WP3: Production of tools (M6-M24)
WP leader: UZAG PBF
Output: O3
Task 3.1: Good practice guidelines

O3: Division of work

Shelf-life guidelines for packaged food product

Partner: UZAG PBF

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1. Definition

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 (EU Regulation, 2011; EC Regulation, 2005).
The shelf-life of a product begins from the time the food is prepared or manufactured. Its length is dependent on many factors including:

- the types of ingredients,
- manufacturing process,
- type of packaging and
- storage conditions

Shelf-life is indicated by labelling the product with a date mark.

Shelf-life testing describes how long a food will retain its quality during storage. Controlling the pathogen content (safety) of foods should be achieved by using a Hazard Analysis Critical Control Point (HACCP) system. Predictive modelling or challenge testing can be used to assess pathogen growth.
During the shelf-life of a food it should:

- remain safe to eat
- keep its appearance (odour, texture and flavour)
- meet any nutritional claims provided on the label.

2. Labelling regulations relating to shelf-life

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 (EC Regulation, 2002; Newsome et al., 2014).
Under European legislation (EU Regulation, 2011), shelf-life is referred to as the "date of minimum durability". The date of minimum durability provides for two different indicators of food shelf-life (EU Regulation, 2011):

"Use-by" date – Used for food which is highly perishable from a microbiological point of view and therefore, after a relatively short period, these foods are likely to present a risk of food poisoning and so they constitute an immediate danger to human health. After the 'use-by' date has passed, a food is deemed unsafe (EU Regulation, 2011; EC Regulation, 2005) and must not be sold or consumed. Typically, a 'use by' date is used for fresh, ready-to-eat and chilled foods (such as yogurt, milk, meat, unpasteurised fruit juices etc.).

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"**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., and so related to the quality of the food. This is the point at which the taste or eating quality may begin to decline.
Typically, a 'best before' date is used for food products such as canned, dried, ambient, frozen foods etc. Many foods that past their 'best before' date may be safe to eat, but their quality may have been deteriorated. Legally food that has passed the best before date is still fit for human consumption and can be sold.

3. 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 (EC Regulation, 2002).

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 (FBO) to follow which will help them to accurately estimate, set and validate the shelf-life of foods.
The decision as to whether a food requires a 'best before' or 'use by' date should be taken when the food manufacturer or producer is developing their food safety management system, based on HACCP principles, for the product. It is strongly recommended that FBO document all work related to estimating, setting and validating food shelf-life. This will allow the FBO 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 FBO 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 FBO is confident that it can consistently produce the same food from batch to batch under real processing conditions (Kilcast and Subramaniam, 2000; Man 2004; Singh and Cadwallader, 2004; Adams and Moss, 1995).

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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

For good practice, FBO 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 (FSAI, 2017).

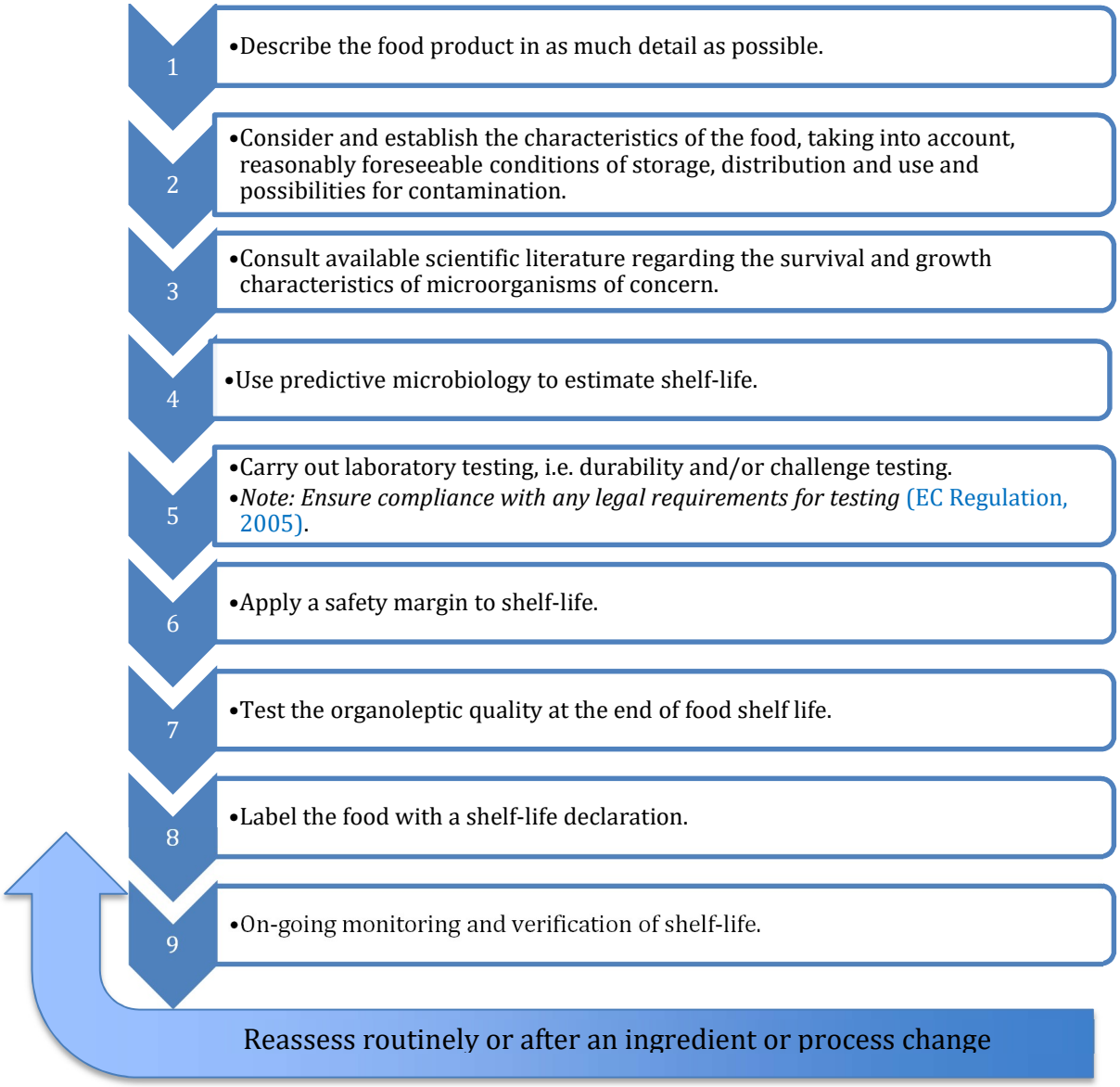

Figure 1. Good practice in estimating, validating and setting shelf-life (FSAI, 2017)

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4.1. Food product description

Typically, when a FBO 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 FBO include as much information as possible in this specification (Kilcast and Subramaniam, 2000; Man 2004; Singh and Cadwallader, 2004; Adams and Moss, 1995; Martins et al., 2008).

4.1.1. Ready-to-eat status of food

FBO 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 FBO should document this information and ensure it is consistent with the products labelling (EC Regulation, 2005).
Legal criteria for certain pathogens in certain types of ready-to-eat foods are set in EC Regulation (2005). With respect to *Listeria monocytogenes*, the Regulation sets legal criteria for this pathogen in all ready-to-eat foods. The Regulation emphasises the importance for manufacturers of ready-to-eat foods which 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 (EU 2008; EU 2014).

4.1.2. Product specification

A product specification should be documented by the FBO 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 FBO 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

There is no simple answer to the question how long a shelf-life should be for specific product. 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 FBO 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 (Table 1).
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 (Valero et al., 2012).

Table 1. Intrinsic and extrinsic characteristics of foods (Valero et al., 2012, FSAI 2017)

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

[a] 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.
[b] May also relate to intrinsic characteristics depending on the nature of the data

4.2.1. Intrinsic characteristics

4.2.1.1. pH and type of acid

The pH and acidity are very important intrinsic characteristics (Table 2) 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.

