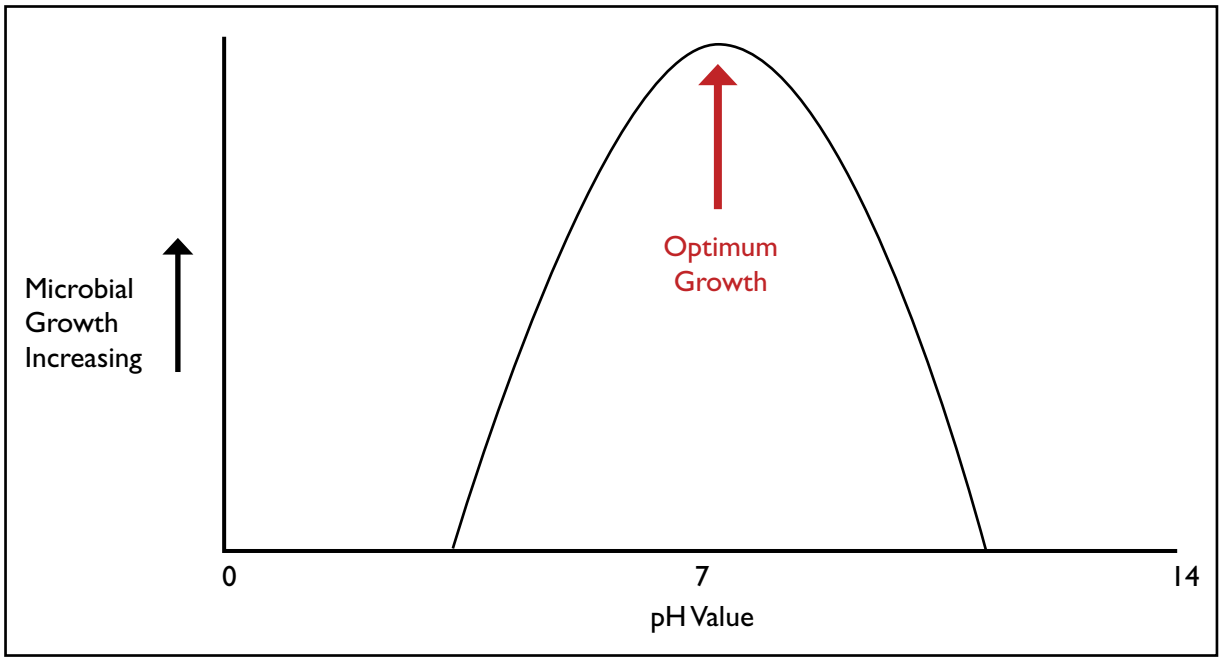
The pH range for microorganisms is defined by a minimum value and a maximum value with a pH optimum at which growth is best. Most microorganisms grow best at or near a neutral pH (i.e. pH = 7.0) as illustrated in Figure 2.

Many foods including meat, poultry, fish and vegetables are slightly acidic while fruits are intermediate to highly acidic. A few food products such as egg white, and baking soda are alkaline (i.e. > pH =7). The pH of food products may vary with time due to microbial activity and product composition or formulation (Section 6.2.5.2). Specific food products may be more prone to pH change than others including vegetables, fresh meats, poultry and mould/smear ripened cheeses.

At a production level, a food product may have a pH which prevents the growth of pathogenic microorganisms. However, if the pH changes during product shelf-life and pathogens are present, the safety of the product is at risk. Therefore, control of pH and the application of a margin of safety (Section 6.5) are required for these food products. Organic acids such as sorbic and benzoic, while antimicrobial in nature, are extensively used in the food industry to control product pH. Appendix 2 outlines the approximate pH of some common food products.

‡ The pH scale ranges from 1 to 14 with the relative strengths of acid and alkaline defined by their pH value on this scale.

Figure 2. Effect of pH on Microbial Growth[1]



[1] It should be noted that a similar graph can be used for other intrinsic and extrinsic properties of food products such as water activity and storage temperature and their effect on microbial growth.

6.2.5.4 Water activity

Water activity (a_w) is one of the most important properties of food governing microbial growth. The a_w can be defined as the free or available water in a food product*. The requirements for moisture by microorganisms are expressed in terms of a_w. Therefore, a_w will determine what the lower limit for microbial growth will be in a food product [26]. Food products can be broadly classified into [22]:

1. High a_w (> 0.92)
2. Intermediate a_w (0.85 to 0.92)
3. Low a_w (< 0.85).

Ingredients, e.g. salt and sugars and processing techniques, e.g. drying, curing, cooking etc used in the production of food products, will influence the a_w and therefore the safety and shelf-life of the product. As with pH (Section 6.2.5.3), the growth range for microorganisms is defined by the minimum, maximum and optimum values of a_w. Most microorganisms cannot grow below an a_w of 0.60 (i.e. no microbial growth occurs below an a_w of 0.50) with the majority growing at an a_w > 0.90 [27]. Appendix 2 outlines the approximate a_w of some common food products.

* Water Activity (a_w) has a scale which ranges from a value of 0 (i.e. 0% water present) to 1.0 (i.e. 100% water present).

6.2.5.5 Antimicrobial constituents

Food products may contain substances (i.e. antimicrobial constituents) which have antimicrobial properties against the growth of specific microorganisms. There is a wide variety of substances with no known antimicrobial activity in a wide variety of food products. Some antimicrobial constituents found naturally in food include [22]:

1. Allicin in garlic and onions
2. Lysozyme in eggs and milk
3. Lactoperoxidase system (consisting of lactoperoxidase, thiocyanate, and hydrogen peroxide) in cow's milk
4. Natural acids in fruits and some vegetables such as malic and citric acids
5. Eugenol in cloves and cinnamon
6. Hydroxycinnamic acid derivatives in tea, fruits and vegetables.

