



# How to Determine the Shelf Life of Food

A Guidance Document

22 July 2014

## Title

Guidance Document: How to Determine the Shelf Life of Food

## About this document

This guidance document has been developed to help food operators to determine the shelf life of their food products and to apply the appropriate date marking. It provides useful information to assist food processors and for other food operators preparing and handling foods for retail sale. Any legal requirements are shown in boxes. They are either directly quoted from the requirements (including any clause numbers) or are summarised when the requirement is too long to include completely. It is the responsibility of the operator to be aware of and comply with all applicable current legislation including any requirements that amend, replace or correspond to the requirements referenced in this document.

## Related Requirements

Food Standards Australia New Zealand, Food Standards Code Standard 1.2.5 – Date Marking of Food  
<http://www.comlaw.gov.au/Series/F2008B00605>

Food Standards Australia New Zealand, Food Standards Code Standard 1.6.1 – Microbiological Limits for Food  
<http://www.comlaw.gov.au/Series/F2008B00630>

Food Act 1981:

[http://www.legislation.govt.nz/act/public/1981/0045/latest/DLM48687.html?search=ts\\_act\\_Food+Act+1981\\_re sel&p=1&sr=1](http://www.legislation.govt.nz/act/public/1981/0045/latest/DLM48687.html?search=ts_act_Food+Act+1981_re sel&p=1&sr=1)

## Change history

Previous Version Date	Current Version Date	Section Changed	Change(s) Description
	December 2013		

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This publication is also available on the Ministry for Primary Industries website at

<http://www.foodsafety.govt.nz/industry/general/labelling-composition/>

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## 1 Scope

This guide is intended to help food operators who process, prepare and handle food to determine the shelf life of their food products and to apply appropriate date marking. It describes:

- how shelf life is defined;
- the causes of food deterioration and spoilage;
- why food may become unsafe during storage;
- how to decide whether a 'best-before' or 'use-by' date mark is required;
- the information needed to work out what the shelf life is; and
- how to ensure the safety of chilled foods.

The shelf life of many foods can be extended through various means including chilled storage. Low temperatures slow down chemical changes and growth of many spoilage and pathogenic microorganisms (bacteria, yeasts and moulds) and any toxin formation. However there are some pathogenic bacteria that are able to grow at the low temperatures used for refrigeration and chilled storage. These are referred to as cold-tolerant bacteria. In some situations, whilst the level of pathogenic cold-tolerant bacteria may be considered to be safe immediately following manufacture, the type and length of storage may provide the suitable conditions and time for the bacteria to grow in number so that the food becomes unsafe after a period of time. This will impact on the shelf life and safety of the food especially where the food is considered to be ready-to-eat. Ready-to-eat foods are those foods where there is no further processing that will reduce or eliminate harmful microorganisms before consumption.

The focus of this guidance document is therefore on determining the shelf life of chilled ready-to-eat foods. This guide may provide some useful information for manufacturers and processors of other foods.

## 2 Definitions

**'Best-before'** means the date until when, provided the food has been stored in intact packaging and in accordance with stated storage conditions, it will be fully marketable and retain its quality.

**Chilled foods** are those foods that require storage at 5°C or less to maintain their suitability and safety.

**Date marking** is the system for packaged foods with a shelf life of less than 2 years.

**Microorganisms** include moulds, yeasts and bacteria. Bacteria includes pathogens and spoilage organisms; spore-forming bacteria and those that may cause food poisoning through the production of toxins.

**Perishable food** is unprocessed or processed food that has a short shelf life at room temperature before showing signs of deterioration or spoilage (often mould or bacterial growth seen as fur or slime), e.g. fruit or pre-packaged bread. Spoiled food should be removed from storage or display as soon as possible. Chilling perishable foods can extend the time before they deteriorate or spoil.

**Shelf life** testing requires foods to be stored under the expected conditions of storage and distribution for a period of time to determine at what point chemical changes, deterioration and/or spoilage of the food occurs.

**Shelf-stable food** is food of a type that, because of its composition (low moisture, high salt or sugar content) does not require to be stored refrigerated e.g. spices, flour, dried pasta or which would normally be stored refrigerated but which has been processed so that it can be safely stored in a sealed container at room temperature for a usefully long shelf life e.g. canned fish and meat.

**Stated shelf life** is the period of time, established under intended conditions of distribution, storage, retail and use, that the food would remain safe and suitable.

**'Use-by-date'** is the date until when, provided the food has been stored in intact packaging and in accordance with stated storage conditions, it is safe to eat.

### 3 Shelf life

The stated shelf life of a food is the period of time for which it remains safe and suitable for consumption, provided the food has been stored in accordance with any stated storage conditions. This means that the food:

- must remain safe to consume, i.e. should not cause food-poisoning because of the growth of pathogenic bacteria, or the production of toxins (bacterial and fungal ) in the food during storage;
- has not deteriorated in quality or spoiled in any way that the consumer would find unacceptable;
- has not lost significant amounts of any nutrients listed on the label.

## 4 Changes that may occur during processing and storage

### 4.1 Deterioration and spoilage

Food is perishable by nature. Changes will take place naturally in all food while it is being handled and stored by the processor, retailer and the purchaser. The changes can be rapid as with spoilage of raw meat and fish or spoilage and deterioration can take place over a period of days or weeks e.g. bread becomes mouldy, biscuits become stale and soft, and processed meats become smelly and slimy. For some foods, e.g. retorted and very dry foods, the deterioration in the quality may not become apparent until after months or even years of storage. These foods are described as shelf stable.

### 4.2 Factors that affect the rate at which food deteriorates and spoils

There are many factors that may affect the shelf life of a product. Some relate to the food itself (intrinsic factors), such as moisture and pH, while others are external to the product, e.g. the packaging conditions, materials and storage conditions. By understanding which are the most important factors impacting on the shelf life of a food, it may be possible to manipulate these factors to extend the shelf life. Information on the factors that influence and cause food deterioration and spoilage and thus the shelf life of a food can be found in Section 9.

It should be kept in mind that altering the composition, formulation, processing or packaging may inadvertently lead to a decrease in the shelf life or make the food more susceptible to the growth of spoilage or even pathogenic microorganisms. So it is important to assess any changes proposed for their potential to have an adverse effect on shelf life. This will be especially important if the safety of a food relies on a number of interacting factors or hurdles to inhibit the growth of pathogenic bacteria.

### 4.3 Hazard Analysis and Critical Control Point (HACCP) systems

It is essential to understand how the ingredients, process, final characteristics, packaging and storage conditions influence the safety, as well as deterioration and spoilage of a food. This will require an understanding of what biological hazards are reasonably likely to be present, the effectiveness of the control measures in place throughout the process at killing or inhibiting the growth of pathogenic bacteria in the food. A review of the entire production process using hazard analysis will assist in identifying the potential for the

hazards of concern to be present, in particular the four key cold-tolerant bacteria, which need to be controlled during the shelf life (refer to Section 10) and the relevant control measures. (See Table 1 for information on the effect of processing on microorganisms).

Control may be applied at critical control points (CCPs) which are steps at which a process is applied to prevent, eliminate or reduce a food safety hazard to an acceptable level e.g. application of heat. Alternatively it may come from the application of hurdle technology. Hurdle technology refers to the concept of achieving control by combining in series, a number of measures that would not individually be adequate for control e.g. uncooked fermented meats such as salami where the hurdles are the rapid development of a low pH along with the reduction in the water content by drying and the addition of inhibitory salts.

Further information on using HACCP is on the MPI website:

<http://www.foodsafety.govt.nz/industry/general/haccp/using-haccp.htm>

## 4.4 Effect of processing on survival of microorganisms

The processing of a food may eliminate or at least reduce the number of microorganisms (bacteria, yeasts and moulds) present. This will help to make food safe by controlling pathogenic bacteria (those able to cause illness) and may extend the shelf life of the food by reducing the numbers of spoilage microorganisms (that cause food to go off). Table 1 in Section 9 provides a summary of the effect of processes applied to food on the elimination and survival of microorganisms that could be present in a food.

It is important to be aware that many processes applied to food, e.g. washing fresh produce or pasteurising, will not eliminate all the microorganisms present and a few may survive processing. Processed foods other than those that are retorted or receive ultra high heat treatment (UHT) are not sterile. So while any pathogenic vegetative bacteria should have been reduced to a safe level by a validated process (and may now be below the limit of detection) if the conditions during storage permit the bacteria to grow, the food could become unsafe to consume. Some pathogenic and spoilage bacteria produce spores that can be very resistant to heat may not be eliminated during processing. If these spore-forming and/or cold tolerant bacteria could be present after processing, this will need to be taken into account when establishing the shelf life. Spores from fungi (mould) on the other hand are easily destroyed by heat processing.

While processing using an appropriate validated heat treatment will decrease the numbers of pathogenic bacteria present in the raw materials and ingredients, some food preservation techniques such as fermenting or cold-smoking, if not adequately controlled, have the potential to increase the number of pathogenic bacteria present and may result in a reduced shelf life.

Where there is an expectation that processing will reduce the number of microorganisms present, make the food safer and extend the shelf life this can be compromised if re-contamination occurs, for example, cross-contamination during processing.

## 4.5 Effects of chilled storage

The shelf life of many foods can be extended through chilled storage. Low temperatures slow down chemical changes and the growth of many moulds, yeasts and spoilage and pathogenic bacteria. However there are some microorganisms including pathogenic bacteria that are able to grow readily at low temperatures. In some situations, while the levels of these cold-tolerant pathogenic bacteria may be considered safe at the end of processing if the duration of the shelf life is extended it provides a greater opportunity for these pathogenic bacteria to grow. This will have a major impact on the shelf life of the food. Section 10 provides information on the four key pathogenic bacteria that are a concern for chilled foods.