Table 2. pH values of canned food (Vitz et al., 2016)

Food system	pH	Classification
Canned cranberry juice	2.30-2.52	High acid foods
Vinegar	2.40-3.40	
Ketchup	3.89-3.92	Acid foods
Honey	3.70-4.20	
Bananas	4.50-5.20	Medium acid foods
Cottage cheese	4.75-5.02	
Corn flakes	4.90-5.38	Low acid foods
Cucumbers	5.12-5.78	
Oysters	5.68-6.17	
Cow's milk	6.40-6.80	
Tofu	7.0	
Camembert cheese	7.44	Alkaline foods
Cooked lobster	7.10-7.43	
Graham crackers	7.10-7.92	
Eggs white	7.96	

It should be noted that the mix and quantity of raw materials used in the development of processed food may also affect parameters such as leaching of colour in layered product or the rate of fat oxidation, which can influence consumer acceptance and thus, the shelf-life of the product.

4.2.1.2. 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 (Table 3) for moist fresh foods (Fontana 1998; Esse and Saari, 2004).
Water activity influences deteriorative chemical reaction rates because water can be a reactant itself, or can change the mobility of reactants through viscosity. One or a combination of any of these factors can lead to faster deterioration and a shortened food shelf life.

Table 3. The water activities (a_w) of some foodstuffs (Esse and Saari, 2004)

a_w	Typical food items
0.95-1.00	Fresh foods and meats, breads, approximately 40% sucrose, 8% NaCl
0.91-0.95	Medium cheeses, cured meat (ham), retail fruit juice concentrate, 55% sucrose, 7% NaCl
0.87-0.91	Fermented hard sausage, dry cheese, margarine, 65% sucrose, 15% NaCl
0.80-0.87	Commercial fruit juice concentrate, chocolate syrup, maple and fruit syrup, flour, fruit cake, fondants, high-ratio cake
0.75-0.80	Fruit and berry preserves, marmalade, marshmallows, meat jerky
0.65-0.75	Rolled oats, fudge, marshmallow, raisins, fruit preserves, molasses, nuts, soft prunes
0.60-0.65	Dried fruit (<20% water), toffee, caramels, honey
0.50-0.60	Pasta (12% water), spices
0.40-0.50	Whole egg powder (5% water)
0.30-0.40	Cookies, crackers, bread crusts (5% water)
0.20-0.30	Whole milk powder, dried vegetables, ready-to-eat cereals, hard cookies

4.2.1.3. Redox Potential

The redox potential (E_h,) like pH, is a parameter of the state of biological media which indicates the capacity to either gain or lose electrons.
E_h of a food (Table 4) 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. When the redox potential is measured, it should be referenced with the pH of the food, as it is dependent on the pH of the food.

Besides the measurements of redox potential in mV, it is more common to use rH value. The rH value is the negative logarithm of the partial pressure of the gaseous hydrogen (pH_2). Clark and Cohen introduced it in 1923 (Jacob, 1970) in order to eliminate pH dependence on the redox potential. rH of 0 corresponds to a pH_2 = 1 atm and pH = 0, to above rH = 42 corresponding to a solution in which pO_2 = 1 atm and pH = 0. Although Clark consider this definition as incorrect and useless, it is still use in practice.
However, in order to compare results with those in the literature using rH value become very convenient.
The measured redox potentials obtained at known pH with a selected reference electrode are referred to the pH dependent hydrogen electrode (E_h). The rH value can be calculated from the following formula (Jacob, 1970):

$$rH = \frac{E_h(in\ volts)}{0.03} + 2 \cdot pH$$

A potential of -530 mV (-0.53 V) is measured at pH 7.0, using a calomel electrode (280 mV at 25 °C). Therefore:

$$E_h = -530mV + 280mV = -250mV$$

$$rH = \frac{-250}{0.03} + 2 \cdot 7 = 8.3 + 14 = 5.7$$

E_h can also be calculated from reported rH values:

$$E_h = 0.03(rH - 2 \cdot pH)$$

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Table 4. The redox potential of different foodstuffs

Foodstuff	pH	Redox potential		Reference
		E_h/mV	rH	
Water extracted spices				
Pepper	6.0	149		Galić and Ciković, 1988
Red pepper	5.4	268		
Garlic	4.5	252		
Rosemary	6.0	250		
Protein solution 0.001 mol/L				
Methionine	5.9		21.2	Ciković and Galić, 1997
Cysteine	5.85		16	
Liquid food				
Fresh cow milk, 20°C		144		Pappas et al., 1989
Fresh sheep milk, 20°C		124		
Coffee	5.11		17	Ogrin Papić and Poljšak, 2012
Green tea	5.77		16	
Beer	4.5	365		Steiner and Länzlinger, 1986
Deaerated wort	5.6	290	21	
Pure wort			20-24	Galić et al., 1988; 1994
Sauvignon Blanc 1999	3.16	36	14.6	Kilmartin and Zou, 2001
Riesling 1999	3.10	65	15.4	
Riesling 1987	3.19	383	19.5	Dikanović–Lučan and Palić, 1992
Merlot 1987	3.50	376	19.9	
Pasteurized skim milk	6.69	225		Schreyer et al., 2008
Apple cider vinegar	2.8	425		Nojeim et al., 1981
Cranberry juice	2.7	401		
Distilled water	6.3	400		
Tomato juice	4.3	241		
Solid food				
Tomato paste in Al-tube, 4°C			14.5	Mesić et al., 1993
Carrot, sliced, in glass container	5.06	-018		Montville and Conway, 1982
Green beans, cut, in glass container	5.12	-149		
Asparagus, in glass container	5.46	-225		
Canned Spinach	5.19	-318		
Canned green beans	5.70	285		Nojeim et al., 1981
Canned sauerkraut	4.5	235		
Cheddar cheese		-118 to -126		Topcu et al., 2008
Raw meat (post-rigor)	5.7	-200		Adams and Moss, 1995
Raw minced meat	5.9	225		
Cooked sausages and canned meats	~6.5	-20 to -150		
Grape	3.9	409		
Pear	4.2	436		
Lemon	2.2	383		

4.2.1.4. 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 and vegetables/fruits (Figure 2). 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.
It is recommended that when FBO remove natural barriers from foods, an appropriate method to reduce microorganisms, e.g. washing, filtration, trimming etc., is used.

Figure 2. Natural barriers of some foods

4.2.1.5. 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.

4.2.1.6. 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, like allicin in garlic and onions and lysozyme in eggs and milk (Gyawali and Ibrahim, 2014). Some antimicrobial substances are also created during food processing, e.g. production of phenols during smoking (Lingbeck et al., 2014) or bacteriocins during fermentation (Tamang et al., 2016). Other antimicrobials can be added to foods, i.e. food additives to the extend shelf-life and/or inhibit pathogens.

4.2.1.7. 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 (LAB) 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, such as LAB, may also retard or prevent the growth of pathogens (Šušković et al., 2010). 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 (Adams and Moss, 1995).

4.2.1.8. Microbiological quality of ingredients

The microbiological quality of ingredients will affect the safety and shelf-life of foods. FBO 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 (Zwietering et al., 2016).

4.2.1.9. 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.

4.2.2. Extrinsic characteristics

4.2.2.1. Temperature

The safety and shelf-life of most foods but in particular foods which require refrigeration, is very dependent on temperature (Fu and Labuza, 1993). The control of temperature during all stages of food manufacture, storage (Table 5), distribution and use should be carefully considered, measured and documented by FBO as it can significantly affect shelf-life. In particular, FBO should consider if foods may be subject to temperature abuse during storage, distribution and use.

Temperature abuse is more likely to occur at loading and unloading of vehicles and whenever the supplier of the load does not bring the temperature of the load down sufficiently prior to transport. Since refrigerated trucks are not designed to cool a cargo during transport, the consequence can be major. In order to avoid claims, modern transport operators will measure the temperature of the load themselves prior to loading, or use a modern datalog system, which would register temperature abuse from the start of the trip (Thoden van Velzen and Lukasse, 2016).

Even with proper handling (e.g., hygienic steps used to prevent contamination), the grower/manufacturer/distributor continues to be responsible for ensuring that the environment for transportation and distribution is such that it controls not only biological, but also chemical and physical hazards.