Other antimicrobial constituents in food products are added as preservatives‡. Permitted preservatives, e.g. nitrites, sulphur dioxide etc. for use in food products are listed under current legislation [28]. Some forms of food processing will also result in the formation of antimicrobial substances in food products including:

1. Smoking, e.g. fish and meat products
2. Fermentation, e.g. meat products
3. Condensation reactions between sugars and amino acids (i.e. Maillard reaction) during heating of certain foods
4. Natural production of antimicrobial substances such as Bacteriocins, e.g. nisin by microorganisms.

6.2.5.6 Biological structures

Some food products 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 food products such as nuts, eggs, vegetables and fruits. However, the effectiveness of these biological structures on preventing external contamination of food products with microorganisms will vary considerably.

6.2.5.7 Presence of other microorganisms in the food product

The presence of non-pathogenic microorganisms in food may influence the growth of pathogens. Non-pathogenic microorganisms may outgrow pathogens, consume available nutrients and predominate in the food (i.e. competitive inhibition). In addition, microorganisms may excrete antimicrobial substances such as metabolites which will affect the growth of pathogens. Some FBOs are beginning to exploit this principle by using non-pathogenic microorganisms, e.g. lactic acid bacteria to prevent the growth of pathogens in food products.

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‡ Preservatives are substances which prolong the shelf-life of food products by protecting them against deterioration caused by microorganisms [28].

6.2.5.8 Nutritional content and availability

All microorganisms require nutrients for growth and maintenance of basic metabolic functions. The amount and type of nutrients required will vary widely depending on the microorganism. Therefore, the nutritional content of food products will affect microbial growth. For microorganisms to grow in a food product, the following is required [22, 29]:

1. Water
2. Energy source, e.g. proteins, fats, carbohydrates, alcohol etc.
3. Nitrogen source, e.g. amino acids, urea, ammonia, creatinine, methylamines etc.
4. Minerals, e.g. iron, calcium, phosphorus, magnesium, sulfur, manganese, potassium etc.
5. Vitamins, e.g. thiamine, nicotinic acid etc.

Quantities of nutrients will vary in food products. However, typically animal foods, e.g. meat, poultry, fish, milk and egg products are high in protein, fats, minerals, and vitamins and low in carbohydrates. Plant foods will be high in different types of carbohydrates e.g. starch, cellulose etc., with variable quantities of fats, proteins, minerals and vitamins.

Food products will have different levels of nutrients available for microbial growth. Typically, bacteria will have the highest nutritional requirements followed by yeasts and moulds. However, due to the wide variation in nutritional content of food products, a range of pathogens will grow in foods. Therefore, it is recommended that FBOs do not use nutritional compositional data solely to assess product safety and shelf-life.

6.2.5.9 Oxidation-reduction potential (Redox Potential)

The oxidation-reduction potential (Eh) of a food product is the ease by which it gains or loses electrons*. The Eh value at which microorganisms will grow determines whether they require oxygen (i.e. aerobic) for growth or not (i.e. anaerobic) [22]. Therefore, microorganisms can be broadly classified into the following groups based on their Eh [29]:

1. Aerobes +500 to +300 mV
2. Anaerobes +100 to ≤ -250 mV
3. Facultative Anaerobes +300 to -100 mV.

The Eh of food products is dependent on its pH (Section 6.2.5.3) and as such, the Eh is particularly important in ensuring the safety of products such as ambient-stable meat products, e.g. salamis, fermented and dried meats [30]. However, it is recommended that FBOs do not use Eh measurements solely to assess product safety due to the high variability of the Eh in food products and limitations in its measurement e.g. low accuracy. Appendix 2 outlines the approximate Eh of some common food products.

* 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 and are measured in positive millivolts (+Eh). If a food product gains electrons, it is said to be reduced. Reduced environments provide anaerobic conditions for microbial growth and their Eh will be measured in negative millivolts (-Eh) [22].

6.2.6 Determining the extrinsic properties

6.2.6.1 Good manufacturing and hygiene practices

Measures to control microorganisms in food products must be complimented by measures to minimise the risk of recontamination from the food processing environment. GMP and GHP, and the development and implementation of a food safety management system based on the principles of HACCP are fundamental for ensuring and maintaining the safety and shelf-life of food products.

6.2.6.2 Hazard Analysis Critical Control Point

Together with the implementation of GMP and GHP (Section 6.2.6.1), all FBOs carrying out any stage of production, processing or distribution of food, after primary production, legally must develop a food safety management programme based on the principles of HACCP [1-2, 16]. HACCP is a structured systematic approach to food safety, which involves identifying potential hazards and planning for their monitoring and control. While HACCP, applied logically and systematically, will reduce or prevent contamination of food products it will also allow FBOs to determine and maintain accurate product shelf-life.

HACCP will help FBOs to understand the interactions of the food product with its processing environment and highlight the factors which may affect product safety and shelf-life. The HACCP plan may identify a Critical Control Point (CCP) e.g. a heat treatment which will reduce or eliminate microbial contamination thereby improving product safety and increasing shelf-life (Section 6.2.6.3). Developing the HACCP system for the product at the design stage will help ensure that the operations which affect the intrinsic and extrinsic properties of the product are controlled and monitored during processing [22].

6.2.6.3 Food processing

The processing of food products will vary widely in its applications and complexity, but should always be designed to maintain and improve food safety. Processing techniques may extend the shelf-life of food products by destroying or reducing numbers of microorganisms. They may also alter the intrinsic or extrinsic properties of the food product sufficiently to destroy, retard or reduce numbers of microorganisms. However, FBOs should determine:

1. How the various stages in production may affect the survival and growth of microorganisms and thus final product shelf-life
2. If there is a stage(s) where prevention, reduction or elimination of microorganisms can be achieved such as a CCP (Section 6.2.6.2).