## 4.6 Loss of nutrients during storage

Nutrients levels may decrease in a food with time. The rate of loss will depend on the stability of the particular nutrient. If the level of the nutrient could decrease to below the level expected by the consumer (i.e. as stated on the label), a 'use-by' date would be needed to indicate the point in time at which the nutrient will drop below the level stated on the label (see Section 6). This will be important if the food is being consumed to ensure an adequate intake of a particular component, such as a vitamin, or is a major nutritional source for a specific group of consumers.

## 5 Shelf life and date marking requirements

Food sold in Australia and New Zealand must meet the requirements of the Australia New Zealand Food Standards Code (the Code) and the New Zealand Food Act 1981. Standard 1.2.5 in the Code details the date marking required for packaged food. A copy of the Code can be found at:

<http://www.foodstandards.gov.au/code/Pages/default.aspx>

The Standard requires that:

2 Food must be date marked

(1) 'Unless otherwise expressly prescribed in this Code, the label on a package of food must include-

- a) its use-by date, where the food should be consumed before a certain date because of health or safety reasons; or
- b) where 2(1)(a) does not apply, its best-before date;

unless –

- c) the best-before date of the food is two years or more; or
- d) the food is –
  - i) an individual portion of ice cream or ice confection; or
  - ii) in a small package, except where the food should be consumed before a certain date because of health or safety reasons.'

Note: Standard 1.2.1 sets out the exemptions to the general labelling requirements in this Code, and provides a definition of 'small package'.

Date marking can be either a 'use-by' or a 'best-before' date and begins from the time when the food is prepared or manufactured. Additional date marking options are provided for bread with a shelf life less than 7 days.

The definitions in Standard 1.2.5 are:

**Best-before date**, in relation to a package of food, means the date which signifies the end of the period during which the intact package of food, if stored in accordance with any stated storage conditions, will remain fully marketable and will retain any specific qualities for which express or implied claims have been made.

**Use-by date**, in relation to a package of food, means the date which signifies the end of the estimated period if stored in accordance with any stated storage conditions, after which the intact package of food should not be consumed because of health or safety reasons.

'Use-by' dates may be applied where the date marking is required for:

- health reasons, e.g. to comply with the label declaration of a nutrient, or



- for safety reasons, e.g. to remain safe (due to the presence and/or growth of pathogenic microorganisms and any toxic substances produced)

Standard 1.2.5 also prescribes the form of date mark and also the form of date. It also requires that the 'label on a package of food must include a statement of any specific storage conditions required to ensure that the food will keep for the period indicated by the use-by or the best-before date' (Clause 6).

For further information refer to the *FSANZ Date Marking User Guide to Standard 1.2.5 – Date Marking of Food* outlines the requirements. The FSANZ User Guide can be used to decide whether a 'best-before' or 'use-by' date is appropriate for a food.

<http://www.foodstandards.gov.au/code/userguide/Documents/Guide%20to%20Standard%201.2.5%20-%20Date%20Marking%20of%20Food.pdf>

This guidance document provides information to assist food processors to understand how to ensure that the shelf life and date marking assigned to a product have a scientific basis. You should be able to explain how a date mark has been arrived at and have records to support this in the event that concerns are raised about the appropriateness or safety of the date marking applied.

Standard 1.2.6 in the Code requires that the label on a package of food must include directions for the use of the food or the storage of the food, or both, if the food is of such a nature as to require the directions for health or safety reasons. This provision may include the need to provide storage instructions of a food product (for both intact and opened packaging) to maintain the determined use-by-date. Standard 1.2.6 is available at: <http://www.comlaw.gov.au/Details/F2011C00535>

## 6 When a 'use-by' date is required for safety reasons

### 6.1 There may be a food safety concern

A 'use by' date is required for safety reasons where a food could become unsafe during its shelf life. The formation of toxic substances or the growth of pathogenic microorganisms may not provide visible signs that the product could have become unsafe to eat.

It is relatively uncommon for constituents of the food to breakdown or change so that toxic substances are formed e.g. oxidation of fats and oils. The potential for this to occur will usually be mitigated by the addition of substances that reduce the potential for the changes to occur e.g. antioxidants, packaging to reduce exposure to light which may cause changes, and storage instructions e.g. refrigerate or store in a dark space. However if the potential remains for toxicity to develop, a 'use-by' date is required for a safety reason.

While modern technological improvements to food processing, ingredients, packaging and storage has decreased the potential for toxicity due to chemical toxicity developing in the food, a greater diversity of foods with a prolonged chilled storage has increased the potential for pathogenic bacteria to be present. This will mean that the use and validation of 'use-by' date marking has become very important.

Before the advent of refrigerated storage and modern food technology, foods were preserved using processes such as drying, salting, pickling and fermentation, either on their own or in combination. These foods could be stored at room temperature for long periods. As well as the food being preserved, pathogenic microorganisms would usually be inhibited from growing and they would die off over time. Today milder forms of processing are preferred, so that foods are not as dry, salty or acidic. This often produces a product that is more acceptable to consumers, but these products will have a shorter shelf life than the traditional product. Chilled storage and special packaging can be used to restrict the growth of pathogens and spoilage bacteria during storage, e.g. gas flushing, vacuum packing, etc. but this does not always result in an extended shelf life. This is because the storage conditions may actually favour the growth of some microorganisms e.g. cold-tolerant spoilage and pathogenic microorganisms, and those that thrive in the absence of oxygen.

There are a number of food products, e.g. dips and sauces, which if made in the home are normally consumed within hours of being made. When these are produced under commercial conditions for retail sale or in restaurant kitchens for later use, they will need an extended shelf life, usually of several weeks. Extending the shelf life may be achieved by a combination of factors relating to the formulation of the food, type of processing applied and refrigerated storage. However these may not be sufficient to prevent the survival and growth of any pathogenic bacteria present and so it may be necessary to:

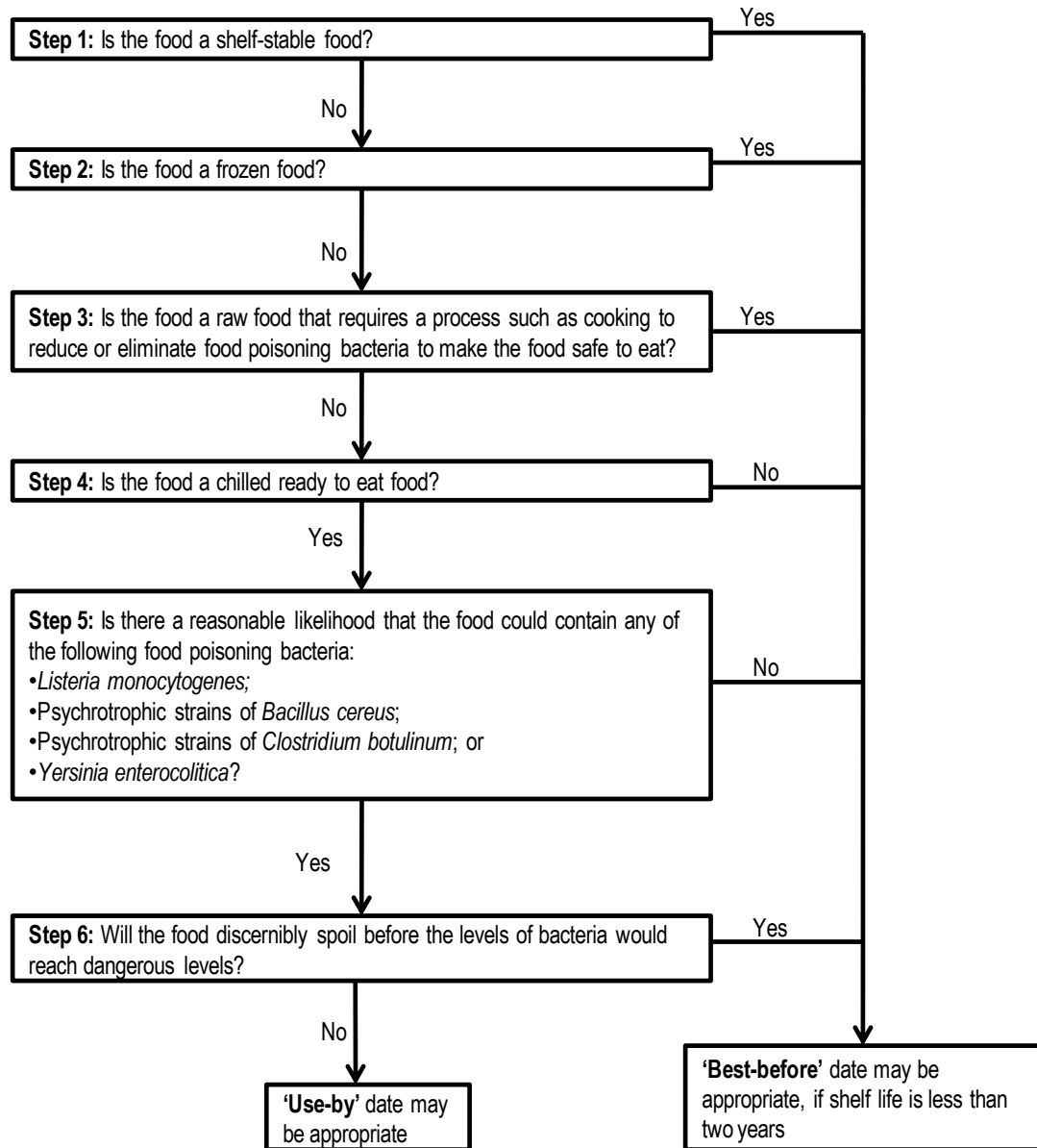
- reformulate or package the food so that growth cannot occur, or
- ensure that there are no pathogenic bacteria present e.g. treat the product in its final packaging, or
- reduce the shelf life. so there is less time for pathogens to grow to unsafe levels, or
- reduce the potential for pathogens to have survived by increasing the severity of processing e.g. replace pasteurisation with UHT, or
- adopt more rigorous ingredient specifications

## 6.2 Using the FSANZ decision tree to determine when a 'use-by' date is needed

Once it has been determined that a 'use-by' date for health reasons is not required (*FSANZ Date Marking User Guide*) this decision tree from the *FSANZ Date Marking User Guide* can be used. <http://www.foodstandards.gov.au/code/userguide/Pages/datemarking.aspx> To assist with the interpretation of the decision tree, each of the steps has been numbered and explanatory text provided.

