Shelf life testing

‘Use-by’ dates for food safety
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Executive summary
Date marking of foods is regulated by Standard 1.2.5 – Date Marking of Food of the Australia New Zealand Food Standards Code.

If:

- nutrient levels decline to unacceptable levels in a food intended by the manufacturer to form the sole source of nutrition for a person’s diet for a specified period or
- the food can become microbiologically unsafe before the food noticeably spoils

then a use by date is applicable.

Where deterioration of a food affects consumer acceptance without impacting health and safety a best before date is applicable. Foods with a shelf life of at least two years are not required to display a best before date.

The length of the use by time for foods can be determined by using storage trials to estimate the physical, chemical and microbiological stability of the food. Interpretation of results requires technical experience and competence. Some products will require additional studies such as computer models of microbial growth or challenge studies.

It is the manufacturer’s responsibility to determine shelf life. Reliable use by or best before times cannot be determined by guesswork or by copying the shelf life of a competitor’s product.
When is date marking required?

Date marking of foods is regulated by *Standard 1.2.5*. A fact sheet (FSANZ 2003) and a user guide (ANZFA 2001) to this standard are available on the Food Standards Australia New Zealand (FSANZ) website. *Standard 1.2.5*, the guidance materials and other labelling standards should be consulted to understand the specific legal requirements relating to date marking.

If food must be eaten within a certain period for **health** or **safety** reasons a *use by* date is required:

- The ‘health reason’ is applicable to food that is intended by the manufacturer to form the sole source of nutrition for a person’s diet for a specified period. This will apply where storage affects the critical nutrient profile of products such as infant formula or special dietary foods manufactured to provide the sole source of nutrition to persons who are ill or are unable to eat normal foods.

- The ‘safety reason’ is applicable to food that can become microbiologically unsafe before the food noticeably spoils. This will not apply to shelf stable, frozen or most raw foods but may apply to certain chilled ready-to-eat foods, for example chilled meals and salads. Development of *use by* dates for safety reasons is discussed below.

A *best before* date is applicable to food where deterioration affects consumer acceptance without impacting on health and safety. Many product changes will affect consumer acceptance, including:

- rancidity
- texture changes
- moisture loss
- moisture gain
- staling
- flavour loss
- light induced changes
- enzymatic browning
- chemical browning, and
- microbial spoilage.

There is an exemption from *best before* date marking for products with a shelf life of two years or longer. A scan of supermarket shelves identified few products that were not date marked. These included sugar, golden syrup, treacle, honey, some soft drinks, canned fruit, canned vegetables, canned soup, vinegar, some canned fish and some cook-in sauces. Apart from these products, a shelf life of two years or longer is uncommon. While is it not mandatory in Australia some international food regulators recommend that all food be date marked to support ‘first in – first out’ food consumption.

The flow chart (over page), which is adapted from the user guide to *Standard 1.2.5*, helps with the decision between *best before* and *use by* date marking.
Food safety date marking decision support

Is the food shelf stable?

Yes ▼

No ▼

Is the food frozen?

Yes ▼

No ▼

Is the food a raw food that requires a process such as cooking to reduce food-poisoning bacteria to make the food safe to eat?

Yes ▼

No ▼

Is the food a chilled ready-to-eat product?

Yes ▼

No ▼

Is there a reasonable likelihood that the food could contain one of the following food poisoning bacteria: *Listeria monocytogenes*, *Yersinia enterocolitica* or cold tolerant strains of *Bacillus cereus* or *Clostridium botulinum*?

Yes ▼

No ▼

Will the food discernibly spoil before levels of bacteria would reach dangerous levels?

Yes ▼

No ▼

Best before date to be applied if shelf life is less than 2 years.

Use by date to be applied

Reference: ANZFA 2001
How is shelf life determined?

There are many answers to this question, depending on the type of deterioration that the product undergoes. The NSW Food Authority has food safety as a primary objective and so considers reliable use by dates to be essential. If use by or best before dates are overstated there is a substantial risk of damage to a business’s reputation and brands. Food businesses must attend to all date marking requirements but this document will focus on the setting of reliable use by dates.

