

**Scenario for justifying the shelf life of a Ready To Eat food in relation to**  
***Listeria monocytogenes (L. monocytogenes)***

**Cold-Smoked Salmon and Fresh Watercress Sandwich**

**Scope**

This is an example of the supporting evidence that may be gathered following the guideline document “*Shelf life of Ready to Eat food in relation to L monocytogenes – Guidance for Food Business Operators*”<sup>1</sup>. The ‘Boxes’ referred to in the text below relate to the boxes in the flow chart (Figure 2) on page 6 of the above document.

This example is given since it relates to the use of long shelf life ingredients.

Article 14 of Regulation (EC) No. 178/2002 ‘General Food Law’ states that “Food shall not be placed on the market if it is unsafe. Food shall be deemed to be unsafe if it is injurious to health or unfit for consumption”.

**Scenario**

*L. monocytogenes* has been isolated at less than 100 cfu/g from a chilled smoked salmon and watercress sandwich. The Local Authority (LA) has challenged the Food Business Operator (FBO) for justification of the shelf life and evidence that levels of *L. monocytogenes* would not exceed 100 cfu/g during its life.

**Product characteristics**

The sandwich is a **Cold-Smoked Salmon and Fresh Watercress Sandwich**.



This comprises cold-smoked salmon; shredded watercress; sliced wholemeal bread and butter. The completed sandwich has a 3 day chilled shelf life.

**Box 1 Requirements for safe manufacture of RTE foods**

The sandwich manufacturer (Food Business Operator (FBO)) has adopted GMP and GHP. The FBO has HACCP in place for the manufacture of the sandwiches and *L. monocytogenes* has been considered as a potential hazard in the HACCP study.

**Box 2 Ingredients**

The highest quality ingredients available are used, and are obtained from reputable suppliers. These were purchased to an agreed product specification which included (with the exception of the bread) a specification for *L. monocytogenes*.

The details of the ingredients are:

- **Salmon** which is supplied in 1kg packs with a 10 day chilled shelf life. The salmon is cold-smoked by a process of 30°C for 16 hours and has a salt content of 3.5%;

As part of the HACCP study the FBO had sought expert advice on this process and from this advice it was ascertained that this 'heat process' used in the cold-smoking of the salmon (30°C for 16h) was not sufficient to inactivate *L. monocytogenes*. (A process equivalent to 70°C for 2 minutes is required for this). Also, the salt concentration of 3.5% is not sufficient to control growth as *L. monocytogenes* can grow in the presence of salt at 10%, and survive in conditions of 25% salt. Some protection may be afforded by the preserving effect of the smoking, and competitive effects of the indigenous microbiological population of the component.

Cold-smoked salmon has been shown to be contaminated by *L. monocytogenes* at frequencies of 2-21%. Levels were generally less than 100 cfu/g with the highest count between 100 and 1,000 cfu/g<sup>1</sup>.

The salmon supplier had been audited by the FBO since the salmon had been highlighted as a potential risk during the HACCP study. A copy of the audit and follow up actions could be supplied to the LA as proof that the salmon had been purchased from a reputable supplier. Control of *Listeria* in the environment, shelf life studies and historical results for *Listeria* had been covered in this audit and demonstrated good control.

The supplier carries out routine testing for *L. monocytogenes* since the salmon is sold as a Ready To Eat (RTE) food. If these data were not held by the sandwich FBO then the supplier would be contacted to request analytical results, in particular for that batch of salmon used in the sandwich.

Once purchased the salmon is stored chilled at less than 5°C. HACCP records of the refrigerators can be retrieved to support this.

Since the salmon had a 10 day life, records would need to be retrieved to demonstrate that the salmon was used early enough within its life to ensure that the 10 days was not exceeded during the life of the sandwich, e.g. the salmon can only be used up to day 7 of its life since it needs a further 3 days for the life of the sandwich.

- **Fresh shredded watercress**, supplied in 500g packs with a 7 day chilled shelf life.

As part of the HACCP study, expert advice had been sought and since *L. monocytogenes* can be found in the environment in which watercress is grown; *L. monocytogenes* may be occasionally isolated. A literature search had cited a survey of 11 samples of watercress, 2 of which were found to be contaminated with *Listeria* spp<sup>1</sup>.

The watercress is washed by the supplier to reduce the microbial load and hence reduce the risk of isolation of *L. monocytogenes*. The supplier carries out routine testing for *L. monocytogenes* since the watercress is sold as a RTE food. If this data is not held by the sandwich FBO then the supplier would be contacted to request analytical results, in particular for that batch of watercress used in the sandwich.

Once purchased the watercress is stored chilled at less than 5°C. HACCP records of the refrigerators can be retrieved to support this.