**Figure 1 Decision tree: Applying a ‘use-by’ date for safety issues**

Source ‘FSANZ Date Marking, User Guide to Standard 1.2.5 – Date Marking of Food’



## Explanatory text

### Step 1

Shelf-stable foods are those that do not require any special storage conditions as they generally do not provide conditions suitable for the growth of microorganisms, e.g. very dry, high acid, high sugar or salt content. Foods preserved in these ways will eventually show deterioration in flavour and appearance but this may take a long time.

Foods that have been subjected to a process capable of killing both vegetative bacteria as well as spores will also result in shelf-stable food provided the food cannot become recontaminated after processing, e.g. canning and retorting in the final package. This often results in a shelf life of greater than 2 years and this situation date marking is not required.

**Note that the exemption from date marking requirements for foods with a shelf life greater than 2 years i.e. shelf-stable does not apply to infant formula. Infant formula must have a date mark see Standard 2.9.1 Infant Formula Products Clause 17(2) of the *Food Standards Code*.**

### Step 2

No pathogenic foodborne microorganisms and very few food spoilage microorganisms other than some moulds can grow in frozen food.

However, if it is intended that the food is to be thawed before consumption, proceed to step 3. If there is an extended time between the thawing of a food and it being consumed without further cooking, any microorganisms present may then be able to grow to harmful levels.

### Step 3

Foods that are intended to be cooked thoroughly by the consumer before eating must be clearly labelled with cooking instructions. These foods are not ready-to-eat and appropriate preparation and storage should reduce any pathogenic microorganisms present to safe levels. A 'best-before' date may be appropriate.

### Step 4

Some pathogenic bacteria are able to grow in chilled foods, i.e. foods stored below 5°C. If a few of these bacteria survive processing or are introduced into the food after processing, e.g. during preparation of consumer packs, they may be able to grow to unsafe levels or enable the production of toxins during chilled storage of the food.

### Step 5

Could any of the four cold-tolerant bacteria listed in the flow chart be present at the start of the product's shelf life?

Spores of *Clostridium botulinum* and *Bacillus cereus* may remain in the product if the process is designed to deal with vegetative pathogens only. The product will be safe to consume as long as the spores are not able to germinate and grow to unsafe levels during storage.

*L. monocytogenes* and *Y. enterocolitica* are potential contaminants of foods that are minimally processed or do not receive a processing treatment that will be able to eliminate the microbiological hazard of concern. (Some foods may become contaminated from the processing environment following a valid processing treatment before final packaging.)

The shelf life is based on the ability of these pathogens, if present, to survive and grow under the intended storage conditions.

For more in depth information on each of the pathogenic bacteria and the impact of food processing on their survival refer to Sections 9 and 10 and to the Pathogen Data Sheets on MPI's website

<http://www.foodsafety.govt.nz/science-risk/hazard-data-sheets/>

### Important note

- For chilled ready-to-eat food produced in New Zealand using locally produced ingredients, *Listeria monocytogenes* is the key hazard of concern, as it has been associated with foodborne illness and is frequently isolated from food and the processing environment
- For *Clostridium botulinum* there are differing situations:
  - Surveys and other scientific studies suggest that cold-tolerant *Clostridium botulinum* is unlikely to be a hazard reasonably likely to occur in ingredients or unprocessed food of New Zealand origin. Therefore specific controls to manage this hazard may not be necessary.
  - For imported ingredients or foods cold tolerant *C. botulinum* may be a hazard reasonably likely to occur. It will be important to determine what controls are in place and how these can be maintained.
  - If you are producing food or ingredients for export using New Zealand-only ingredients, although cold-tolerant *C. botulinum* is not a hazard likely to occur, overseas markets may require evidence that the process is capable of inactivating these hazards.
- Cold-tolerant *B. cereus* is a spore-forming bacteria that is a hazard reasonably likely to occur in foods and ingredients.
- While *Yersinia enterocolitica* does occur in New Zealand, it is unclear to what extent it is transmitted through food. Overseas *Yersinia* has been linked foods such as processed meat products. MPI believes that processes capable of managing *Salmonella* and *L. monocytogenes* will be equally capable of dealing with any *Y. enterocolitica* that may be present.
- Operators should review available evidence including surveys of incidence and cases of illness associated with these four cold-tolerant bacteria in New Zealand.  
<http://www.foodsafety.govt.nz/science-risk/human-health-surveillance/>

### You can identify whether growth of microorganism in the food will occur by:

- Identifying the intrinsic compositional characteristics of the food (e.g. pH, salt content, water activity, etc.) that would prevent growth occurring. Refer to Sections 9 and 10, and the hazard data sheets at <http://www.foodsafety.govt.nz/science-risk/hazard-data-sheets/> for more information on what conditions the pathogenic bacteria need for growth;
- Using predictive microbiological models (computer based models) to predict the growth of some microorganisms (spoilage and pathogenic bacteria) in foods with specific characteristics e.g. pH, salt content and water activity, etc. The models may be limited in their applicability due to the range of parameters that they are able to cover, and they may over estimate growth if the model was developed using growth studies in laboratory media. Section 10 lists the most commonly used models and where information on how to use them can be found
- Undertaking challenge tests, i.e. inoculate the food with a known concentration of appropriate strains of the pathogenic bacteria and see if they can grow and at what rate. Protocols for challenge studies are shown in Section 11. While challenge tests are the best method for determining whether or not growth will occur, they are expensive to do. However the cost would be offset by the assurances testing provides.

Before undertaking any investigation to determine the shelf life or the growth of pathogenic bacteria, it is important to ensure that the processing consistently produces a safe food with the same characteristics, e.g. acidity; moisture content, etc (refer to Section 9). This can be achieved by implementing a HACCP programme and undertaking process validation studies. For further information on validation refer to the [Risk Management Programme Manual](#).

Shelf life testing is where foods are stored under the expected conditions of storage and distribution for a period of time. This helps to determine at what point chemical changes, deterioration and/or spoilage of the food occurs and helps to determine the shelf life with respect to these characteristics rather than with respect to the growth of a pathogenic microorganism or toxin production.

Further information on direct and indirect methods of shelf life testing is provided in Section 7 of this guide.

If challenge testing or predictive microbiological modelling predicts that growth of *L. monocytogenes* will occur, consider risk management strategies that would reduce or limit growth such as:

- using frozen rather than chilled storage and distribution, e.g. for ready-to-eat cold smoked fish, especially if it is to be transported over long distance;
- increasing the use of microbiological hurdles and other factors that would minimise growth such as reducing moisture or increasing salt or acidity;
- the addition of preservatives specific for the pathogen of concern; or
- an in-pack pasteurisation step. This will reduce the numbers of both spoilage microorganisms and vegetative pathogenic bacteria present.

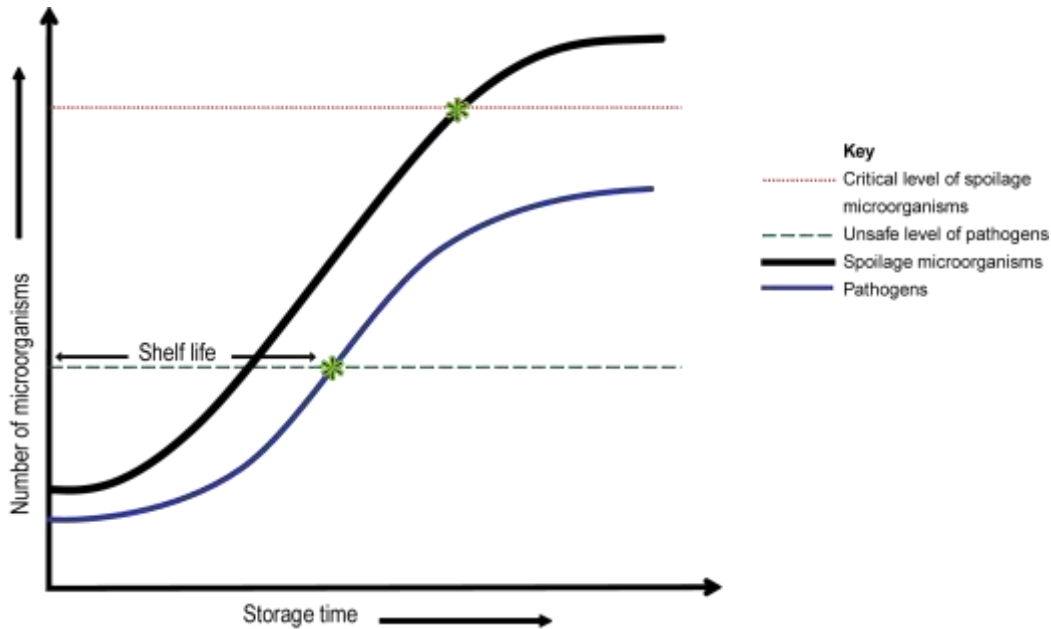
## Step 6

If it is possible that cold-tolerant pathogenic bacteria could be present in the food and could grow during storage, a 'use-by' date could be necessary. This however would only be the case if the level of these pathogenic bacteria could make the food unsafe before the growth of spoilage microorganisms has made the food unacceptable. In Figure 2, three scenarios for the growth of spoilage microorganisms and pathogenic bacteria in a chilled food are shown to demonstrate this.