Table 5. Practical storage life (PSL) for selected food products (McKenna, 2012)

Product	PSL (days) at different storage temperatures		
	12°C	-18°C	-24°C
Fruits			
Peaches, apricots, cherries	4	18	>24
Raspberries, strawberries (raw)	5	24	>24
Raspberries, strawberries (in sugar)	3	24	>24
Concentrated fruit juices	-	24	>24
Vegetables			
Asparagus	3	12	>24
Beans (green)	4	15	>24
Broccoli	-	15	24
Brussels sprouts	6	15	>24
Carrots	4	12	>24
Cauliflower	-	12	24
Corn on the cob	4	15	18
Mushrooms	2	8	>24
Peas	6	24	>24
Peppers (red and green)	-	6	12
French fried potatoes	9	24	>24
Spinach	4	18	>24
Onions	-	10	15
Leeks	-	18	-
Meat and meat products			
Beef, ground/minced	6	10	15
Beef steaks	8	18	24
Veal steaks	6	12	15
Lamb steaks	12	18	24
Pork (steaks, cuts, chops)	6	10	15
Bacon (sliced, vacuum packed)	12	12	12
Chicken (whole or cuts)	9	18	>24
Turkey (whole)	8	15	>24
Seafood			
Fatty fish (lazed)	3	5	>9
Lean fish	4	9	>12
Shrimps (cooked/peeled)	-	2	5
Eggs			
Whole egg	-	12	>24
Milk products			
Butter (lactic, unsalted, pH 4.7)	15	18	20
Butter (lactic, salted, pH 4.7)	8	12	14
Cream	-	12	15
Ice cream	1	6	24
Bakery and confectionery			
Cakes (cheese, sponge, chocolate, fruit)	-	15	24
Breads	-	3	-
Raw dough	-	12	18

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4.2.2.2. Gas atmosphere

The gas atmosphere and its composition which surround a food will affect shelf-life (Table 6).
Foods can be classified according to the degree of protection required (Table 7), such as maximum moisture gain/loss or O_2 uptake. This then enables calculations to be made to determine whether or not a particular packaging material would provide the necessary barrier required to give the desired product shelf-life. In the case of metal cans and glass containers, these can be regarded as essentially impermeable to the passage of gases, odours and water vapour, while flexible packaging materials can be regarded as permeable.
Typically, the gas atmosphere and its composition are altered using modified atmosphere packaging (MAP), i.e. gas flushing or vacuum packing (VP) to extend shelf-life (Emblem 2000; Brandenburg 2009; Tucker 2011; Galić, 2013). 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 and/or nitrogen, before sealing.

Table 6. Effect of different packaging applications on the dairy products shelf-life (Galić, 2016)

Dairy product	Packaging material characteristics	Packaging method	Storage conditions or shelf-life	Reference
Pasteurized (HTST) milk	PE/PAP/PE	Aseptic	14-17 days at 6 °C	Fromm and Boor, 2004
Pasteurized (HTST) milk	Bottle: PE-HD+TiO_2		2 °C (43d), 4 °C (36d), 9 °C (8d), 14 °C (5d), 16 °C (3d).	Petrus et al., 2010
	Pouch: PE-LD+TiO_2		2 °C (37d), 4 °C (35d), 9 °C (7d), 14 °C (3d), 16 °C (2d).	
Provolone (semi-hard drawn-curd) cheese	PA/PE (20/80µm): P(O_2)= 50 cm^3/m^2 24 h bar (at 23 °C)	CO_2/N_2: 10/90	100 days at 8 °C	Favati et al., 2007
		CO_2/N_2: 20/80	118 days at 8 °C	
		CO_2/N_2: 30/70	280 days at 8 °C	
		CO_2/N_2: 100/0	175 days at 8 °C	
		vacuum (control)	190 days at 8 °C	

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.
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" (EU Regulation, 2011). 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.

Table 7. Degree of protection required by various foods and beverages, assuming one-year shelf-life at 25°C (Salame, 1974; Robertson, 2013)

Food or beverage	Maximum O_2 gain (ppm)	Maximum water gain or loss
Canned milk, vegetables, flesh foods, baby foods, soups, and sauces	1–5	3% loss
Beers and wines	1–5	3% loss
Instant coffee	1–5	2% gain
Canned fruits	5–15	3% loss
Dried foods	5–15	1% gain
Dry nuts and snacks	5–15	5% gain
Fruit juices, drinks and carbonated soft drinks	10–40	3% loss
Oils, shortenings, and salad dressings	50–200	10% gain
Jams, jellies, syrups, pickles, olives, and vinegars	50–200	3% loss
Liquors	50–200	3% loss
Condiments	50–200	1% gain
Peanut butter	50–200	10% gain

4.2.2.3. Relative humidity

Relative humidity (RH) 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 FBO (Emblem 2000; Powers and Calvo, 2003). Some foods are expected to be dry, e.g. cereals, some moist, e.g. cooked meats, and others will be very wet, e.g. chilled chicken soup. If dry products like cereals are held at high humidity, the water activity will increase. The relative humidity is also associated with the storage and distribution temperature of foods (Paull, 1999).

4.2.2.4. Light

While food products may be exposed to daylight at various points in the supply chain, good working practices and the correct transport packaging should largely prevent this. However, the effects of exposure to artificial light when products are on display on the retail shelf and, to a lesser extent, when the consumer takes them home, should be considered (Conrad et al., 2005). These effects include colour fade, or product degradation (example vitamin C).
Regarding glass bottles, the brown container revealed more resistance to oxidative stability followed by colourless and black containers (Ramos et al., 2015). It is usually the high-energy UV part of the light spectrum which is concerned, i.e. around 290–400 nm. For foods containing fats the effect of exposure to light is more complex and critical, since light accelerates the oxidation process and therefore the shelf-life is reduced (Table 8). For this reason, potato crisps show a considerable increase in shelf-life if packaging with a light barrier, such as metallised film, is used (Emblem, 2000; Lu and Xu, 2009).

Table 8. Effect of light illumination (1.9 μW/cm^2) on the shelf-life of cookies in different packaging materials (Lu and Xu, 2009)

Package	Thickness (mm)	OTR (Barrer) x 10^{-3}	WVTR (g/m^2 d)	Rate of UV-light transmis-sion (%)	Shelf-life under ASLT (days)
Unpacked					32
PET/OPA/PE semi-transparent	170	2.6	1.81	42.9	52
OPA/PE, transparent	125	1.93	3.04	85.7	37
BOPP/vAl cPP, almost opaque	45	0.694	0.81	7.1	76

4.2.2.5. Packaging

Packaging provides a barrier between the food and the environment. It controls light transmission, the rate of transfer of heat, moisture and gases, and movement of microorganisms or insects. However, FBO 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 (Table 9).

Table 9. Shelf-life of instant coffee in different plastic packages for 20 and 50 grams packages (Alves and Bordin, 1998)

Package	Thickness (μm)	WVTR (g/m^2 day)	Shelf-life (Days)	
			25 g	50 g
PE-LD	30	6.1	15	16
BOPP/BOPP	20/40	1.2	84	94
PET met/PE-LD	12/70	0.9	108	112

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. FBO 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 (Emblem, 2000; Fellows, 2000).

4.2.2.6. 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 (Ozen and Floros 2001; Devlieghere et al., 2004; Min and Zhang, 2005;).

Non-thermal processes: high-pressure processing (HPP), thermosonication, pulsed electric fields (PEF) treatment, irradiation or ultraviolet (UV) light processing, cold plasma etc., do not utilize increased temperature to inactivate decomposing microorganisms and enzymes. This is the biggest advantage of non-thermal processes because this low-temperature pasteurization does not overcook food and/or degrade foods thermally (Min and Zhang, 2005). However, it is important to study not only the effects of these techniques on the inactivation of micro-organisms, but also the influence on the food product itself and on the packaging material (Table 10). The reason is that, in many of the non-thermal applications, the products is processed in their packaging (Galić et al., 2011).

For example, HPP technology involves different packaging considerations, based on whether a product is processed in-container or packaged after processing. The packaging material must be able to withstand the operating pressures, have good sealing properties, and the ability to prevent quality deterioration during the application of pressure. At least one interface of the package should be flexible enough to transmit the pressure. Thus, materials as metal, glass, or rigid plastic containers cannot be used. Due to the fact that air or gases are very compressible under high pressure, the more the headspace, the bigger the deformation strains on the packaging materials. The presence of headspace must be kept as small as possible (Rastogi et al., 2007).