While there are many different processing techniques e.g. chilling, freezing, drying, irradiation, modified atmosphere packaging, vacuum packaging etc. available to treat food, the most commonly used is heat treatment. Heat treatments such as cooking should be sufficient to ensure that heat penetration at the centre or thickest part of a food product (i.e. core) will result in the destruction of the vegetative stages of any pathogenic microorganisms that may be present. This is normally achieved when a food reaches a

minimum temperature of ≥ 70°C for two minutes or equivalent, e.g. 75°C instantaneously at the centre or thickest point [19].

However, cooking processes will not destroy all viable microorganisms e.g. spoilage organisms, microbial spores or microbial toxins. Slow chilling of food products following cooking can be a food safety hazard, if during the chilling period, pathogenic spore-former or any surviving vegetative pathogenic microorganisms are given sufficient time and temperature conditions to grow and/or produce toxins or metabolites [19]. Therefore, many cooked food products are rapidly chilled after heat treatment. Other thermal processes such as sterilisation which are applied to canned foods are designed to destroy all viable microorganisms.

Food business operators should seek advice from a competent body and/or an appropriate equipment manufacturer before implementing any food processing technique such as a heat treatment which will be a CCP (Section 6.2.6.2) designed to increase product safety and shelf-life.

6.2.6.4 Storage temperature

Depending on the storage temperature of food products, the survival and growth of specific microorganisms will be inhibited, retarded, or in some cases enhanced. As such, the shelf-life of many food products is dependent on storage temperature [23]. Where a FBO specifies a storage temperature (Section 6.2.6.9) for a food product e.g. store at 0°C to 5°C, this should be used by that FBO in determining the shelf-life. At a minimum, FBOs should determine:

1. If the maximum recommended storage temperature will support or inhibit microbial growth?
2. How quickly will microorganisms grow at this temperature?
3. If the product could be prone to temperature abuse during storage and what affect this will have?

There are three arbitrary temperature ranges within which microorganisms will grow [22]:

1. Psychrotrophic microorganisms have an optimum temperature range of 20°C to 30°C. However, many of these microorganisms can survive and grow at refrigerator temperatures ≤ 5°C. Foodborne pathogens which will grow at refrigerator temperatures include *Listeria monocytogenes*, *Yersinia enterocolitica* and non-proteolytic *Clostridium botulinum* (i.e. Types B, E and F)
2. Mesophilic microorganisms typically have an optimum temperature range of 30°C to 40°C. However, many of these microorganisms survive and grow well between 20°C and 40°C. Many foodborne pathogens are mesophiles including *Salmonella* species, Verotoxigenic *Escherichia coli* (VTEC) and *Staphylococcus aureus*
3. Thermophilic microorganisms typically have an optimum temperature range of 55°C to 65°C. However, many of these microorganisms survive and grow well at 45°C but not < 30°C. Some foodborne pathogens are thermophiles such as *Clostridium perfringens*.

6.2.6.5 Gas atmosphere

The composition of the gas atmosphere surrounding a food product can have an effect on the survival and growth of microorganisms. Some FBOs use modified atmosphere packaging (MAP) and vacuum packing techniques* (Section 6.2.6.7) to change the gas composition of the atmosphere surrounding food products and extend shelf-life.

The most commonly used gases in MAP are oxygen, carbon dioxide and 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.

The use of vacuum packing and MAP requires specialised equipment, packaging materials and trained personnel [31]. FBOs should seek advice from a competent body and an appropriate equipment manufacturer before using MAP or vacuum packaging.

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 [4].

6.2.6.6 Relative humidity

Relative humidity is the quantity of moisture in the atmosphere surrounding a food product (i.e. 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 product and the surrounding atmosphere which continues until the food reaches equilibrium with the surrounding atmosphere.

Relative humidity can affect the a_w (Section 6.2.5.4) of food products [22]. If a food product requires a specific a_w to control microbial survival or growth particularly pathogens, 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/packaging conditions (Section 6.2.6.7) for a food product, it is important to note that relative humidity is associated with temperature (Section 6.2.6.4) during storage. Typically, for lower storage temperatures, a higher relative humidity is required and vice versa [32]. 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.

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* Vacuum packing involves the removal of air from the package leaving a small i.e. residual air content. MAP involves the removal of air from the packaging and substituting it with another gas, or a mixture of gases e.g. oxygen, carbon dioxide or nitrogen. These gases retard and/or inhibit specific microbial growth. However, the concentrations of gases used must be carefully regulated.

If dry products like cereals for example, are held at high humidity, the a_w will increase, moulds may grow with potential production of carcinogenic mycotoxins and the product will spoil.

6.2.6.7 Packaging

Many packaging systems such as MAP and vacuum packing will control the gas atmosphere surrounding a food product and extend shelf-life (Section 6.2.6.5). However, the choice of packaging used is largely dependent on the type of food product. Different packaging will have different properties, such as gas and water vapour permeability. Other packaging may be opaque and help prevent light damage, such as discoloration or rancidity.

Active packaging employs a packaging material that interacts with the internal gas atmosphere (i.e. by removing gases from, or adding gases to, the headspace inside a package to inhibit or eliminate specific microbial survival and growth) and/or the food product (i.e. by releasing authorised food additives including preservatives) to extend shelf-life* [33]. FBOs should seek advice from the supplier and/or the manufacturer before using packaging materials for the first time to ensure their compliance with legislation [33].

The choice and use of packaging may require specialised equipment, packaging materials and trained personnel. Whatever the packing system used, the FBO should determine if it will promote, prevent, reduce or eliminate the survival and growth of microorganisms. FBOs should seek advice from a competent body and/or an appropriate equipment manufacturer before using a specific packaging technology for the first time.

6.2.6.8 Retail practices

Conditions experienced by food products during storage, distribution and retail display, such as temperature abuse will affect product shelf-life. FBOs should under all reasonably foreseeable conditions factor temperature abuse into the determination of product shelf-life by applying a margin of safety (Section 6.5).