**Figure 2: How the growth of microorganisms impacts on shelf life and date marking**

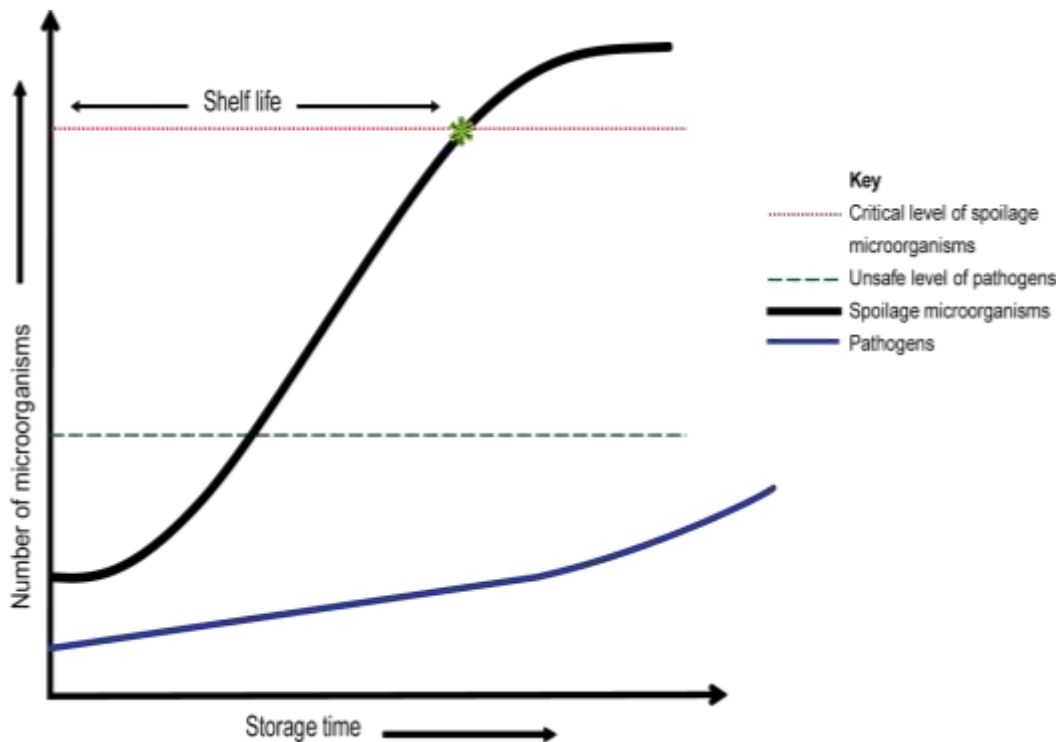
**Scenario A: Food supports the growth of both pathogenic and spoilage bacteria during storage; the pathogenic bacteria reach unsafe levels before the food is visibly spoiled**

**Outcome:** A 'use-by' date is required to ensure the food is not consumed when pathogen levels could be unsafe.



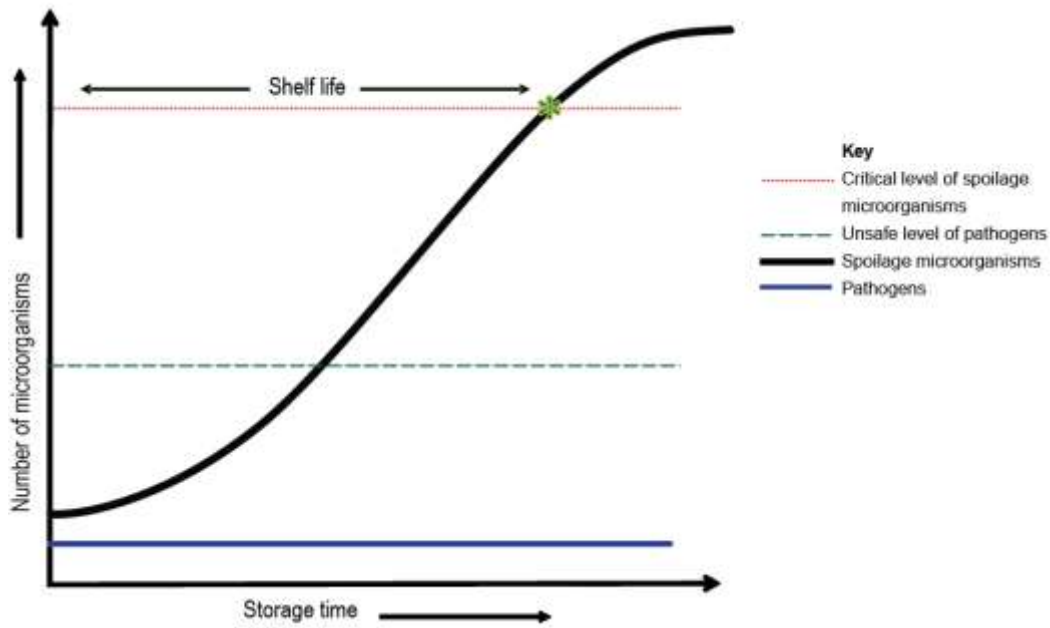
**Scenario B: Food supports the growth of both pathogenic and spoilage bacteria during storage but the food is visibly spoiled before pathogenic bacteria have reached unsafe levels**

**Outcome:** A 'best-before date' may be appropriate



**Scenario C: The pathogenic bacteria may sometimes be present at very low (safe) levels but do not grow in the food. Spoilage bacteria can grow and the food becomes visibly spoiled**

**Outcome:** A 'best-before' date is appropriate





## 7 How to determine the shelf life of a ready-to-eat food

### 7.1 Methods

Both direct and indirect methods are possible. Direct methods may take longer but will be the most accurate. Indirect methods are quicker but less accurate, which may mean adjustment is needed once product is in the marketplace.

Before undertaking any investigation to determine the shelf life or the growth of pathogenic bacteria in a food, it is important to ensure that the processing consistently produces a safe food with the same characteristics, e.g. acidity; moisture content, etc (refer to Section 8). This can be achieved by implementing a HACCP programme and undertaking process validation studies. For further information on validation refer to the [Risk Management Programme Manual](#).

### 7.2 Shelf life studies (direct method) for a 'best-before' date

This requires the food to be stored for a period of time that is longer than the expected shelf life, in order to observe, test and record changes in the products characteristics. From this information a shelf life can be estimated. The shelf life will need to take into account possible variability between product batches and in storage conditions, including whether the product is intended to be consumed over a period of time and so will be subjected to a number of temperature cycles. For some products it will be important to take into account conditions that could impact unfavourably during normal storage and transport. For example, some emulsions may be adversely affected by being shaken during distribution.

While it is important that the shelf life determination is made with product processed under normal commercial conditions, it is recommended that during the development of new products, shelf life studies are included. This will allow changes to the formulation, processing or packaging to be made during the development stage if the shelf life appears to be less than what is expected or there are unacceptable variations between batches.

#### Step 1: Setting up the study

- Identify the type(s) of spoilage or loss of quality most commonly associated with the food. These will be yeast, mould and/or bacterial spoilage, changes in texture, smell, taste or appearance. Decide which of these are most important and which changes will occur first. One type of deterioration may dominate or several may be equally important.
- Identify whether there is likely to be any growth of pathogens during the shelf-life. If there is, challenge testing may also be appropriate (refer to Section 6).

If the testing is to include tasting the food, it is important that there is confidence that the food could not be a potential source of food poisoning. If there is any doubt in this respect, do not do taste tests.

- Identify the observations and tests that will be undertaken. These may be made by subjective sensory testing e.g. colour and textural changes, smell and taste or by objective laboratory tests e.g. numbers of spoilage bacteria or yeasts, appearance of mould growth, presence of a chemical indicator of deterioration, such as D-alanine in fruit juice, rancidity, histamine in seafood, etc.
- Use published literature, observation of similar products in the marketplace and past experience to identify the expected shelf life so that you know whether the testing is likely to take days, weeks or months.
- Decide on the storage conditions for the trial. These must reflect the normal expected conditions of distribution and storage for the product and must be controlled to be the same every trial.

- Consider including additional storage conditions in the trial if these could have an impact on the shelf life in an intended market or due to the actions of the purchaser of the product. Conditions can be defined as:
  - optimum i.e. storage as on the label for the whole shelf life;
  - realistic e.g. repeated short periods of elevated temperatures or different levels of humidity;
  - worst case e.g. to mimic product moving from a temperate to a tropical market, poor temperature control in a domestic refrigerator, the effect of light on a sensitive product, effect of movement and vibration.

In each situation, at least temperature and humidity may need to be taken into account. Incubators and cabinets may be used to provide a constant environment for storing the trial samples. Refrigerators set at different temperatures e.g.  $< 4^{\circ}\text{C}$  and  $10^{\circ}\text{C}$ , can provide insight into the impact of temperature on shelf life. Ideally a range of 6 temperatures (and not less than 3) should be used that reflect the range and extremes that the product could be exposed to.

For products with a long shelf life, 'accelerated' studies may be performed in which the product is exposed to elevated temperatures to hasten the development of spoilage and deterioration and shorten the time that the study takes. However this would only be useful if the spoilage patterns remain the same as for the normal storage conditions. Get advice from an expert before doing this type of study.