Table 10. Effects of processing techniques on the packaging material properties

Packaging material	Effect of processes	Reference
High pressure processing		
PET/PA/Al/PP	No detectable PG migration	Schauwecker et al., 2002
PA/EVOH/PE	PG migration: • similar at 30, 50, 75 °C after 10 min at atmospheric pressure, • significantly decreased at high pressure (200, 400, 690 and 827 MPa) at 30, 50, and 75 °C.	
PE/PA/Al/PP	PG migration • at 75, and 50 °C, was significantly higher than the amounts detected at 30 °C. Visible signs of delamination was between the PP and Al layers (at≥200 MPa and 90 °C for 10 min)	
Ionizing radiation		
BOPP; EVAC; PE-LD; PE-HD; PS; Ionomers	No significant changes in gas or water vapour permeability (5, 10 and 30 kGy). Tensile strength, percentage elongation at break and Young's modulus remained unaffected (5 and 10 kGy). 30 kGy increase overall migration values of BOPP and decrease in PE-HD and Ionomers. Tensile strength of PE-HD, BOPP and Ionomers decreased (at 30 kGy). Mechanical properties of PS and EVAC remained unaffected at 30 kGy.	Goulas et al., 2002
Ultrasound		
BOPPcoex; BOPP/AcPVDC	O_2 permeability increased at highest HPUS treatment (6 min; 100% amplitude)	Ščetar et al., 2017
Ozone		
OPP; BOPA	Significant changes in the thermal properties. Tensile strength (24 h exposure, 4.3 mg/L of ozone) of OPP decreased (75%), and in BOPA increased (30%)	Ozen and Floros, 2001
PE-LLD; BOPA	O_2 permeability decreased considerably with increasing treatment time	

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4.2.2.7. 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 FBO 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 (Kilcast and Subramaniam, 2000).
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. If an inappropriate storage temperature, e.g. recommended temperatures for distribution, catering and retail 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.
Consumer practices during purchase, storage and use are predominately outside the control of the food business operator. Scientific studies of consumer practices and performance of domestic refrigerators have shown a relatively poor understanding of basic food hygiene and food safety, particularly temperature control among consumers.
As such, FBO 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. 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 (EU Regulation, 2011).

4.2.2.8. 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 good hygiene practices (GHP) and the development and implementation of procedures based on HACCP are fundamental in maintaining food safety and setting and validating food shelf-life. All food business operators, including primary producers, are legally obliged to implement GHP. EU Regulation (2006) on GMPs recognizes that business operators should establish an effective quality management system at their facilities, which should be adapted to their position in the supply chain. Industrial associations that have issued guidelines for GMPs are, for instance: British Glass for glass (2009); CEPE for coatings (2009); EMPAC for metals (2009); CEPI for paper and board (2010); EuPIA for printing inks (2011); Plastics Europe, EuPC, and FCA-CEFIC for plastics (2011); FPE and CITPA for flexible and fiber-based FP (2011); CEFIC, CEPI, CITPA, and FPE for paper and board (2012); EAA for aluminium (2012); SPI for plastics (2012); ECMA for cartons (2013); FoodDrinkEurope for recycled paper and board, and printed cartons (2014); FEICA for adhesives and sealants (2015); etc. (Ariosti, 2016).

4.2.2.9. 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. Procedures based on HACCP provide a structured systematic approach to food safety, which involves identifying potential hazards and planning for their monitoring and control (Wallace and Mortimore, 2016). 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.

4.2.2.10. Historical data

Historical data are an important component of records which all FBO 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 (FSAI, 2017).

4.2.2.11. 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. (FSAI, 2017).

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5. Shelf-life study

Depending on the product nature and all above mentioned facts, various quality indices must be experimentally followed as a function of time in order to evaluate the degradation of the product quality in terms of the sensory, the microbiological and the physicochemical properties (Labuza and Contreras-Medellin, 1982). In order to fully account for all the degradation criteria, a well-planned experimental investigation and analysis must be adopted (Figure 3).
A shelf-life study is an objective, methodical means to determine how long a food product can reasonably be expected to keep for, without any appreciable change in quality. A separate study needs to be carried out for each type of product. The two main methods are used: direct and indirect (Fu and Labuza, 1993; Betts and Everis, 2000; Man 2004; Singh and Cadwallader, 2004; NZFSA, 2005; Valero et al., 2012).

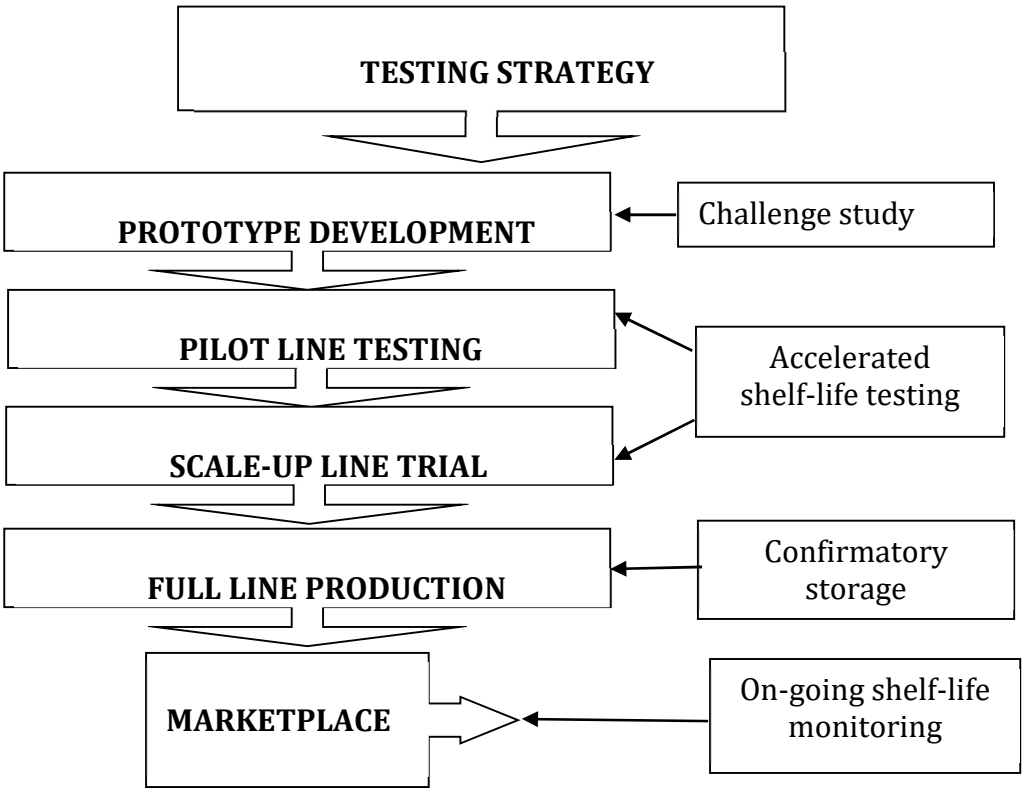

Figure 3. Shelf-life testing strategy at different product development stage (Fu and Labuza, 1997)

5.1. Determination of shelf-life by the direct method

Direct method is the one most commonly used for shelf-life determination (Figure 4). It involves storing the product under preselected conditions for a period of time longer than the expected shelf-life and checking the product at regular intervals to see when it begins to spoil. It is important to mention that the exact procedure is unique for each product.