6.2.6.9 Consumer practices

Consumer practices during purchase, storage and use of food products in the home are predominately outside the control of FBOs. Detailed scientific studies of consumer practices are minimal, but FBOs should take account of poor consumer handling in determination of product shelf-life by applying a margin of safety (Section 6.5). As required, FBOs will specify storage temperatures, e.g. store at 0°C to 5°C on the labelling of their food products (Section 6.2.6.4). However, many domestic refrigerators may not operate at these temperatures, which can affect the safety and shelf-life of food products.

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* This Regulation came into force on the 3rd December 2004. Article 17 of this Regulation which deals with traceability of packaging material applies from the 27th October 2006.

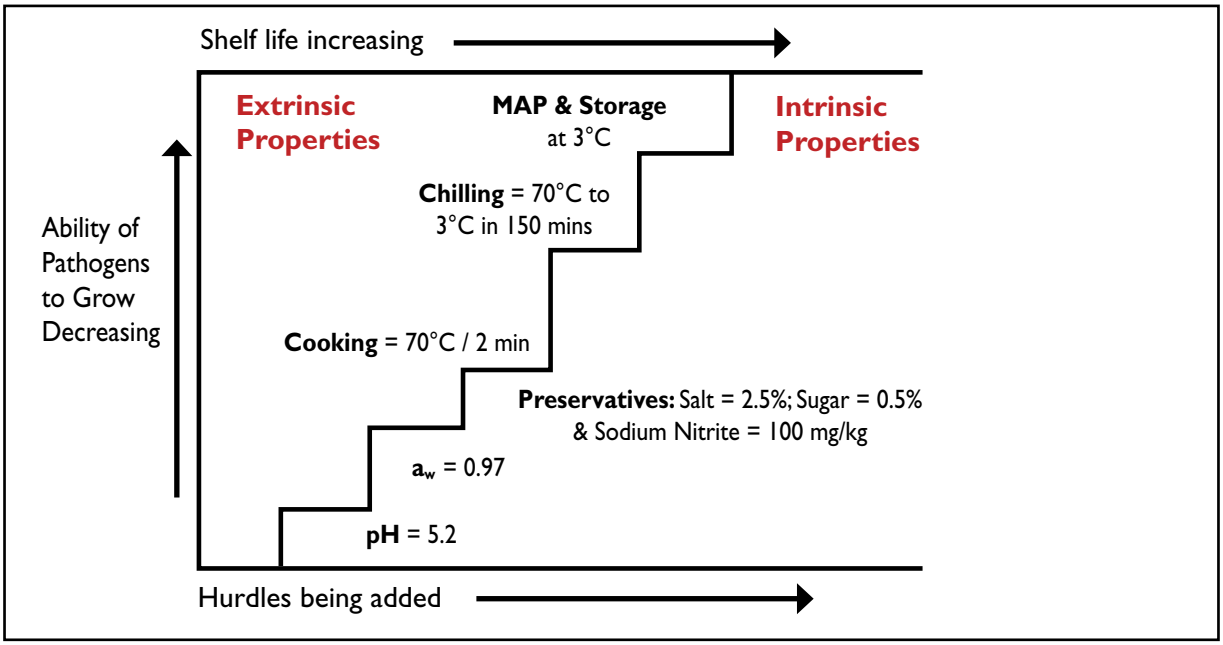
6.2.7 Hurdle technology

Hurdle technology is a term which refers to the concept of achieving control of product safety by combining in series, or parallel, a number of intrinsic and/or extrinsic properties that individually would not be adequate for control [34]. In relation to product shelf-life, each individual intrinsic and extrinsic property is considered a hurdle to the survival and growth of microorganisms during and up to the end of product shelf-life.

Typically, different combinations of intrinsic and extrinsic properties should inhibit the survival and growth of specific pathogens in food products (Table 1). However, in some products, spoilage microorganisms may survive and grow and be important in determining the shelf-life. This is typically the case in Ireland with pasteurised liquid milk products. The aseptic nature of the processing and packaging pasteurised liquid milk products receive, means that the shelf-life is largely dependent on the survival and growth of spoilage microorganisms rather than pathogens.

A hurdle may be based on pH, a_w, storage temperature and other intrinsic and extrinsic properties [34]. The hurdle effect allows FBOs to address some of the safety and shelf-life issues of food products. It also allows FBOs 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. As further steps are added, it becomes more difficult for microorganisms to survive and grow in the food product.

Figure 3. Example of the Application of Hurdle Technology in Packaged Cooked Sliced Ham [1]



[1] 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.

An example of a food product preserved by the hurdle effect is a pre-packaged, sliced, cooked ham. This product is preserved using a combination of preservatives, (Section 6.2.5.4) processing techniques (Section 6.2.6.3) and packaging (Section 6.2.6.7). In this product, the interaction of intrinsic (i.e. salt, sugar, nitrites, pH, a_w) and extrinsic properties (i.e. storage temperature, packaging materials, gas atmosphere) inhibits survival and growth of pathogens and ensures product safety up to the determined shelf-life. The hurdle effect for this product can be represented by a series of steps on a graph as shown in Figure 3 [34].

The exact combination of hurdles required for inhibiting survival and growth of specific microorganisms, such as pathogens is dependent on the properties of the specific food product and what the FBO requires from the product in terms of safety and shelf-life [34].

6.3 Will Microorganisms Survive and Grow in the Product?

It is important for FBOs to understand how the interactions of the intrinsic and extrinsic properties can affect product safety and shelf-life [5]. Minimum and maximum growth conditions for foodborne pathogens are limited by the intrinsic and extrinsic properties of the food product. Table 2 outlines some of the published minimum and maximum growth conditions of pathogens in food products. 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 grow outside these limits.