- If the product could be stored once opened for more than a few days by the consumer, the impact of breaking the seal of the original packaging needs to be factored into the studies, e.g. exposure to air, movement to/from ambient to chilled storage.
- Decide on the number and frequency of observations and/or tests that will be done, e.g. daily or weekly. If the food has a fairly long shelf life it may be sensible to start with less frequent observations and to increase the frequency as the expected end of shelf life approaches.
- Prepare log sheets on which to record the sequence of observations. Describe the observations to be made and provide a scale for recording the results. It is important that the trials are repeatable. Colour charts, pictures and descriptions of how to make the observations will be essential to ensure this. Trained panels should be used where tests are highly subjective, e.g. taste, smell, etc.
- Calculate the total number of samples that will be needed for the trial. If the tests involve observation only, fewer samples will be needed than if the tests are destructive. It is important to examine multiple product samples (at least three product samples, and preferably more than five from each batch) from a number of different batches when performing the trial to help to determine the variability between and within each batch.

## Step 2: Doing the study

- Obtain enough product samples for the number of observations and/or tests needed over the study period. Samples should be randomly selected from a batch of product and be in the packaging format available for the consumer. Samples need to be labelled or numbered to allow easy identification before they are placed under selected storage conditions.
- Carry out the study.
- Analyse the results.
- Calculate a shelf life from the observations made e.g. the earliest time at which mould storage occurs, the time at which 50% of samples have an unacceptable loss of a major or several quality attributes.

The study should be repeated with several (at least three) batches of product to identify variability within and between batches. If there is a large amount of variability within and/or between batches you will need to work out how to reduce the variability. This could be due to how the product is made, the composition of the food and the type of packaging, the hygiene of the processing environment or the quality of the ingredients.

### Step 3: Setting the date mark; verification and review

- **Determine the product date marking.** This should be no longer than the number of days before unacceptable deterioration occurs (based on the shelf life study undertaken in step 2) plus a safety margin. A safety margin is needed because the shelf life is only an approximation and not a fixed value and will vary from time to time. The size of the safety margin needs to take into account the potential for the shelf life to be easily compromised by less than ideal conditions for storage, distribution and use.
- **Retention samples.** Once production commences, samples should be retained, ideally from each batch of product. These can then be checked at the end of their shelf life to confirm that the date marking is appropriate. In the event of customer complaints that the product has spoiled before the end of the shelf life, the retained samples can be examined to see if the complaint is justified and an appropriate response made e.g. review processing records, review date marking.
- **Monitor customer complaint records.** Review on a regular basis for trends and evidence of shelf life failures e.g. impact of seasonal conditions, distribution chain effects, retailers, etc.
- **Repeat the shelf life tests if there are major changes** made to the product composition, ingredients, processing or packaging to ensure that the shelf life has not been compromised by the changes.

If you do not have suitable facilities or expertise to undertake shelf life studies, seek help from commercial service providers.

## 7.3 Indirect methods for 'best-before' date marking

The direct methods to determine the shelf life can take too long for some products and can be costly. An alternative is to use indirect methods such as predictive models to predict the shelf life and then use this information in parallel with ongoing observation of how the product performs in the market place and the nature of customer complaints.

### Products where chemical changes are critical

It is possible to use models and calculations to predict the shelf life of some types of food products, such as pickles and sauces. These require technical expertise if they are to be applied correctly and so the appropriate experts should be consulted.

### Products where microbiological spoilage is critical

Predictive models can be used to predict the growth, survival and non-thermal inactivation of microorganisms. Many of these models are for pathogenic bacteria but there are some models for specific spoilage issues. The limitation of the models is that the conditions of the food must be the same as those in the model; otherwise they will not be applicable. The models require detailed knowledge of compositional factors such as pH and water activity which affect the growth of microorganisms.

Refer to Section 11.5 for further information on predictive models, how they work and can be applied.

## 7.4 When there is significant nutrient loss and a 'use-by' date is required

This can be determined in the same way as for a 'best-before' date (Section 7.2) but the focus of the study will be the characteristic of concern e.g. the time taken for the level of a vitamin to go below the level indicated on the label. It will be important that these studies replicate the normal storage conditions of the product. Manufacturers may choose to reformulate the products by increasing the amount of the nutrient added (provided this does not exceed tolerable daily intakes or maximum levels permitted by the Food Standards

Code) which will compensate for amounts lost during storage, allowing for the extended shelf life of a product to be retained .

## 7.5 When there is potential for growth of a pathogen and a 'use-by' date is required

### Challenge studies

If there could be pathogenic microorganisms present at low levels in the product **and** it is possible that they could grow during the shelf life of the product , it is important to know how fast the bacteria can grow and to what level. The best information on growth comes from challenge studies where the food is inoculated with a cocktail of several strains of the pathogen and then tested at intervals to see if the bacteria increase in number. This will establish a growth curve (see Figure 2). If the pathogen levels could reach unsafe levels before the food shows significant spoilage which would put the customer off eating it, then a 'use-by' date will be essential. (Refer to Figure 2, scenario A).

For foods for which *L. monocytogenes* is a known hazard and to which a listericidal process cannot be applied, such as cold-smoked fish and salads it is important to be aware that in Standard 1.6.1 of the FSC, 'a ready-to-eat food that does not receive a listericidal process during manufacture is considered as a food in which growth of *Listeria monocytogenes* will not occur if the level of the *Listeria monocytogenes* will not exceed 100 cfu/g within the expected shelf life.' If the characteristics of the food or storage conditions would allow the bacteria to grow then a challenge study will be required to demonstrate the growth curve and to verify that the 'use by' date is appropriate.

In the diagram below the steps of a challenge study are outlined. There are several detailed protocols available for conducting challenge studies (see Section 11.6).

Important points that must be included when designing a challenge study are:

- The food tested must be the same as that supplied to the consumer.
- The inoculation level should reflect the purpose of the study i.e. when a ready-to-eat food is contaminated with a small number of pathogens, are they able to grow to unsafe levels during the expected shelf life of the food and the application of this information to an appropriate date mark.
- When inoculating the food with the bacteria, the method of inoculation should reflect the way contamination is likely to occur e.g. for a sliced cooked meat surface contamination from a slicer.
- The inoculated food should then be packaged as intended for retail sale or the packaged product may be inoculated, taking care that the integrity of the packaging is not compromised.
- Incubation temperatures should reflect the anticipated range of temperatures conditions and possible consumer abuse temperature (see Table 2 in *Listeria monocytogenes* Challenge Testing of Ready-to-Eat Refrigerated Foods (Health Canada) [http://www.hc-sc.gc.ca/fn-an/legislation/pol/listeria\\_monocytogenes-test-eng.php](http://www.hc-sc.gc.ca/fn-an/legislation/pol/listeria_monocytogenes-test-eng.php)
- For foods where there are potentially variable levels of spoilage or other bacteria present, it may be helpful to monitor their levels also, as they may impact on the rate of growth of the pathogens.
- Documentation of all aspects and details of the challenge study.

**Figure 3: The steps of a Challenge Trial**

Diagram provided by FSANZ (2013)

### Predictive modelling of growth of bacteria in food

An alternative to challenge studies is to use predictive models. Entering the characteristics of the food into the model will predict whether growth will occur and provide a growth curve. While several of these models have been refined in recent years, it would always be recommended that a challenge study is also undertaken to confirm that the model reflects your product accurately. There are a number of predictive models available and these are listed in Section 11.5.

## 7.6 Shelf life of composite foods

When calculating the shelf life of a product that is made up of 2 or more individual separate food components e.g. yoghurt with a fruit sauce layer or a ready meal, the shelf life of each food must be taken into account when assigning a date mark. The shelf life should not exceed the shortest value.

Where the foods have been blended together the shelf life for the composite food will be affected by the characteristics of the components. If the components have similar characteristics e.g. several types of cereal blends, the shelf life of the composite food would usually reflect that of the component food with the shortest shelf life. However if the components are very different e.g. a salad with dressing, the shelf life of the components is no longer relevant and a shelf life for this new food needs to be established. (see Section 8 for more information on how intrinsic and extrinsic factors impact on shelf life)

## 8 Date marking changes

The shelf life of a food may change if it is taken from its original packaging. While it is acceptable to repackage a food and place a new label with an accurate date mark on it, there are certain requirements that must be met to change the date mark.

## 8.1 When a date mark may need to be changed

The shelf life reflected by the date mark applied by a food manufacturer takes into account anticipated storage conditions of the product until it is used. If these change, for example the temperature is higher or the humidity increases, or packaging is damaged or opened, the product is no longer being kept under the conditions expected by the manufacturer. The shelf life will have changed and the original date mark may also need to be changed. Examples of this include chilled food that is later frozen; and bulk products that are divided into smaller lots.

## 8.2 The regulatory requirements

The Food Standards Code, Standard 1.1.1 Clause 11 prohibits altering a label unless certain conditions are met. It states;

11 Prohibition on altering labels

- (1) Subject to subclause (2) the label on a package of food must not be altered, removed, erased, obliterated, or obscured except with the permission of the relevant authority
- (2) A package of food may be relabelled by placing a new label over the incorrect one provided that the new label is not able to be removed so the incorrect information is visible.

Food with a 'use by-date' must not be sold beyond its 'use-by' date so requests to extend a 'use-by' date are not automatic. Additional information will need to be submitted with the application to enable the relevant authority to determine whether permission can be granted. Permission can only be granted in situations where the food will remain safe and suitable to consume.

Food with a 'best-before' date can legally be sold past its 'best-before' date, provided that the safety and suitability of the food is maintained. There is no requirement to apply to a relevant authority to change a 'best-before' date.

In New Zealand the 'relevant authority' is the Ministry for Primary Industries (MPI).

## 8.3 Applying for permission to change a date mark

To change a date mark an application must be submitted to MPI as the relevant authority. Anyone (a food manufacturer, importer, distributor or retailer) may change a 'use-by' date. If the applicant is not the food manufacturer they will need to obtain supporting information from the food manufacturer about the product's shelf life to show continued safety and suitability of the food.