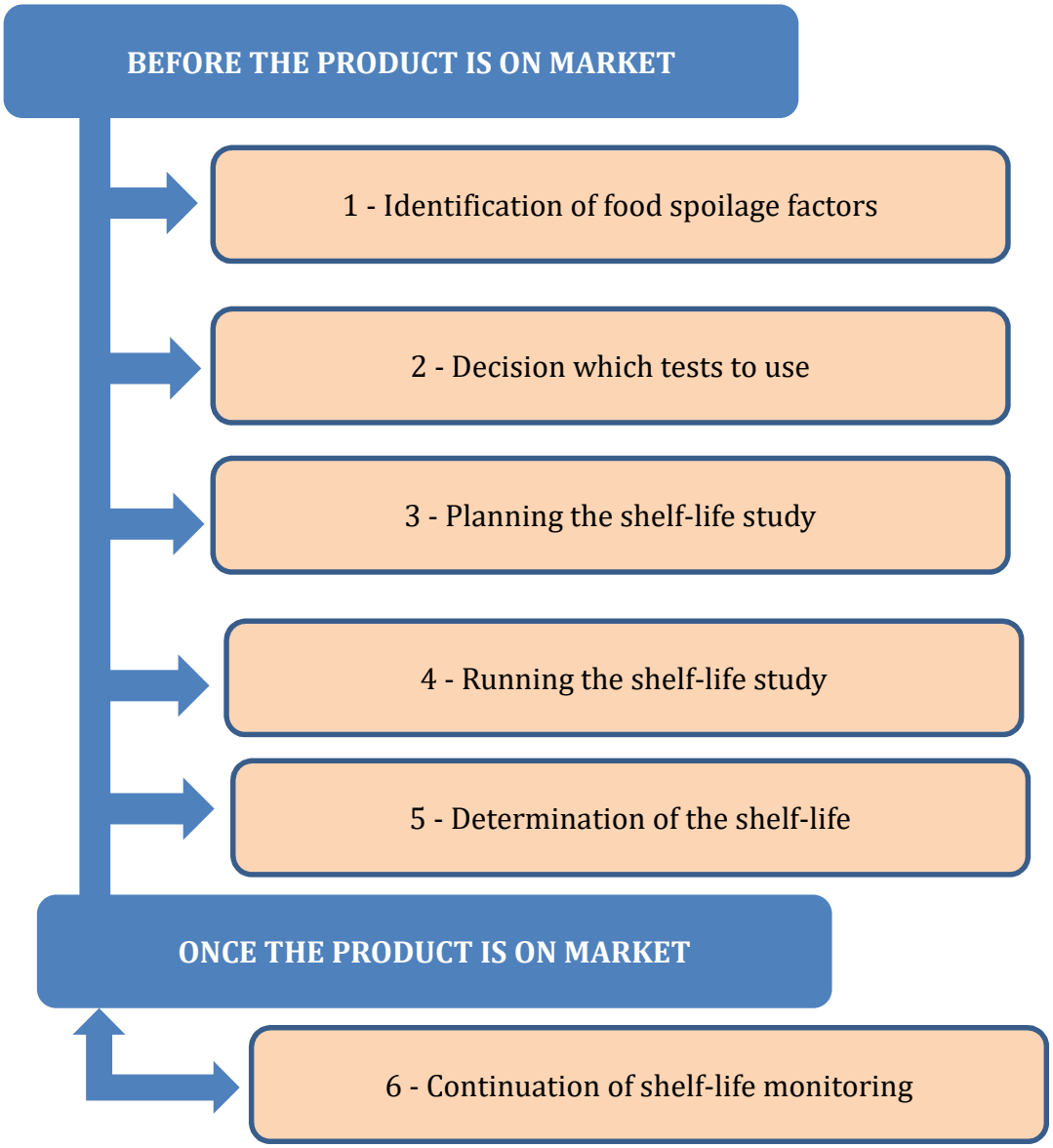

Figure 4. Steps involved in shelf-life determination by the direct method (NZFSA, 2005)

STEP 1. Identification of food spoilage factors

Each product has its own set of factors that may limit its shelf-life. The following lists can be used as a starting point to help identify all the possible ways that the product may deteriorate in quality and/or safety. It is also important to identify the factors that can help to prolong the shelf-life. Here, it is important to consider the entire process, from the purchase of ingredients and packaging materials right through to the end use by the consumer. The time of year is factor to be considered as well, as some products will deteriorate faster in summer than in winter due to higher temperatures.

Product related spoilage includes everything from raw materials, ingredients used, intrinsic and extrinsic factors, packaging and storage conditions. It is important to select proper package material, package size and packaging method (vacuum, nitrogen flushing, modified atmosphere packaging, etc.).

The specific location of the samples should be recorded. Temperature controllers should be checked for accuracy periodically.

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At this point all the possible ways the product could deteriorate and the factors involved should have been identified.

STEP 2. Decision which tests to use

Suitable tests for determining the safety and quality of the product need to be selected. It is well known that all tests are not appropriate for all products. If laboratory tests are needed, the best practice is to select the laboratory which is accredited for those tests. In general, tests can be divided into the following **four** categories:

1. Sensory evaluation

Sensory evaluation assesses characteristics of food such as smell, appearance, flavour, and texture. It can be used to monitor and record obvious changes that occur over time, and is therefore, useful when determining the shelf-life of a food. The food should be assessed under the conditions at which it is designed to be stored and consumed. Ideally, this should be done by a trained panel using recognised evaluation methods.

It is important to check if the food is safe to eat before using a taste panel.

If possible, without destroying the texture or other properties of the food, samples should be frozen at the beginning of the study. These can then be used as a comparison (control sample) at each testing session. If the food cannot be frozen, it is recommended to use a freshly prepared sample (which however may not be identical to previous one) as a comparison.

2. Microbiological

These tests can be used to evaluate both food quality and safety.

3. Chemical

Chemical tests can detect changes in the product's quality throughout its shelf-life. Examples of instrumental chemical tests include pH, headspace gas analysis, free fatty acids, etc.

4. Physical

These include tests for measuring product texture, examination of packaging, 'travel tests' and determining the best, worst and average retail conditions. A 'travel test' helps to identify any hazards involved in transport and handling. It involves transporting the product through the expected distribution and storage chain.

STEP 3. Planning the shelf-life study

Following points need to be considered when preparing detailed shelf-life study plan:

1. What tests need to be carried out?

2. How long will the study run for, and how often will the tests be carried out?

Here, actual sampling dates are included in the plan. It is suggested that sampling be carried out at the beginning, at the target end point and at about three occasions in between. Another sampling should be carried out beyond the target to confirm the end point selection.

3. How many samples will be tested each time?

At least triplicate packs of product should be tested at each sampling,

4. How many samples will be needed for the whole study period?

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5. When will the study be run? Ideally it should be carried out in the season most likely to cause problems, usually summer. The study should be carried out more than once to take account of variability of the product. The product, process and packaging should be the same as it is intending to use for the final product. Written records of everything is used or done should be kept, as they are helpful in results interpretation.

Before running the shelf-life test, it is advisable to check availability of ingredients, packaging materials and storage space, time and resource available for sample preparation. Check the time and resources available in laboratories involved in this protocol. A copy of the test request and schedule should be sent in advance to those who will be doing the work. Mark holidays and weekends on scheduling calendar and arrange testing in the case when important data points should not be skipped.

STEP 4. Running the shelf-life study

During the study samples should be stored under the same conditions as normal production samples, from manufacture through to consumption. If this is not possible the samples should be stored at a known temperature and humidity. These data need to be checked and recorded regularly.

STEP 5. Determination of the shelf-life

Eventually a point is reached when the product no longer meets the quality standard. Using all the information recorded and observed, it can be now decided how long the product can be kept and still be of an acceptable quality and safety. However, maximum storage times for quality and safety may not be the same. The shelf-life of a product should be whichever is shortest.
It is important to look at the test results and if any of them do not make sense, repeat them. If the results still do not make sense or are variable, check that the ingredients, their quality and the processing are the same for all batches. Determine what is causing the variability; fix it, then repeat the sampling and tests.

Now the shelf-life is estimated, based on ideal storage conditions. It is well known fact that in the 'real world' storage conditions may be variable, and product abuse can occur. The shelf-life selected for the product should be reasonable, not ideal, and one should allow a safety margin. The possibility of product abuse can be limited to some extent by specifying the storage conditions for the product and limiting its distribution.

STEP 6. Monitoring the shelf-life

Samples should be tested for the factors that the shelf-life study indicated were the most important for that product, e.g. acidity, loss of flavour, level of spoilage organisms etc. Samples could also be taken from various points within the distribution and retail system. If this testing shows that the preliminary shelf-life is inappropriate, it should be adjusted.

It is also critical that the shelf-life study is repeated after any changes have been made in the production or the processing environment.