Using the preliminary data collected on the intrinsic and extrinsic properties (Sections 6.2.5 – 6.2.6) of a food product a FBO should now determine what pathogens (Table 2) may survive and/or grow in their food product. Depending on the level of resources and expertise available, a FBO should do one or more of the following at this point:

1. Review any available scientific literature/research data/FBO records on similar food products and determine what pathogens may survive and grow in the food product (A non-exhaustive list of data resources is given in Appendix 3)
2. Consult with a competent body
3. Carry out microbiological testing of samples to establish product safety (Section 6.6).

If the FBO establishes (or is unsure) that the food product from a microbiological point of view is (perishable) able to support the survival and growth of microorganisms (particularly pathogens) and therefore likely after a short period of time, to constitute a possible danger to human health, a shelf-life should be determined using collected data (Figure 1).

Table 2. Published Minimum and Maximum Growth Conditions for Foodborne Pathogens

Pathogen	Temp. (°C) (minimum)	pH (minimum)	a_w (minimum)[6]	Salt (% Aqueous) (maximum)	Commonly Associated Foods
Salmonella species [1]	5.2	3.8	0.94	4.0	Eggs, poultry, meats and dairy products
Clostridium botulinum [2] Mesophilic/ Proteolytic (Types A, B and F)	10	4.6	0.93	10.0	Canned foods, vacuum packed and MAP foods
Clostridium botulinum [2] Psychrotrophic/Non-Proteolytic (Types B, E and F)	3.3	4.8	0.97	5.0	Canned foods, vacuum packed/ MAP foods and jarred foods
Staphylococcus aureus [1]	6.0[5]	4.5	0.83[5]	7.5	Eggs, poultry, meats, dairy products and confectionary
Campylobacter jejuni [3]	25	4.9	0.98	2.0	Poultry, meat and milk products
Yersinia enterocolitica [1]	-1.3	4.2	0.94	7.0	Fresh meats and milk
Listeria monocytogenes [1,7]	-0.4	4.3	0.92	12.0	Chilled foods, ready-to-eat foods, long shelf-life foods
Clostridium perfringens [2]	10	5.0	0.93	6.0	Cooked meat and poultry products
Escherichia coli O157 and other VTEC [1,4]	6.5	4.0	0.95	8.0	Meat, poultry, milk and vegetable products
Bacillus cereus [1]	4.0	4.3	0.92	7.5	Cooked rice and spices
Vibrio parahaemolyticus [1]	5.0	4.8	0.94	8.0	Fish and seafood products

[1] Grows either with or without oxygen (i.e. Facultative Anaerobes)

[2] Requires the absence of oxygen for growth (i.e. Anaerobic). Microorganisms which require oxygen for growth are Aerobic

[3] Requires limited levels of oxygen for growth (i.e. Microaerophilic)

[4] (VTEC): Verotoxigenic *Escherichia coli*

[5] For growth only: temperature 6°C and $a_W \geq 0.83$ For toxin formation: temperature 10°C and $a_W \geq 0.85$

[6] 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 the minimum a_W value is normally higher

[7] Generally ready-to-eat foods with a pH of ≤ 4.3 or $a_W \leq 0.92$, or with a pH of ≤ 5.0 and $a_W \leq 0.94$ are considered to be unable to support the growth of *L. monocytogenes* [(5)].

Table adapted from [(5, 22, 27, 31, 35-38)]

6.4 Determining the Shelf-life Based on Collected Data

Food products will have a different shelf-life based on their intrinsic and extrinsic properties (Section 6.3). The end point of product shelf-life is indicated by the 'use-by' date (Section 3). Data collected by FBOs on the intrinsic and extrinsic properties should establish if a food product requires a 'use-by' date declaration (Sections 6.2.2 - 6.2.3). If a food product does require a 'use-by' date, a reference point is required to allow the FBO to decide when the end of shelf-life has been reached. A non-exhaustive list of useful sources of data to help determine the end of shelf-life (i.e. 'use-by' date) is given in Table 3.

Table 3. References to Determine the End of Product Shelf-Life [1]

Source	Example and References (Appendix 3)
Legislation	European Union and Irish Legislation [1-5]
Standards (International)	International Standards Organisation
Standards (European)	European Committee for Standardisation
Standards (Irish)	National Standards Authority of Ireland [9-13]
Standards (Industrial)	An Bord Bia
Guidelines (International)	Codex Alimentarius
Guidelines (European)	European Food Safety Authority
Guidelines (Irish)	Food Safety Authority of Ireland [14-18]
Guidelines (Industrial)	American Meat Science Association
Guidelines (Institutional)	International Commission Microbiological Specifications Foods [34]
Guidelines (Market)	Analysing collected data on competitors products
Opinions (European)	European Food Safety Authority [37-38]
Opinions (Irish)	Food Safety Authority of Ireland
Published Literature	Scientific and Trade Journals
Professional Organisations	Institute of Food Science and Technology (United Kingdom) Institute of Food Technologists (United States of America)
Research	RELAY (Ireland) International Life Sciences Institute (ILSI)
Specifications	As agreed between the FBO and its customer
Consumer Complaints	Consumers Association of Ireland

[1] All sources of data in Table 3 are subject to change and revision and are illustrated for information purposes only.

When using any source of data the most recent version should always be used. Where a reference point (Table 3) to determine the end of product shelf-life is not available, the responsibility for food safety still rests with the FBO [1-2]. The use of challenge testing may be required (Section 6.7). Consultation with a competent body is strongly recommended. A non-exhaustive list of food products which typically require a shelf-life declaration is listed in Table 4.