Product development

Product development must be well advanced before a business can have confidence in shelf life estimates. The business must be able to reliably produce homogeneous product with consistency from batch to batch. Physical and chemical factors that impact on the capacity of bacteria to grow, such as pH, water activity and evenness of mix (distribution of moisture, salt, preservative or food acid) must be well controlled. The physical, chemical and microbiological profile of several batches of finished product must be established. The potential for product contamination must be evaluated. The packaging materials must be identified.

Product stability and food safety

Initial studies are likely to consist of storage trials under the recommended storage conditions. Refrigerated storage trials should be run at 5°C and under conditions of mild temperature abuse equal to what might be encountered in the commercial cold chain. Products should be inspected at suitable times and samples tested for stability of the critical physical and chemical characteristics. These trials also provide an opportunity to commence microbiological tests for both spoilage organisms and the cold-tolerant pathogens named in the flow chart above. The trials should continue beyond the targeted shelf life unless the product fails earlier.

Subtle changes during storage can be significant:

- Does pH change eg due to microbial growth or failing buffering systems?
- Is water redistributed within the product eg due to syneresis, condensation or a broken emulsion?
- Is the preservative system stable?
- Are there any signs of surface growth of microorganisms?
- Does any modified atmosphere persist for required times?
- Do chemicals migrate from the food-contact materials into the food?
- Are there any unforeseen changes to the product?

The trials should lead to an understanding of target levels and ranges for the critical physical and chemical characteristics of the product over the intended shelf life. The worst case or least restrictive values (maximum or minimum as the case may be) of the key chemical characteristics can then be compared to published values to evaluate the opportunity for microbial growth, particularly for the key cold-tolerant pathogens.

The user guide to Standard 1.2.5 provides much of the information likely to be required to complete the evaluation. Critical values for individual factors are shown in Table 1.
Table 1: Limits for growth of cold-tolerant pathogens

<table>
<thead>
<tr>
<th>Pathogen</th>
<th>Temperature</th>
<th>Salt</th>
<th>pH</th>
<th>(a_w)</th>
<th>Comment</th>
</tr>
</thead>
<tbody>
<tr>
<td><em>Bacillus cereus</em></td>
<td>(&lt;4^\circ C)^2</td>
<td>&gt;7%^1</td>
<td>&lt;4.3^1</td>
<td>&lt;0.91^1</td>
<td>Grows in the presence and absence of oxygen</td>
</tr>
<tr>
<td><em>Clostridium botulinum</em></td>
<td>(&lt;3.3^\circ C)^1</td>
<td>&gt;5%^1</td>
<td>&lt;5^1</td>
<td>&lt;0.97^1</td>
<td>Requires absence of oxygen</td>
</tr>
<tr>
<td><em>Listeria monocytogenes</em></td>
<td>(&lt;-0.4^\circ C)^2</td>
<td>&gt;10%^1</td>
<td>&lt;4.39^2</td>
<td>&lt;0.92^2</td>
<td>Grows in the presence and absence of oxygen</td>
</tr>
<tr>
<td><em>Yersinia enterocolitica</em></td>
<td>(&lt;-1.3^\circ C)^1</td>
<td>&gt;7%^1</td>
<td>&lt;4.2^2</td>
<td></td>
<td>Grows in the presence and absence of oxygen</td>
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References: 1 ANZFA 2001; 2 ICMSF 1996

If single factors will not prevent the growth of the cold-tolerant pathogens it is still possible that two or more factors might combine to inhibit growth. Microbiological growth models can be used to examine that possibility. A number of microbial growth modelling programs are available but interpretation of results requires experience and technical expertise.

Figure 1 is the output from a model (ComBase Predictor undated) for growth of *Listeria monocytogenes* in a hypothetical food. The graphic compares three food formulations; one at pH 5; the second with water activity \((a_w)\) 0.94 and the third with pH 5 and \(a_w\) 0.94.