A longer shelf-life may be developed by identifying the limiting factors in the shelf-life study, modifying them and repeating the study.

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Investigating customer complaints relating to product failure before the expiry date may help to identify a recurring problem and indicate a need to recalculate the shelf-life. The records made while designing and carrying out the shelf-life study will assist in the evaluation of customer complaints, trouble shooting, production and distribution problems and in reviewing the shelf-life of the product. It is important that all test results are written down and that these records are kept in a safe, but accessible, place.
Continue to monitor the product to ensure it is safe and of good quality throughout its whole shelf-life.

Shelf-life test is completed when a termination summary has been written (Figure 5).

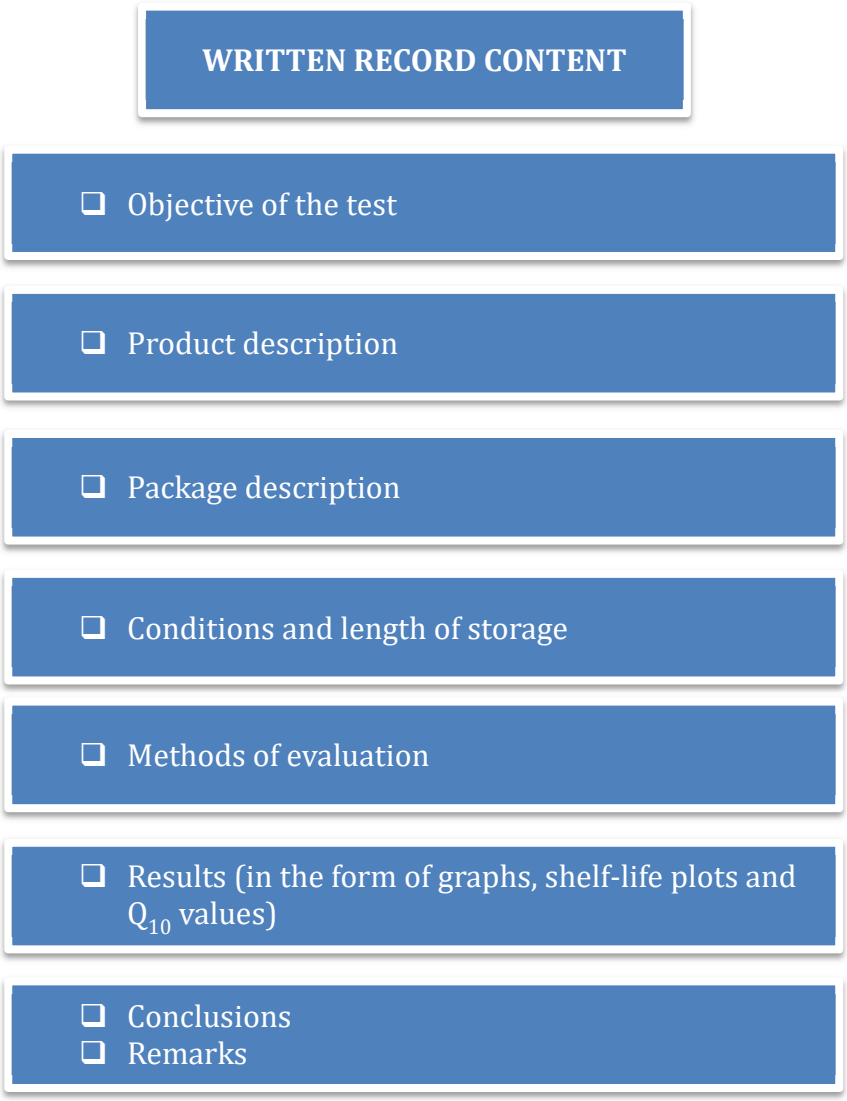

Figure 5. Content of the shelf-life written record

Termination summaries should become a permanent record in the company library for future reference and preferably indexed well on a computer data base for later retrieval when needed.

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The final shelf-life should also be set to give a clear margin of safety. In any case, the shelf-life of a new product, particularly of the high risk category, should be set based on data that relate to the worst case manufacturing and storage scenario. The shelf-life can then be reviewed and if necessary re-set in the light of further experience in manufacturing and control after the product has been launched.

5.2. Determination of shelf-life by the indirect methods

Indirect methods attempt to predict the shelf-life of a product without running a full length storage trial. These tests can be useful for products with long shelf lives. This approach uses accelerated storage and/or predictive microbiological modelling to determine a shelf-life.

5.2.1. Accelerated shelf-life studies

For practical reasons, especially when the actual storage time is long, the industry resorts to accelerated test techniques that considerably shorten the process of obtaining the necessary experimental data. Therefore, accelerated shelf-life testing (ASLT) is referred to any method that is capable of evaluating product stability, based on data that are obtained in a significantly shorter period than the actual shelf-life of the product. ASLT is applicable to any deterioration process that has a valid kinetic model. That process may be chemical, physical, biochemical or microbial. The principles of the ASLT will be the same in all cases (Taoukis et al., 1997; Mizrahi, 2004).
ASLT involves the use of higher testing temperatures in food quality loss and shelf-life experiments and extrapolation of the results to regular storage conditions through the use of the Arrhenius equation. Thus the testing time is substantially reduced.

ASLT: Controlled testing conditions in time

Example: 40°C; 90% RH

A reaction of an average E_A of 90 kJ/mol may be accelerated by 9 to 13 times with a 20 °C increase in the testing temperature, depending on the temperature zone. Thus an experiment that would take a year can be completed in about a month. Designing a shelf-life test is a synthetic approach that requires sufficient understanding of all food related disciplines, namely food engineering food chemistry, food microbiology, analytical chemistry, physical chemistry, polymer science and food regulations.

The following steps outline the ASLT procedure (Taoukis et al., 2015):

1. Evaluate the microbiological safety factors for the proposed food product and process. Use of the Hazard Analysis Critical Control Point (HACCP) principles is a good approach to be followed from the design stage. If major potential problems exist at this stage (i.e. CCP's exist that are difficult to control), the formula or process should be changed.

2. Determine from a thorough analysis of the food constituents, the process and the intended storage conditions, which biological and physicochemical reactions will significantly affect shelf-life and hence can be used as quality loss indices. A good knowledge of the system, previous experience and a thorough literature search are the tools to fulfil this step. If from this analysis it seems likely, without actual testing, that required shelf-life is not likely to be achieved because of serious quality loss potential, product design improvement must be considered.
3. Select the package to be used for the shelf-life test. Frozen, chilled and canned foods can be packaged in the actual product packaging. Dry products should be stored in sealed glass containers or impermeable pouches at the product's specified moisture and a_w.
4. Define the test's storage temperatures. The Table 11 can be used as guideline.

Table 11. Test storage temperature (Robertson, 2013)

Product type	Test temperatures (°C)	Control (°C)
Canned	23, 30, 35, 40	5
Dehydrated	23, 30, 35, 40, 45	0
Chilled	5, 10, 15, 20	0
Frozen	-5, -10, -15	<-40

5. From the desired shelf-life at the expected storage and handling temperatures, and based on available information on the most likely Q_{10}, calculate testing time at each selected temperature. If no information is available on the expected Q_{10} value, minimum three testing temperatures should be used.
6. Decide the type and frequency of tests to be conducted at each temperature. A useful formula to determine the minimum frequency of testing at all temperatures based on the testing protocol at the highest temperature is:

$$f_2 = f_1 \cdot Q_{10}^{\Delta T/10} \qquad (1)$$

Where:
f_1 is the time between tests (e.g., days, weeks) at highest test temperature T_1;
f_2 is the time between tests at any lower temperature T_2; and
ΔT is the difference between T_1 and T_2.

Thus, if a canned product is held at 45 °C and tested once a month, then at 40 °C (i.e. $\Delta T=5$) and a Q_{10} of 3, the product should be tested at least every 1.73 months:

$$f_2 = 1 \cdot 3^{(\frac{5}{10})} = 1.73 \; months$$

Usually, more frequent testing is recommended, especially if the Q_{10} is not accurately known. Use of too long intervals may result in an inaccurate determination of shelf-life and invalidate the experiment.
At each storage condition, at least six data points are required to minimize statistical errors; otherwise, the statistical confidence in the obtained shelf-life value is significantly reduced.