Table 4. Examples of Foods Typically Requiring a Shelf-Life Declaration

Raw and Uncooked	Cooked Food
Uncooked or Untreated Products [1]	Ready-to-Eat Foods
Prepared Raw Mushroom Products	Chilled Ready Meals
Prepared Raw Fruit and Vegetable Products [2]	Chilled Pasta, Rice, Noodles and Pulses
Cold Smoked Meat and Fish Products	Processed Meats [3]
Fermented and Dried Meat and Fish Products [4]	Egg and Dairy Based Sauces [4]
Fresh Pasta and Noodles	Meat Gravies
Raw Meat	Hot Smoked Meat and Fish
Raw Seafood	Chilled Soups, Broths and Consommés
Raw Egg Products	Meat Pies and Pastries etc.
Raw Milk Products [5]	Seafood
Pre-Packaged Fresh Poultrymeat	Fermented and Dried Meat and Fish Products [3]
	Pasteurised Milk, Yoghurts and Cheese [7]
	Vegetables [6]
	Egg and Dairy Based Desserts [7]
	Confectionery Products [8]
	Vacuum-packed or MAP food requiring refrigeration [9]
	Some Meat and Milk Substitutes

[1] Comprising or containing ingredients of animal origin including meat, poultry, fish, dairy or egg
[2] Including juices prepared from raw fruit and vegetables
[3] Whether or not they are intended to be eaten without further reheating
[4] Not necessarily applicable to all varieties of these products as some may be frozen or ambient products
[5] Unpasteurised cheeses and other unpasteurised products, soft cheeses ripened by moulds and/or bacteria once maturation is completed
[6] Sliced/whole cooked meats and fish including hams, pate, some salami, and some fermented sausages (depends on processing, curing etc.)
[7] Dairy-based desserts (e.g. fromage frais, éclairs, products containing fresh cream)
[8] Particularly desserts containing fresh dairy cream or raw eggs such as cakes, pastries, mousse etc.
[9] Sliced cooked meats, pre-packaged sandwiches etc.

6.5 Applying a Margin of Safety

The reproducibility and reliability of the determined shelf-life will be affected by the intrinsic and extrinsic properties of a food product (Sections 6.2.4 - 6.2.6). However, it is unrealistic to expect the shelf-life of food products to be 100% reproducible every time and 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 the shelf-life of each product produced or packed by a FBO.

The margin of safety should be determined and applied by the FBO after examining all reasonably foreseeable conditions of processing and use. It is not possible to define exact margins of safety for food products in this Guidance Note as it will vary between different food products and businesses. However, possible variations in intrinsic and extrinsic properties (Section 6.3) should be taken into consideration by the FBO when applying the margin of safety.

Applying a margin of safety will reduce the shelf-life of a food product to a shorter interval than the determined shelf-life. This allows the FBO to take account of the reasonably foreseeable conditions of use which may affect product safety and shelf-life e.g. temperature abuse during storage. In applying a margin of safety, the FBO should take account of any expected variations in production, product storage (Section 6.2.6.1–6.2.6.9), distribution and use.

6.6 Is the Microbiological Quality of the Food Product in Compliance with Legislation?

Typically, it will be necessary to carry out some microbiological testing of food products to confirm a determined shelf-life. These tests will evaluate the growth of the microorganisms present in the food product under reasonably foreseeable conditions of distribution, storage and use. Tests should include the pathogens associated with the specific intrinsic and extrinsic properties of the food product (Table 2). Some of the questions FBOs may have in relation to microbiological testing of food products and shelf-life are outlined in Appendix 4.

However, due to reasons related to sampling, methodology and uneven distribution of microorganisms in food products, microbiological analysis of finished food products alone, is insufficient to guarantee the safety and shelf-life of the tested food product.

The safety of food products should be principally ensured by a preventative approach incorporating product and process design (Sections 6.2.5.1–6.2.5.9), application of GHP and GMP (Section 6.2.6.1) and HACCP (Section 6.2.6.2). Microbiological criteria can be used in validation and verification of HACCP procedures and other hygiene control measures (Section 3).

Food business operators using external laboratory services should only use laboratories with relevant expertise and accreditation to a recognised standard for microbiological testing and shelf-life evaluation of food products. Furthermore, FBOs should request the analysis of product properties, e.g. pH, a_w etc. rather than just provision of microbiological data from laboratories they use.

6.7 Challenge Testing

Challenge testing will establish and validate the safety of food products 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 FBO 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 (Table 2). Challenge testing may be required for food products where controlling factors, e.g. pH, a_w etc. for pathogen(s) has not been demonstrated by the food business. In addition, if no safety data are available for the product or a closely related product challenge testing may be required (Section 6.4).

Challenge testing must always be used with great caution. Consultation with a competent body is strongly recommended before its use. It is strongly recommended that FBOs only perform challenge testing if they have appropriate facilities, understanding, training and experience with these microbiological techniques. Preferably, external laboratories (with appropriate experience), off-site from the FBO should be used if challenge testing is required [20].

6.8 Predictive Mathematical Modelling

Laboratory based microbiological tests (Sections 6.6–6.7) 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 graphically describe the responses of microorganisms to specific intrinsic and extrinsic properties (Sections 6.2.5–6.2.6) without the need to carry out microbiological tests.

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 of microbial responses, and procedures to interpret and interact with the database in a mathematical model are then developed (i.e. predictive food microbiology).

Predictive mathematical models are normally developed assuming that microbial responses are consistent [20]. 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 mathematically models do not accurately predict the survival and growth of pathogens in food products [39].

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 (Sections 6.2.5–6.2.6). 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 (Section 6.1) to give an estimation of the shelf-life. A range of predictive mathematical modelling programs are available on the internet for download (Appendix 3).

Predictive mathematical models must be used with great caution and only used by trained, experienced personnel with an understanding of the limitations of use. Microbiological training and experience are required for their use. Consultation with a competent body is strongly recommended before their use.

6.9 Product Labelling

When a FBO has established the shelf-life of a food product, it is important that the product is correctly labelled in compliance with current food labelling legislation [4].

6.9.1 Storage and handling instructions

The particulars of the 'use-by' date (Section 6.2.2.1) must be followed on the product label by a description of the storage conditions which must be observed for the food product [4].

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 label [15]. The 'use-by' date applies to unopened food. A FBO should provide handling instructions for the food product once opened, e.g. once opened store in the refrigerator for two days only. In addition, other options for storage of products (if applicable) must be labelled [15].