## 8.4 Examples where permission is not required from MPI to change a date mark

### Errors on labels

When there are errors on a label, e.g. the wrong year is displayed, and the food is still in the control of/held by the food manufacturer, corrective actions can be taken without applying to MPI. For example, a re-printed label including the correct date can be placed over the incorrect label. This corrective action should be recorded by the manufacturer as it will provide their verifier or a Food Act Officer with a degree of confidence that the business understands and applies its food safety system.

## Repackaged foods

If food is removed from its original packaging, it is very unlikely to have the same shelf life as originally given by the manufacturer. The shelf life is likely to be shorter (and very unlikely to be extended) once the original protective packaging has been removed. When this happens:

- there is the opportunity for the product to become contaminated during handling, e.g. slicing, portioning, repackaging;
- the temperature of the product may increase and provide opportunity for microbial growth as temperature increases.

It is recommended that, before date marking the repackaged product, the food manufacturer is contacted to obtain information that will accurately determine the new date mark to be applied. The manufacturer may want to know about the conditions under which the product is to be handled once it has been removed from its original packaging.

If slicing a product for display in a cabinet, for example in a deli, it is also important to ensure the shelf life is calculated correctly. If a bulk product is not used in one go e.g. an opened vacuum-pack of bulk ham is sliced and sold over several days, the shelf life of ham sliced on day 3 may be shorter than the shelf life of ham sliced on day one. The increased amount of handling and time away from temperature control will increase the risk that the remaining bulk ham will become subject to the bullet points above. The deli should be able to show their verifier how they calculate the shelf life of ready-to-eat foods in displays to ensure safe products. The deli may want to label foods with a date mark or information about storage/use but only have to provide information if a customer requests it. If the deli repackages the ham, the packages will need to be labelled with an accurate date mark. This does not require permission from the relevant authority provided that the original date mark has not passed.

Further information for delis will be provided in the Retail Food Control Plan template (currently draft) which will be published on the MPI website (when available).

## 9 Resource material - Factors that influence shelf life

Factors that influence the shelf life are either intrinsic; the product characteristics, e.g. acidity, moisture content, etc or extrinsic; external characteristics, e.g. storage temperature, packaging, etc.

### 9.1 Intrinsic and extrinsic factors

Even if two products look similar, their shelf life can be quite different. It is not safe to take the shelf life from one and apply it to the other. You need to know what has occurred during manufacture and understand the factors that will influence its storage characteristics before being able to arrive at an appropriate shelf life for your food.

#### Characteristics of the food itself (i.e. intrinsic)

The intrinsic factors that impact on its shelf life include:

- **The nature and quality of the raw materials.** Good quality raw materials with low numbers of microorganisms present will help ensure products with a consistently acceptable shelf life. If raw materials could sometimes be heavily contaminated, this needs to be taken into account during processing. For example, produce harvested in wet conditions may need a further wash to achieve the same and consistent shelf life as produce harvested on a dry day. If the numbers of spoilage microorganisms or pathogenic bacteria are highly variable this may impact on the process and consequently the shelf life. In this case consider setting microbiological limits (specifications) on

raw materials, ensure that the process is validated under worst case conditions.

- **Product formulation** including the use of preservatives. Mould and bacterial growth can be inhibited or slowed down by removing moisture. It is important to take into account that substituting or removing ingredients, or modifying them in some way may allow microorganisms to grow where previously they were inhibited. Replacing sugar with an artificial sweetener; using a reduced-acid vinegar; changing the type of acid; removing nitrates from a processed meat; reducing the amount of added salt can all reduce the effectiveness of hurdles introduced to control microorganisms and so change the shelf life of a product.
- **Product structure.** Liquids and semi-solid foods will usually have a homogeneous composition, but many products do not, including composite foods. Moisture and flavours will migrate between layers, while coatings and surface treatments can either restrict or enhance the spoilage potential. For example: herbs and spices on the surface of a pâté may grow mould, but a layer of aspic over the herbs will exclude air and prevent mould growth; the pastry crust covering a meat pie will make the content anaerobic, but will allow bacterial spores such as *Clostridium perfringens* - commonly associated with meat - to germinate and grow; however anaerobic conditions are less likely with a potato topping. It is important to understand the structure of your products, for example where there is the potential for anaerobic pockets to form that could provide the right environment for anaerobic bacteria to grow.
- **Oxygen availability and redox potential within the food.** This can have a major effect on which sorts of spoilage and pathogenic microorganisms will grow on the food. This also impacts on oxidation-reduction reactions which cause rancidity, loss of vitamins, browning, and flavour changes resulting in product deterioration. Moulds need oxygen to grow and so are usually found on food surfaces but will grow in crevices within food.

More information on intrinsic factors of specific foods is available at the following site:

<http://www.fda.gov/Food/FoodScienceResearch/SafePracticesforFoodProcesses/default.htm>

### External factors (i.e. extrinsic) to the food

These will also have an impact on shelf life and include

- **Processes applied to the food.** While retort processes can be used to inactivate the most heat-resistant organisms, milder heat processes will inactivate only some bacteria and a proportion will survive. The more bacteria in the raw materials, the greater the number of bacteria that will survive and shorten shelf life, which is why it is important to validate the process using the worst case conditions. Generally the more intense the process, the longer the shelf life can be.
- **Cooling methods** applied to heat treated products. Some spoilage and pathogenic bacteria produce spores that may not only survive but may be activated during the heating process. If the food is not cooled rapidly after the heat treatment, these activated bacteria may increase rapidly in the warm food and cause spoilage and in some cases food poisoning. This is important for meat where *Clostridium perfringens* can be a concern, whereas for dairy processing, cereals and baked goods *Bacillus spp.* are more likely to be associated with these products. Cooling can be hastened by techniques such as spreading the product to be cooled into a thin layer, dividing into smaller lots or blast chilling.
- **Type of packaging** including the gaseous environment. Packaging will have a primary role of protecting a food after processing but may also be used to extend the shelf life. If the gaseous environment is changed e.g. vacuum packing or gas flushing, this will favour the growth of certain pathogenic bacteria and spoilage bacteria, while inhibiting the growth of microorganisms that



require oxygen (including moulds).

- **Storage temperature** i.e. ambient, chilled or frozen. While frozen storage will stop the growth of all but a very few spoilage microorganisms, chilling will only slow growth. A number of spoilage microorganisms and a few important pathogenic bacteria will actively grow under chilled conditions as they are cold-tolerant, although their growth will usually be slower than would occur during ambient storage.
- **Conditions during distribution, storage, retail display and storage by the consumer.** At any point in the product's shelf life, it may be exposed to conditions that will lead to the food showing signs of deterioration and a shortened shelf life. These conditions include elevated or fluctuating temperatures, U.V. light, high humidity, freezer burn, vibrations, etc.

Table 1 provides a brief overview of the impact that processes applied to food may have on the microbiological safety and spoilage of food.

**Table 1: Impact of processing on microbiological food safety and shelf life**

Processes applied to foods	Effect on microorganisms		Impact on food safety	Impact on length of shelf life due to spoilage
	Vegetative bacteria (either spoilage or pathogenic), and mould spores and yeasts	Bacterial spores (cause spoilage or food poisoning depending on type)		
Washing of raw materials e.g. plant material	Numbers present are reduced	Numbers present are reduced	May improve food safety by physically reducing pathogenic bacteria present but levels may increase if the water is poor quality, not changed frequently, or if too great a volume of fresh produce is washed at the same time	Variable. Washing may damage surfaces which would allow microbial growth and decrease shelf life
Cooking – includes baking	Numbers present are reduced to very low levels	No decrease in numbers and the process may activate germination of the spores	Vegetative pathogenic bacteria inactivated using a validated process Spores will survive and may germinate to make the food unsafe if it is not consumed or cooled immediately Some but not all pre-formed bacterial toxins will be inactivated	Extended (providing that cooling is managed), unless spores are able to germinate and grow post-cooking or baking
Cooling of cooked foods	Minimal reduction in numbers	Potential for spores to germinate and grow if cooling is slow or uncontrolled	Spore-forming pathogenic bacteria will germinate if cooling is not managed correctly and the food may become unsafe	Decreased if cooling is not managed correctly and any spore-forming bacteria present germinate
Pasteurisation of liquids or solids	Numbers are reduced to low levels	No decrease in the number of spores and may be activated	Significant improvement provided that the time and temperature applied is appropriate and cooling managed correctly	Extended provided that cooling is managed correctly
UHT / aseptic processing	Inactivates most vegetative bacteria and yeasts/moulds	Inactivates most spores except for a few heat resistant spoilage types (however these are usually unable to grow in the anaerobic environment at ambient temperatures in the container)	Foods become low risk	Significant extension
Canning and retorting	Inactivates most vegetative bacteria and yeasts/moulds	Inactivates most spores except for a few heat resistant spoilage types (however these are usually unable to grow in the anaerobic environment at ambient temperatures)	Foods become low risk	Significant extension