7. Plot the data as it is collected to determine the reaction order and to decide whether test frequency should be altered. It is a common practice for the data not to be analysed until the experiment is over and then it is recognized that changes in the testing protocol, affected early on, would have added significantly to the reliability of the results.
8. From each test storage condition, determine reaction order and rate, make the appropriate Arrhenius plot, and predict the shelf-life at the desired actual storage condition. Product can also be stored at the final condition, to determine its shelf-life and test the validity of the prediction. However, in industry this is uncommon because of time and cost constraints. It is a much more effective and realistic practice to test the obtained predictive shelf-life model by conducting an additional test at a controlled variable temperature.

With an effective use of ASLT, an experiment that normally takes a year, can be completed in about a month, if the testing temperature is raised by 20 °C. The duration of the shelf-life determination by ASLT depends on the E_A of the quality deterioration phenomena as shown in Table 12 (Taoukis et al., 2015).

Table 12. Time to complete ASLT test for low moisture food product of 2 years targeted shelf-life at ambient storage depending on the temperature sensitivity (E_A) of the shelf-life determining reaction (Taoukis et al., 2015).

E_A (kJ/mol)	ASTL storage temperature	
	Testing time at 40 °C (days)	Testing time at 45 °C (days)
45	224	171
85	78	47
125	28	13

To predict the actual shelf-life, it is important to evaluate how the deterioration process behaves as a function of time. In chemical reactions that information is provided by the order of reaction (n). In the case of monitoring the change in concentration A of a component of interest, the kinetic equation may be expressed as (Mizrahi, 2004):

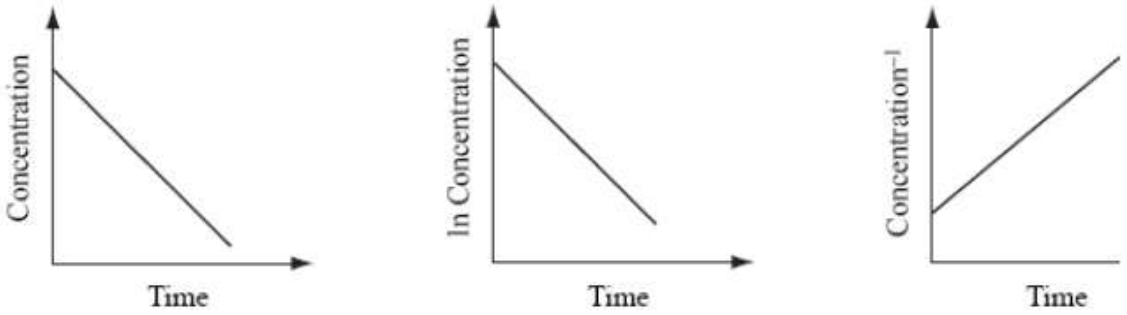
$$rate = -\frac{d[A]}{dt} = k\,[A]^n \qquad (2)$$

The equations given in the Table 13 are obtained for n = zero (0), first (1) and second (2) order.

Table 13. Reaction order (n) using the integrated rate equations

n	Rate Law	Integrated Form, $y = mx + b$	Straight Line Plot	Half-Life $t_{1/2}$
0	$rate = k[A]^0 = k$	$[A]_t = -kt + [A]_0$	$[A]_t$ vs. t (slope = $-k$)	$t_{1/2} = \frac{[A]_0}{2k}$
1	$rate = k[A]^1$	$\ln[A]_t = -kt + \ln[A]_0$	$\ln[A]_t$ vs. t (slope = $-k$)	$t_{1/2} = \frac{\ln 2}{k} = \frac{0.693}{k}$
2	$rate = k[A]^2$	$\frac{1}{[A]_t} = kt + \frac{1}{[A]_0}$	$\frac{1}{[A]_t}$ vs. t (slope = k)	$t_{1/2} = \frac{1}{k[A]_0}$

The useful feature of these equations is that they may be written in straight-line form, $y = mx + b$ (where m = *slope* and b = *y-intercept* are constants, Figure 6).



Zero order
k = negative slope

First order
k = negative slope

Second order
k = the slope

Figure 6. Graphical presentation for order reaction

The value of the quality index A_{t_s} that corresponds to the limit of acceptability of the food can be translated to a value of the quality function $f_q(A_{t_s})$. The time to reach this value at specified conditions, i.e. the shelf-life, t_s, is inversely proportional to the rate constant at these conditions:

$$t_s = \frac{f_q(A_{t_S})}{k} \qquad (3)$$

Most reactions responsible for shelf-life loss, based on a characteristic physicochemical, chemical or microbial index, have been classified as zero-order (e.g. frozen food overall quality, Maillard browning) or first-order (e.g. vitamin loss, oxidative colour loss, microbial growth).

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Kinetic equations for shelf-life estimation are specific to the food studied and the environmental conditions used. Among the environmental factors considered, the one being invariably emphasized and introduced in the shelf-life model is temperature. It strongly affects post-processing reaction rates and during subsequent handling, distribution and storage cannot be controlled a priori by means such as food packaging and depends on the imposed environmental (storage) conditions. Of the mathematical equations that have been proposed to describe the temperature dependence of the quality loss rate, the Arrhenius relation, derived from thermodynamic laws and statistical mechanics principles, is the most widely used. The Arrhenius relation, developed theoretically for reversible molecular chemical reactions, has been used to describe the effect of temperature on the rate of several reactions of quality loss, as follows (Mizrahi, 2004; Robertson, 2010):

$$k = k_A exp\left(\frac{-E_A}{RT}\right) \qquad (4)$$

where k_A represents the Arrhenius equation constant and E_A, in joules per mole, is defined as the activation energy, i.e. the excess energy barrier that quality parameter A needs to overcome to proceed to degradation products. R is the universal gas constant (8.3144 J/mole K) and T is absolute temperature (K).

To estimate the effect of temperature on the reaction rate of a specific quality deterioration mode, values of k are estimated at different temperatures in the range of interest, and ln k is plotted against the term of $1/T$ in a semilog graph (Figure 7). A straight line is obtained with a slope of $-E_A/R$ from which the activation energy is calculated.

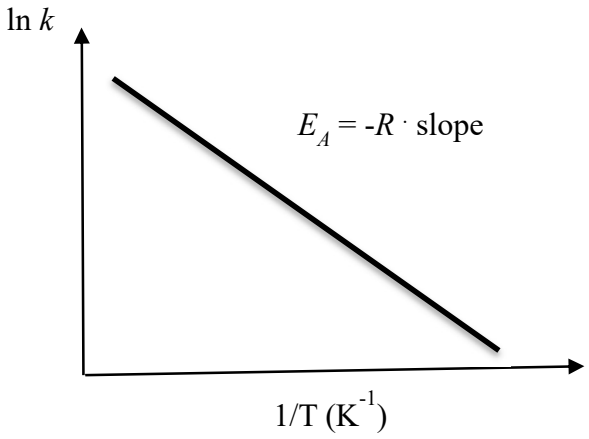

Figure 7. Arrhenius plot

An alternative to the Arrhenius law to describe the temperature dependence of reaction rates is through the Q_{10} concept. Q_{10} is the ratio of the reaction rate constants at temperatures differing by 10 °C or, equivalently, it shows the reduction of shelf-life t_s when the food is stored at a temperature 10 °C higher:

$$Q_{10} = \frac{k_{(T+10)}}{k_{(T)}} = \frac{t_{s(T)}}{t_{s(T+10)}} \qquad (5)$$

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The Q_{10} approach in essence introduces a temperature dependence equation in the form of the following equation:

$$k(T) = k_o e^{bT} \rightarrow lnk = lnk_o + bT \quad (6)$$

which implies that if ln k is plotted against temperature (instead of $1/T$ of the Arrhenius equation), a straight line is obtained. Alternatively, shelf-life (t_s) can be plotted against temperature, as follows:

$$t_s(T) = t_{s_o} e^{-bT} \rightarrow lnt_s = lnt_s - bT \quad (7)$$

where the resulting plots are often called shelf-life plots, where b is the slope of the shelf-life plot and t_{so} is the intercept (Figure 8).