6.9.2 Temperature controls

The storage temperature of food products before, during and after processing will directly influence the safety and shelf-life of the product. Regulation (EC) No. 853 of 2004 as related European Commission implementing Regulation lists the current legislative requirements in relation to temperature control of food products (Sections 1 - 2) [2].

Other labelling issues are discussed in Appendix 1.

Appendix 1. Legislative Issues on Labelling

1.1 Labelling Exemptions

The following foods are specifically exempt from carrying a date of minimum durability declaration [4]:

1. 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)
2. Wines, liqueur wines, sparkling wines, aromatised wines and similar products obtained from fruits other than grapes, and beverages falling within CN codes* 2206 00 91, 2206 0093 and 2206 00 99 and manufactured grapes or grape musts
3. Beverages with greater than 10% volume of alcohol
4. Soft drinks, fruit juices, fruit nectars and alcoholic beverages in individual containers greater than five litres intended to supply mass caterers only
5. Bakery products which are normally consumed within 24 hours of manufacture such as baguettes and cream buns
6. Vinegar (including wine vinegar)
7. Cooking salt (mineral and herbal salts are not included)
8. Solid sugar (sucrose). This exemption does not apply to fructose or sweeteners or mixtures of sugars
9. Confectionery products consisting of mostly flavoured or coloured sugars such as hard sweets. Toffee, winegums and fruit jellies are not exempt
10. Chewing gums or similar products
11. Individual portions of ice-cream

1.2 Labelling Derogations

The following foods have a specific derogation from the general labelling regulations and do not require a label which indicates the date of minimum durability [4]:

1. 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

* 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.

2. Pre-packaged flour confectionery for sale on the premises from which they are produced by the person producing the flour confectionery 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
3. 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. For example, ham slices at a deli counter
4. 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
5. 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 50g 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.

1.3 Other Date Marks

Some FBOs will label food product 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 labelling are sometimes used by suppliers for stock control purposes. From a consumer 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.

1.4 Instructions for Use

The FBO responsible for the production and/or packaging of a food product must determine whether that product is RTE or requires cooking, reheating or other proprietary preparation before consumption, to ensure its safety and compliance with relevant legislation. 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 [4, 15].

Appendix 2. Intrinsic Properties of Food Products

All values given are approximate and intended as a guide:

2.1 Formulation and Compositional Issues

Table 2.1 outlines a non-exhaustive list of examples of formulation and compositional issues which may affect the shelf-life of food products.

Table 2.1. Formulation and Compositional Issues

Issue	Example
An incorrect quantity of raw material/ ingredient is added to a product	Too little sugar is added to a jam and as the sugar has a preservative function the shelf-life of the jam is reduced
Raw materials and ingredients from different suppliers may have different levels of microbiological quality	The regular supplier of raw meat to a FBO cannot meet the order so the FBO orders from a competitor but the microbiological quality of the new suppliers meat is lower than the regular suppliers resulting in a reduction in final product shelf-life
A crucial raw material/ingredient is inadvertently omitted from a product completely	In producing a cooked ham, sodium nitrite is accidentally omitted in the curing solution, resulting in a product with increased susceptibility to pathogenic growth and a reduced shelf-life due to an increase in a_w
A raw material/ingredient is replaced with a different raw material/ingredient	White sugar (i.e. sucrose) used in jam is replaced with an artificial sweetener, e.g. aspartame which results in a product with a reduced shelf-life
Components of the food product are in close proximity to each other, causing migration of some of the components, e.g. flavours, odours, colours, water, fats within and out of the product	A cheese based sauce separates on standing as no emulsifier is present which results in a reduced product shelf-life
Combining individual raw materials/ ingredients which on their own are relatively microbiologically stable resulting in a product with a reduced shelf-life	A pre-prepared packaged sandwich

2.2 pH

Routine pH measurement of food products is common in all sectors of the food industry, particularly using hand-held pH metres. On a larger industrial scale, in-line pH measurement is becoming more common place.

Table 2.2. pH of Selected Foods [1]

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
Cow's Milk	6.2-7.3
Butter	6.1-6.4
Fresh Pork	6.0-6.2
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	4.0-4.5
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

[1] The pH of foods is inherently variable
Table adapted from [22, 29, 35]

2.3 a_w

Typically, bacteria require a higher a_w to grow than moulds or yeasts. Most foodborne pathogenic bacteria require an a_w > 0.91 to grow. However, *Staphylococcus aureus* can grow at an a_w of 0.83 (Table 2). Most spoilage bacteria do not grow below an 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 (i.e. microorganisms which live in high osmotic pressures) yeasts can grow at a_w between 0.65 and 0.61, respectively [22].

Table 2.3. a_w of Selected Foods [1]

Food	Water Activity
Distilled water	1.00
Fresh meats, poultry, fish, 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, maple syrup	≥ 0.80 – 0.93
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, breakfast cereals, milk powders and soup mix	≥ 0.20 – 0.30
Coffee powder	≤ 0.20

[1] Values taken at 20°C
The a_w of foods is inherently variable
Table adapted from [22, 26-27, 29]

2.4 Eh

The Eh values for various foods are given below in Table 2.4.

Table 2.4. Eh of Selected Foods

Food	Eh (Millivolts)
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

Table adapted from [22, 29]

When the Eh is measured, it should be quoted with the pH of the food product. Routine measurement of Eh in food products is quite simplistic. However, difficulties may arise in taking accurate, reproducible measurements and in accounting for differences in the Eh throughout a food product [29].

2.5 Measurement of pH, a_w and Eh

Advice on the choice of procedure to measure pH, a_w and Eh and the appropriate equipment should be sought from manufacturers or 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.