Figure 1: Microbial growth models in shelf life studies

This combination of reduced pH and \(a_w\) significantly inhibit the growth of *Listeria monocytogenes*.

Affects of nitrite and lactate can be explored in some of the microbial growth models. However, the modelling programs do not extend to the impact of preservatives such as sorbates and sulphites and specialised technical expertise may be required to evaluate preservative efficacy.

The use of all food additives must comply with *Standard 1.3.1*. 
Microbial growth models, such as ComBase, can also be used to illustrate the importance of using realistic rather than ideal temperatures for storage trials. Figure 2 shows the hypothetical growth rate of *Listeria monocytogenes* in food with a pH of 5.5 and salt content of 2%.

Figure 2: The importance of using realistic temperatures in storage trials

This figure demonstrates that *Listeria monocytogenes*, under conditions of mild thermal abuse—temperatures that could well be encountered in the Australian cold chain—can grow (hypothetically) from a count of 10/g to about 100,000/g within the shelf life of many chilled foods. The use of ideal temperatures in shelf life studies is bad practice and likely to be misleading.

It must be noted that that model predictions are based on observations made in artificial growth media and available product studies. To understand how a pathogen will behave in a specific product requires challenge tests.

**Challenge tests**

A challenge test is similar to the microbiological testing used in storage trials mentioned above. The difference is that specific cold-tolerant pathogens are added to the product prior to packaging. Storage tests on products where pathogenic bacteria are only occasionally present are likely to be misleading. The design and evaluation of challenge tests should be done by an expert food microbiologist (NACMCF 2009).

If ‘growth – no growth’ is not clear from other studies then challenge tests can be very useful. Their use is not required where it is obvious that either growth won’t occur or growth will occur. Challenge tests are used to clarify areas of uncertainty and verify growth models for products with chemical characteristics near to the growth – no growth border.

**Cultures of pathogenic bacteria should never be introduced into a food processing factory.** Challenge tests should only be done in an off-site laboratory or research facility.
Expiry testing program
Retained samples from commercial batches of product should be tested for microbiological and chemical quality upon expiry of shelf life. Newly launched products should be tested more frequently while proven products should be tested occasionally. Samples for testing should be stored under realistic rather than ideal temperature conditions. Expiry testing provides further assurance that manufacturing systems are under control.

Use by estimation – an auditable program
A series of linked documents can be used to provide objective evidence that use by dates are reliable.

Product specification: this should list the physical, chemical and microbiological characteristics of the product. In some cases the document might specify both release (start of shelf life) and expiry (end of shelf life) criteria. The specified criteria should be traceable by formulation / recipe / block code to product development records.

Even seemingly minor changes to ingredients, manufacturing procedures, packaging or distribution can have adverse affects on product safety and use by dates. The shelf life of the revised product should be verified, for example, by expiry testing of trial batches.

For the same reason, similar precautions should be taken when applying the same use by date to a family of products with very similar characteristics. The product where growth is least restricted should be used in the shelf life study.

The specification should also correlate with quality assurance test results for manufactured batches. The specification should include recommended storage conditions and the shelf life. This should be traceable to the shelf life study.

Shelf life study: this should summarise the storage trial results and any required microbial growth modelling and challenge tests. The report should justify the shelf life estimate.

Expiry testing records: quality assurance test results on retention samples stored for the product’s shelf life at realistic temperatures should verify the shelf life claims.

Determination of best before dates
There are potentially many questions to be answered about product deterioration and many approaches to getting the answers. If products have a long shelf life then real time testing is not likely to fit in with product development cycles. In many cases accelerated stability testing can be used to estimate shelf life; but technical expertise is a necessity. Real time testing—after the product has been launched if necessary—should be used to verify estimated best before dates.

Accelerated stability testing typically involves storing products at high temperature / humidity / light intensity or similar. Products are tested following storage for different times and conditions. For some products, tests other than those used for routine quality control might be required. The calculations to convert the results of testing into an estimated shelf life are complex. Some businesses will require the services of a consulting chemist to supervise the studies.
References


Further reading
The following documents provide information that might be relevant for some products types.