Microbiological hurdles i.e. multiple factors such as high salt, lowering of pH, nitrates, high sugar, fermentations, decreased moisture/drying	Variable effect depending on the specific microbiological hurdles applied	No decrease in numbers but spores may be inhibited from germinating	Combinations of hurdles will vary in ability to inactivate or inhibit growth of pathogenic bacteria	Extended as long as conditions remain unchanged
Addition of preservatives including some spices and herbs <sup>1</sup>	Prevents increases of a specific range of microorganisms	No decrease in numbers but spores may be inhibited from germinating	Improves food safety by inhibiting growth of a specific range of pathogenic bacteria	May provide some shelf life extension by inhibiting spoilage May ensure shelf life met by preventing growth of contaminants introduced into product during use
Salting, drying and pickling	Will inhibit the growth of most pathogenic bacteria and some spoilage microorganisms	No decrease in numbers but spores may be inhibited from germinating	Vegetative forms of pathogenic bacteria may survive for a while but will usually die off over time	Extended as long as conditions remain unchanged
Packaging and gaseous atmosphere including excluding air with oil <sup>2</sup>	Will inhibit the growth of many pathogenic bacteria and spoilage microorganisms. Could promote growth if not careful	Variable - depends on the gaseous requirements of any spore-forming bacteria that could be present	Pathogenic bacteria could grow if conditions are suitable. Gaseous environment may favour pathogenic bacteria by suppressing growth of spoilage microorganisms that would inhibit pathogenic bacteria	Extended as long as conditions remain unchanged
Storage temperature	Chilled (<5°C) – decreases growth Frozen – stops growth of most microorganisms	Chilled (<5°C) – stops growth except for cold-tolerant Frozen – variable; stops the germination and growth of most bacterial spores whilst for other spores the numbers will decrease	Chilled (<5°C) – cold-tolerant pathogenic bacteria will be a concern if present Frozen – stops growth of most pathogenic bacteria and some will decrease in number over time	Extended for chilled; major extension for frozen

<sup>1</sup> Herbs and spices used as preservatives must be free of pathogenic bacteria and spoilage microorganism or they will adversely impact on the food safety and shelf life of the food

<sup>2</sup> The gaseous environment created may however favour the growth of some pathogenic bacteria and of spoilage microorganisms that do not grow in air or favour low oxygen environments. Of particular concern are *Clostridium botulinum* spores which may be present on some seafood and plant material harvested from locations where this bacterium is found. Not thought to be of major concern for material grown in New Zealand soil or locally sourced seafood.

## 10 Resource material - Pathogenic bacteria associated with ready-to-eat chilled foods

There are four cold-tolerant bacteria that it is essential to consider when determining a date mark for a chilled ready-to-eat food (identified in Figure 1, *step 5* of the decision tree). It is important that if any of these pathogenic bacteria could be present in the food at the end of processing, that the storage conditions and time will not result in the bacteria growing to unsafe levels during the shelf life. A 'use-by' date will be needed if there is the potential for this to occur to ensure that the consumer does not eat the food beyond this date.

Of the four cold-tolerant pathogenic bacteria listed, the most relevant to New Zealand produced food is *Listeria monocytogenes*. For information on all the pathogenic bacteria, refer to the Pathogen Data Sheets published on the MPI website together with the information provided below:

<http://www.foodsafety.govt.nz/science-risk/hazard-data-sheets/pathogen-data-sheets.htm>

### 10.1 *Listeria monocytogenes*

[Listeria monocytogenes Pathogen Data Sheet](#)

#### Illness that could result if present in food

Food containing large numbers of *Listeria monocytogenes* may cause listeriosis when consumed, especially if the consumers are vulnerable to infection, which includes women who are pregnant, the frail elderly and those whose immune system is suppressed. Listeriosis is fatal in about a quarter of the cases.

#### How it gets into food

*Listeria monocytogenes* is widespread in the environment and so can be introduced into the food at any stage from raw ingredient to the end of processing if the opportunity exists. It will therefore be important to keep levels as low as practicable in raw ingredients and in the processing environment.

*Listeria* is a frequent contaminant of wet processing environments and forms a biofilm inside and on the surface of all types of processing equipment. Biofilms are layers of the bacteria which attach to surfaces and become hard to remove. However bacteria can detach from the biofilm and contaminate the food being processed. In the processing environment drains are a potential source of contamination.

It is vital to prevent ready-to-eat foods from becoming contaminated once they have been processed. Where this potential exists it is essential that post-processing activities are carried out in a specialist care area where hygiene is strictly controlled.

Risk management options	Effectiveness in controlling <i>Listeria monocytogenes</i>
Pasteurisation	Susceptible to commonly used time/temperature combinations – see the appropriate pathogen data sheet for details
Raw materials and ingredient controls and specifications	For ingredients that could be heavily contaminated, apply incoming raw material specifications at levels that processing can eliminate; reject or apply additional controls to incoming raw materials harvested under conditions that could result in elevated levels e.g. milking animals with mastitis, vegetables harvested in bad weather
Formulation of food	Will not usually grow in foods with pH <4.4, water activity <0.92; Combinations of hurdles will also be effective e.g. pH 5.0 with a water

	activity of <0.94; minimum salt level of 3.5% in the aqueous phase throughout the food
Gaseous environment of packaging	<i>Listeria</i> will grow both in air and in the absence of air (vacuum packaging); will grow at 30% CO <sub>2</sub> but not at 100%.
Presence of spoilage or other microorganisms, e.g. fermentative	Poor competitor so will not grow well in fermented foods and when spoilage organisms present
Cold storage	Chilled storage (<5°C) only reduces growth rate; growth stops during frozen storage but they will survive freezing
Preservatives	Many commonly used preservatives will prevent growth but effectiveness should be confirmed. May be most effective when used with other inhibitory factors e.g. low pH, fermenting microorganisms
Pasteurisation of food in retail packs	For processed food, especially where competing bacteria have been eliminated, post-processing contamination is a concern. A validated treatment, such as pasteurisation in-pack will eliminate this contamination
Processing environment	For foods vulnerable to contamination, a <i>Listeria</i> Management Programme with a well designed environmental monitoring programme will identify when there is the potential for contamination to occur

Refer to the MPI Guidance for the control of *Listeria monocytogenes* in ready-to-eat foods  
<http://www.foodsafety.govt.nz/science-risk/programmes/hazard-risk-management/listeria.htm>

## 10.2 *Clostridium botulinum*

[Clostridium botulinum Pathogen Data Sheet](#)

### Illness that could result if present in food

Toxins released into the food during bacterial growth are powerful neurotoxins and may cause botulism which is very often a fatal illness.

### How it gets in to food

The bacteria occur in the soil and so are commonly associated with plant material. They may also be found in association with seafood. Only some strains are of concern for refrigerated foods. These strains are identified as non-proteolytic (Group II) *C. botulinum* Types B, E and F. While there is one recorded event in New Zealand where two sisters were diagnosed as having botulism from eating incorrectly preserved mussels and watercress, *C. botulinum* was not isolated from the food. Previous surveys of the New Zealand environment have not detected *C. botulinum* Type E, a hazard for smoked fish, nor *C. botulinum* Type A. Other strains of *C. botulinum* have been isolated in New Zealand, but are not human pathogens (types C and D). Notwithstanding any conclusion that New Zealand ingredients could be considered unlikely to be contaminated with human pathogenic *C. botulinum*, ingredients and raw materials imported from other countries could carry the botulinum spores. *C. botulinum* grows only in the absence of air (anaerobic) so is only an issue in foods in sealed packaging from which air is excluded e.g. vacuum packaging, foods packed in oil, canning and retorting.

Risk management options	Effectiveness in controlling cold-tolerant (non-proteolytic) <i>Clostridium botulinum</i>
Heat treatment	Both spores and vegetative cells of cold tolerant <i>C. botulinum</i> can be inactivated by heat processing (heating to 90°C for 10 min) (unlike other types of <i>Clostridium botulinum</i> which produce heat resistant spores); toxin in food can be inactivated by heating (D74°C = <3 minutes)
Raw materials and ingredient controls and specifications	While there are now simple cultural or molecular tests that suggest the presence of <i>C. botulinum</i> vegetative cells and spores in food samples, confirmation requires demonstration of the presence of genes for the toxins and co-factors, as detected by PCR or NGS, and confirmation by mouse bioassay of toxin production. Review the source of critical materials from countries where <i>C. botulinum</i> could occur
Formulation of food	Will not usually grow in foods with pH <5.0 but this may then encourage spores to form; minimum water activity for growth 0.97; minimum salt level of 3.5% in the aqueous phase
Gaseous environment of packaging	Will not grow in air; will grow in the absence of air i.e. vacuum packaging, retorted and canned product; growth rate reduced in 100% CO <sub>2</sub>
Presence of spoilage or other microorganisms e.g. fermentative	Will be inhibited by the presence of fermentative microorganisms
Cold storage	Will not grow at temperatures <3°C or during frozen storage
Preservatives	Nitrites/nitrates most commonly used preservatives in meat are effective only in combination with lowered pH and fermenting microorganisms
Pasteurisation of food in retail packs	Pasteurisation in-pack will not inactivate spores

A useful source of information from the U.K. is the Food Standards Agency Guidance on the safety and shelf life of vacuum and modified atmosphere packed chilled foods with respect to non-proteolytic *Clostridium botulinum*

<http://www.food.gov.uk/multimedia/pdfs/publication/vacpacguide.pdf>

## 10.3 *Bacillus cereus*

[Bacillus cereus Pathogen Data Sheet](#)

### Illness that could result if present in food

*B. cereus*-associated foodborne illness occurs as two distinct intoxication syndromes: emetic and diarrhoeal. Recovery is rapid for both syndromes, usually within 12-24 hours of consuming food contaminated with large numbers of the bacteria which grow and produce toxin. There are usually no long-term effects.

## How it gets into food

Widely found in the environment and associated with raw ingredients including milk, so where they are a concern, the levels need to be as low as possible. Only a very few strains of *B. cereus* and other related *Bacillus* species are both pathogenic and cold-tolerant and so would be a potential issue for chilled ready-to-eat foods and there is little evidence that these strains of *B. cereus* are widely found in New Zealand.