Appendix 3. Selected Data Resources*

A wide resource of data on food safety and food safety issues including shelf-life is available from the various Irish and international universities and institutions. In addition, many statutory and state bodies such as the FSAI have a wide resource of data available. This appendix is intended to act as a guide and does not purport to be comprehensive or applicable in every situation. FBOs are responsible for determining the safety and shelf-life of their products, under all reasonably foreseeable conditions of production, storage, distribution, display and use. A non-exhaustive selection of data resources is given below:

Athlone Institute of Technology	www.ait.ie/
An Bord Bia	www.bordbia.ie/
Carlow Institute of Technology	www.itcarlow.ie/news_events/index.php
Codex Alimentarius	www.codexalimentarius.net
Consumers Association of Ireland	www.consumerassociation.ie/
Dept. of Agriculture and Food	www.irlgov.ie/daff/
Excellence Ireland Hygiene	www.hygienemark.com/
Cork Institute of Technology	www.cit.ie/
Dublin Institute of Technology	www.dit.ie/DIT/Homepage/index.html
Dundalk Institute of Technology	www.dkit.ie/
European Committee for Standardisation	www.cenorm.be/cenorm/index.htm
European Food Safety Authority	www.efsa.eu.int
European Legislation	http://europa.eu.int/eur-lex/en/index.html
European Union Risk Analysis Information Network	www.eu-rain.com/
Food and Agriculture Organisation	www.fao.org/
Food and Drug Administration	www.fda.gov/default.htm
Food Safety Authority of Ireland	www.fsai.ie
Galway-Mayo Institute of Technology	www.gmit.ie/
Institute of Food Research	www.ifrn.bbsrc.ac.uk/
Institute of Food Science and Technology	www.ifst.org/
Institute of Food Technologists	www.ift.org/

* All websites referenced in this appendix were last accessed in November 2005

International Journal of Food Microbiology	www.elsevier.com/
International Life Sciences Institute	www.ilsi.org/
International Standards Organisation	www.iso.org/iso/
Irish Legislation	www.irishstatutebook.ie/front.html
Irish National Accreditation Board	www.inab.ie/
Journal of Food Protection	www.foodprotection.org/
Journal of Food Safety	www.foodscipress.com/
Limerick Institute of Technology	www.lit.ie/
Microbial Risk Assessment of Meat Products	http://smas.chemeng.ntua.gr/miram/
Physical Properties of Food Database	www.nelfood.com
Relay (Research for the Food Industry)	www.relayresearch.ie/
Teagasc	www.teagasc.ie/
National University of Ireland	www.nui.ie/
University of Limerick	www.ul.ie/
Waterford Institute of Technology	www.wit.ie/

Appendix 4. Microbiological Testing

This appendix is intended to act as a guide and does not purport to be comprehensive or applicable in every situation. FBOs are responsible for determining the safety and shelf-life of their products, under all reasonably foreseeable conditions of production, storage, distribution, display and use. A non-exhaustive selection of questions related to microbiological testing is given below:

4.1 How should food products be stored?

To determine an accurate, realistic shelf-life, microbiological data should be collected while food products are kept under reasonably foreseeable conditions of storage. Products for testing should not be stored at temperatures which do not reflect normal practice, even if these storage temperatures are not the recommended temperature, e.g. product should be stored at ≤ 3°C, however, in reality, the storage temperature can be ≤ 5°C. It is important to note that the shelf-life of food products produced and stored under specific conditions, e.g. refrigeration temperatures cannot be more rapidly determined by storing the product under different and unrealistic conditions, e.g. higher temperature. This is because microbial growth is influenced directly by extrinsic characteristics such as storage temperature.

4.2 How long should testing last?

Initially, shelf-life testing should last as long as the target 'use-by' date. For example, if a product has a target shelf-life of plus seven days (i.e. seven days after the day of manufacture) testing should last a minimum of seven days. Microbiological analysis should be performed during this period. If, after this time, the qualifying criteria are still being met (Table 3), the shelf-life can becontinued 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 FBO should either give the product the determined shelf-life or continue with product development and further testing until the desired shelf-life is achieved.

4.3 What samples are required for testing?

Samples should be the same as the final commercial product.

4.4 How many samples should be tested?

The number of samples to be tested should be based on experience with similar foods, and knowledge of the intrinsic and extrinsic properties of the food product. The nature of food products will largely determine the frequency of sample testing. For example, perishable food products may require testing at daily intervals while less perishable foods may only require twice weekly or weekly testing intervals.

4.5 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. This is because the distribution of microorganisms in food products is typically not uniform. In the absence of specified sample numbers [5] it is recommended that at least three random 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 FBO 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, then the sampling and testing plan should be implemented at each measurement point.

4.6 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 product shelf-life. However, FBOs must comply with the requirements of legislation on the microbiological criteria of food products [1, 5]. Competent bodies may also produce guidance on microbiological tests and associated microbiological criteria for food products [14].

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 were FBOs have insufficient resources to decide which microbiological tests may be required to determine product safety and shelf-life.

4.7 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 performed [5]. It is recommended that all microbiological tests are standard or recognised tests, e.g. ISO, EN, BS etc. However, a FBO may use alternative microbiological methods e.g. rapid microbiological methods if they provide equivalent results to standard methods and guarantees of food safety [5]. In this case, and where FBOs have developed their own (in-house) microbiological tests, they should be validated against a recognised standard method and accurately documented.

4.8 How do I interpret collected microbiological data?

The interpretation of data is only reliable if testing has been designed and implemented correctly, e.g. correct sampling plan. For example, if the shelf-life is determined during product development and this indicates that the shelf-life is unacceptable for the product's target market, then that product may have to be redeveloped. The data collected from microbiological testing should be compared to current microbiological criteria legislation, standards and guidelines.

4.9 What records and documentation should be kept?

It is recommended that FBOs document and record all data generated during shelf-life determination. The data can be used as verification of a determined shelf-life. Details of all methods, procedures and correspondence during determination should also be recorded and maintained as long as the product is manufactured. It is recommended that records should be held by FBOs for at least six months after the shelf-life of food products has expired.

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