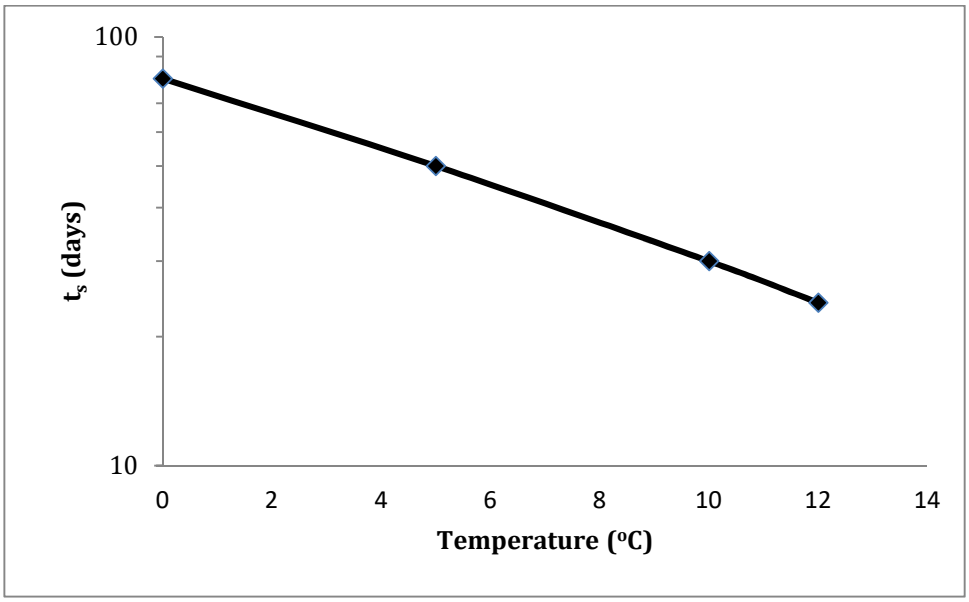

Figure 8. Shelf-life plot

Shelf-life plots are practical and easier to understand as one can read directly the shelf-life of the food at any storage temperature. These plots are true straight lines only for narrow temperature ranges of 10-20 °C.
If the temperature differenced is ΔT rather than 10 °C, the following equation can be used:

$$(Q_{10})^{\Delta T/10} = \frac{t_s(T_1)}{t_s(T_2)} \quad (8)$$

For example, if the Q_{10} for the key deteriorative reaction was 3 and the shelf-life t_s at 37 °C was 4 months, then the shelf-life at 23 °C would be:

$$t_{23} = t_{37}\, x\, (Q_{10})^{\Delta/10} = 4\, x\, (3)^{14/10} = 18.6\, months \quad (9)$$

If, however, the Q_{10} was 2 rather than 3, then:

$$t_{23} = t_{37}\, x\, (Q_{10})^{\Delta/10} = 4\, x\, (2)^{14/10} = 10.5\, months \quad (10)$$

This example illustrates the importance of having an accurate estimate of Q_{10}. It can be shown when the Arrhenius model is used that:

$$lnQ_{10} \approx \frac{10E_a}{RT^2} \quad (11)$$

Note that Q_{10} is not constant but depends on both the E_a and the temperature; when Q_{10} is reported, the temperature ranges over which it applies should also be specified (Robertson, 2010).

5.2.2. Predictive Modelling

Predictive models are mathematical equations which use information from a database to predict bacterial growth under defined conditions. Predictive models can be used to calculate the shelf-life of a food. Information on the changes that occur in the product when it deteriorates, the properties of the product and packaging is required for the calculations. Most predictive models are specific to particular types of organisms.

Models are useful as a first step in the evaluation of a product's shelf-life. However, information from modelling programmes needs to be verified by challenge testing or a shelf-life trial (durability study). Food safety and technology consultants should be able to assist with specific predictive modelling trials or problems. Predictive microbiological models are normally developed assuming that microbial responses are consistent. 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 (NZFSA,2005; Del Nobile and Conte, 2013; FSAI, 2017).

5.2.3. Challenge testing

Challenge testing is used to assess whether a product formulation and storage conditions of a food can control the growth of pathogens, if present, during the designated shelf-life. The procedure involves inoculation of the product with relevant microorganisms and incubation of the product under controlled environmental conditions in order to assess the risk of food poisoning, or to establish product stability.
A challenge study is often used in the laboratory to study the factors and factor interactions as they affect the shelf-life of the product. Such simulated experiments enable the researcher to better control the study (NZFSA, 2005; NACMCF, 2010; FSAI, 2017).

A challenge study is necessary for frozen foods for two reasons:
(i) to predict:

- microbial growth and potential risk of the product upon temperature abuse in a distribution chain

(ii) to assess:

- the relative stability
- the relative risk of different formula,
- different processes or
- different packaging materials, which is a must in new product development.

- A challenge study may also be considered as a preliminary shelf-life determination in terms of microbiological safety.
- It is often used in the early stage of development since if microbial safety is a concern at this stage, then reformulating can be done quickly.

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

For example, the EURL *Lm* technical guidance document (ANSES, 2014) is basically intended for laboratories conducting challenge tests and durability studies on *L. monocytogenes* in RTE foods, on behalf of the FBOs. These laboratories should have the required expertise for such studies and demonstrate good laboratory practices. This document describes laboratory studies, challenge tests and durability studies related to the growth of *L. monocytogenes* in RTE foods, and it is mainly dedicated to packaged products. Challenge tests for packaged products should be conducted using the product in its final packaged format including gas atmosphere if present. For products which are intended to be displayed in bulk (i.e. large blocks of cheese, pieces of ham or tubs of deli-salads), the tests should be conducted using the typical packaging which is expected to be supplied to consumers (e.g. ham may be overwrapped with packaging film, salads may be filled into plastic pots). The aim of a challenge test is to simulate as closely as possible the likely storage conditions of the product. The challenge test report should record what packaging and storage conditions were used as the results are not applicable to different storage conditions.

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Abbreviations	Description
AcPVDC	Acrylic coated poly(vinylidene chloride)
Al	Aluminium
ASLT	Accelerated shelf-life test
a_w	Water activity
BOPA	Biaxially oriented polyamide
BOPP	Biaxially oriented polypropylene
BOPP coex	Biaxially oriented coextruded polypropylene
BOPP/vAl cPP	Biaxially oriented polypropylene vacuum aluminized cast polypropylene
CEFIC	European Chemical Industry Council
CEPE	European Council of the Paint
CEPI	Confederation of European Paper Industries
CITPA	International Confederation of Paper and Board Converters
cPP	Cast polypropylene
EAA	European Aluminium Association
ECMA	European Carton Makers Association
Eh	Redox potential
EMPAC	European Metal Packaging
EuPC	European Plastics Converters
EuPIA	European Printing Ink Association
EVAC (EVA)	Ethylene/vinyl acetate
EVOH	Ethylene/vinyl alcohol
FBO	Food business operators
FCA	Food Contact Additives
FEICA	European Adhesive and Sealant Industry
FPE	Flexible Packaging Industry.
GHP	Good hygiene practices
GMP	Good manufacturing practices
HACCP	Hazard Analysis Critical Control Point
HPUS	High power ultrasound
HTST	High Temperature Short Time
LAB	Lactic acid bacteria
MAP	Modified atmosphere packaging
OPA	Oriented polyamide
OPP	Oriented polypropylene
OTR	Oxygen transmission rate
$P(O_2)$	Oxygen permeability
PA	Polyamide (Nylon)
PAP	Paper
PE	Polyethylene
PE-HD (HDPE)	High density polyethylene
PE-LD (LDPE)	Low density polyethylene
PE-LLD (LLDPE)	Linear low density polyethylene
PET	Poly(ethylene terephthalate)
PET met	Metallized poly(ethylene terephthalate)
PG	1,2-propanediol
PP	Polypropylene
PS	Polystyrene
PS-HI (HIPS)	High-impact polystyrene
PVDC	Poly(vinylidene chloride)
rH	Redox potential
UV	Ultraviolet
vAl	Vacuum aluminized
VP	Vacuum packaging
WVTR	Water vapour transmission rate