Risk management options	Effectiveness in controlling cold-tolerant <i>Bacillus cereus</i>
Heat treatment	Both spores and vegetative cells can be inactivated by heat processing but the inactivation of spores will require elevated temperatures. If vegetative cells are allowed to grow and produce toxins, the toxins are not easily destroyed by heat
Raw materials and ingredient controls and specifications	Spores associated with starchy foods and dairy ingredients. May apply specifications for aerobic spores; spores survive well in dry ingredients
Formulation of food	Will not usually grow in foods with pH <4.5 and water activity <0.91
Gaseous environment of packaging	Will grow in presence or absence of air; i.e. in most modified atmosphere packaging (MAP) but toxin production only when oxygen present
Cooling of foods post-processing	Spores that survive a heat process e.g. cook step will become vegetative cells and grow in numbers if the cooling stage is extended. Rapid controlled cooling therefore vital so that toxins are not formed by the growing cells
Cold storage	Few strains will grow at temperatures <7°C or during frozen storage
Preservatives	Vegetative cells inhibited by a number of preservatives e.g. sorbate and benzoate
Pasteurisation of food in retail packs	Pasteurisation in-pack will not inactivate spores
Processing environment	Can form biofilms in processing equipment and become difficult to remove; ensure cleaning programme capable of removing and preventing biofilm formation

## 10.4 *Yersinia enterocolitica*

[Yersinia enterocolitica Pathogen Data Sheet](#)

### Illness that could result if present in food

Infection can cause diarrhoea and abdominal pain one week after consuming contaminated food. Symptoms may be mistaken for appendicitis. The illness is usually self-limiting but may be more severe and complicated in children under five years and other vulnerable consumers.

### How it gets into food

The bacteria are transmitted from food animals and so can be contaminants of pork, beef, lamb and poultry. Fresh produce may become contaminated from the environment or directly from animals and possibly birds. While food has been suggested as a source of infections in New Zealand, cases have not been linked to processed foods.

<b>Risk management options</b>	<b>Effectiveness in controlling cold-tolerant <i>Yersinia enterocolitica</i></b>
Heat treatment	Readily inactivated by heat processing including pasteurisation
Raw materials and ingredient controls and specifications	Associated with raw meat, including offal – contamination of carcasses may be reduced by certain practices; potential to be associated with plant material reduced by good agricultural practices
Formulation of food	pH variable and may grow in foods with pH 4.2; does not grow if water activity <0.96
Fermentation and drying	In meat products, survival will be inhibited in a well controlled and effective fermentation or drying process
Gaseous environment of packaging	Will grow in presence or absence of air; i.e. in most MAP packaging
Cold storage	Will grow at temperatures as low as -1.3°C
Preservatives	May be inhibited by preservatives but data limited
Pasteurisation of food in retail packs	Pasteurisation in-pack will inactivate
Processing environment	Evidence that contaminated water used in processing has been a source of contamination in some outbreaks



## 11 Resource material - Useful links

### 11.1 Shelf life and date marking in general

- *Guide to labelling requirements* <http://www.foodsafety.govt.nz/elibrary/industry/nzfsa-food-labelling-guide/>
- *FSANZ user guide to date marking*  
<http://www.foodstandards.gov.au/code/userguide/Pages/datemarking.aspx>
- *Validation of Product Shelf life. Guidance note* (Food Safety Authority of Ireland) (Includes a discussion of intrinsic and extrinsic factors influencing the growth of microorganisms)  
[www.fsai.ie/Guidancenote18validationofproductshelfliferevision1.html](http://www.fsai.ie/Guidancenote18validationofproductshelfliferevision1.html)
- *Code of Hygienic Practice for Refrigerated Packaged Foods with Extended Shelf Life CAC/RCP 46-(1999)* (Codex) [http://www.codexalimentarius.net/download/standards/347/CXP\\_046e.pdf](http://www.codexalimentarius.net/download/standards/347/CXP_046e.pdf)
- *Evaluation and Definition of Potentially Hazardous Foods* (USA)  
<http://www.fda.gov/food/foodscienceresearch/safepracticesforfoodprocesses/ucm094141.htm>

### 11.2 Foodborne disease surveillance

<http://www.foodsafety.govt.nz/science-risk/human-health-surveillance/>

### 11.3 *Listeria monocytogenes*

- [Listeria monocytogenes Pathogen Data Sheet](#)
- *Shelf life in relation to L. monocytogenes guidance for food business operators* (U.K.)  
<http://www.chilledfood.org/Resources/Chilled%20Food%20Association/Public%20Resources/Shelf%20life%20of%20RTE%20foods%20in%20relation%20to%20Lm%20FINAL%20v1.1.1%2023%203%2010.pdf>
- Technical guidance on *Listeria monocytogenes* shelf life studies for ready-to-eat foods (EC)  
[http://ec.europa.eu/food/food/biosafety/salmonella/docs/guidoc\\_listeria\\_monocytogenes\\_en.pdf](http://ec.europa.eu/food/food/biosafety/salmonella/docs/guidoc_listeria_monocytogenes_en.pdf)
- Guidance document on *Listeria monocytogenes* shelf life studies for ready-to-eat foods, under Regulation (EC) No 2073/2005 of 15 November 2005 on microbiological criteria for foodstuffs  
[http://ec.europa.eu/food/food/biosafety/salmonella/docs/shelflife\\_listeria\\_monocytogenes\\_en.pdf](http://ec.europa.eu/food/food/biosafety/salmonella/docs/shelflife_listeria_monocytogenes_en.pdf)

### 11.4 *Clostridium botulinum*

- [Clostridium botulinum Pathogen Data Sheet](#)
- *Clostridium botulinum* in New Zealand marine sediments: Very low prevalence of *Clostridium botulinum* in New Zealand marine sediments (368 KB PDF)  
[http://foodsafety.govt.nz/elibrary/industry/Clostridium\\_Botulinum-Science\\_Research.pdf](http://foodsafety.govt.nz/elibrary/industry/Clostridium_Botulinum-Science_Research.pdf)
- Guidance on the safety and shelf life of vacuum and modified atmosphere packed chilled foods with respect to non-proteolytic *Clostridium botulinum* (U.K. Food Standards Agency)  
<http://www.food.gov.uk/multimedia/pdfs/publication/vacpacguide.pdf>
- Information sheet for manufacturers of vacuum packed chilled foods (U.K. Food Standards Agency)  
<http://www.food.gov.uk/multimedia/pdfs/publication/vacpack0708.pdf>

## 11.5 Predictive modelling

- Instructions on how to use predictive modelling and the main models can be found at <http://portal.arserrc.gov/>
- **ComBase** - includes Combase Predictor (previously Growth Predictor and Food MicroModel) with growth or inactivation models for 12 foodborne pathogenic bacteria, a growth model for *Brochothrix thermosphacta*, and *Perfringens* Predictor. <http://www.combase.cc>
- **Pathogen Modeling Program** - The latest version includes more than 40 models for different bacterial pathogenic bacteria and allows growth or inactivation of pathogenic bacteria to be predicted for different combinations of constant temperature, pH, NaCl/ $a_w$  and, in some cases, other conditions such as organic acid type and concentration, atmosphere, or nitrate. <http://www.ars.usda.gov/services/docs.htm?docid=6786>
- **Seafood Spoilage and Safety Predictor Software**, Danish Institute for Fisheries Research - The SSSP software predicts shelf life and growth of bacteria in different fresh and lightly preserved seafood e.g. the effect of product temperature profiles recorded during storage and distribution by data loggers. <http://sssp.dtuqua.dk/>
- **Sym'Previus** - an extensive French decision support system that includes (i) a database with growth and inactivation responses of microorganisms in foods and (ii) predictive models for growth and inactivation of pathogenic bacteria and some spoilage microorganisms <http://www.symprevius.net>
- **Shelf Stability Predictor** - Developed by the Center for Meat Process Validation at the University of Wisconsin - Madison to predict the growth of *Listeria monocytogenes* and *Staphylococcus aureus* on ready-to-eat meat products as a function of pH and water activity ([http://meathaccp.wisc.edu/ST\\_calc.html](http://meathaccp.wisc.edu/ST_calc.html) )
- **FORECAST** - is a shelf life prediction service for chilled foods where predictions for *Pseudomonas spp.*, *Bacillus spp.*, *Enterobacteriaceae*, Yeast and Lactic acid bacteria are available. FORECAST is available from Campden BRI, Chipping Campden, Gloucestershire, GL55 6LD, UK, phone +44(0)1386 842071, [g.betts@campden.co.uk](mailto:g.betts@campden.co.uk) or [l.everis@campden.co.uk](mailto:l.everis@campden.co.uk) (<http://www.campdenbri.co.uk/services/predictive-microbiological-models.pdf> )
- **Purac™** Listeria Control Model 2012 - predicts the growth of *Listeria monocytogenes* in food products, with the use of eight food characteristics. <http://www.purac.com/EN/Food/Calculators/Listeria-Control-Model.aspx>

## 11.6 Challenge testing

- USFDA Evaluation and Definition of Potentially Hazardous Foods - Chapter 6. Microbiological Challenge Testing <http://www.fda.gov/Food/FoodScienceResearch/SafePracticesforFoodProcesses/ucm094154.htm>
- *Listeria monocytogenes* Challenge Testing of Ready-to-Eat Refrigerated Foods (Health Canada) [http://www.hc-sc.gc.ca/fn-an/legislation/pol/listeria\\_monocytogenes-test-eng.php](http://www.hc-sc.gc.ca/fn-an/legislation/pol/listeria_monocytogenes-test-eng.php)
- *Clostridium botulinum* Challenge Testing of Ready-to-Eat Foods (Health Canada) <http://www.hc-sc.gc.ca/fn-an/legislation/pol/sop-cbot-eng.php>

- Challenge Testing of Microbiological Safety of Raw Milk Cheeses: The Challenge Trial Toolkit <http://foodsafety.govt.nz/elibrary/industry/challenge-trial-toolkit/index.htm> This report provides information about the conduct of challenge trials for raw milk cheeses and is a useful background on the conduct of challenge trials in other foods, including the need to characterise the microorganisms used

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