Since the watercress had a 7 day life, records would need to be retrieved to demonstrate that 7 days was not exceeded during the life of the sandwich, e.g. the watercress can only be used

up to day 4 of its life since it needs a further 3 days for the life of the sandwich. The life had been demonstrated by the supplier to be limited to 7 days due to organoleptic quality rather than as a result of microbiological growth of *Listeria*.

- **Sliced wholemeal bread** supplied in 800g bags with a 7 day ambient shelf life.

As part of the HACCP study the FBO had ascertained that bread has no history of being contaminated with *L. monocytogenes* and it is prevented from growing due to the low  $a_w$  and because appropriate nutrients are not available. It is also specifically mentioned in the Regulation (EC) No. 2073/2005 as being a commodity where testing against *L. monocytogenes* is not useful under normal circumstances<sup>1</sup>.

Since the bread had a 7 day life, records would need to be retrieved to demonstrate that 7 days was not exceeded during the life of the sandwich, i.e. the bread can only be used up to day 4 of its life since it needs a further 3 days for the life of the sandwich. The life had been demonstrated by the supplier to be limited to 7 days due to organoleptic quality.

- **Butter**, supplied in 2kg tubs with a 6 week shelf life at chill temperatures.

As part of the HACCP study it was found from published data that butter has been associated with listeriosis, but this was an unusual occurrence, and came about as a result of butter being made incorrectly. (Butter is an emulsion of water droplets in a fat matrix. *L. monocytogenes* is normally controlled by the water droplets being of insufficient size to physically allow growth.)

The supplier carries out routine testing for *L. monocytogenes* since butter is a RTE food. If these data were not held by the sandwich FBO then the supplier would be contacted to request analytical results, in particular for that batch of butter used in the sandwich.

Once purchased the butter is stored chilled at less than 5°C. HACCP records of the refrigerators can be retrieved to support this.

### Box 3 Ensuring ingredients are RTE

All the ingredients are sold by their suppliers as RTE and no further processing other than combining the ingredients into the final sandwich product is carried out by the sandwich FBO.

### Box 4 Final product's characteristics

From Regulation (EC) No. 2073/2005, products are not considered to support the growth of *L. monocytogenes* if:

- pH is no more than 4.4, or
- $a_w$  is no more than 0.92, or
- pH is no more than 5.0 and the  $a_w$  is no more than 0.94
- shelf life is less than 5 days

The sandwich has a life of less than 5 days so under the Regulation (EC) No. 2073/2005 it would not be considered to support the growth of *L. monocytogenes*.

The individual ingredients have greater than 5 days life but have been used within their justified life and data is available to support this as part of the HACCP study with respect to the ingredients.

### Box 5 Historical testing data

Historical data may be collated from a number of sources:

- Ingredient supplier data as indicated in Box 2
- Temperature checks of ingredient intake and storage
- Temperature checks of final product during storage and despatch
- *Listeria* swabs of the manufacturing environment to demonstrate that GHP is functioning
- *L. monocytogenes* tests on final product demonstrating that a count of 100 cfu/g had not been exceeded during life.
- Although information and data on *Listeria* and *L. monocytogenes* is of prime importance, other microbiological data such as indicator organisms can be used to demonstrate that production is under control.

The level of confidence increases with the amount of data available. Ideally, this should cover eventualities of variability such as seasonality of ingredient/component supply.

Occasional counts of *L. monocytogenes* are to be expected in this type of product, as ingredients and factory environments may be contaminated from time to time. Positive results of this sort indicate that sampling procedures and testing methods are working.

Any isolation of *Listeria* from any RTE product or in the manufacturing environment must be investigated, appropriately actioned and records kept.

Deviations from other checks also need appropriate action and their potential affect on the final product considered and any necessary action documented.

## **Box 6 Additional data**

### **i. Predictive Microbiology**

It is not possible to carry out predictive microbiology on the final product due to the variety of distinct ingredients.

However predictive microbiology for *L. monocytogenes* could be carried out on the sandwich ingredients using appropriate commercially-available models such as ComBase (<http://www.combase.cc>). This software is designed to give an idea of how the pathogen might grow, but it does not take into account factors such as: the anti-microbial effects of smoking the salmon; competing microflora etc.

### **ii. Durability studies**

It is difficult to carry out durability studies on the final product due to the variety of distinct ingredients.

Although durability studies could be carried out on individual ingredients, durability studies as defined by the EU document on shelf life studies<sup>1</sup> are generally not easily used for determining the growth of pathogens in a foodstuff, as there is no guarantee that *L. monocytogenes* will be naturally present in sufficient numbers of products at the level required for the study.

### **iii. Challenge test**

It is difficult to carry out durability studies on the final product due to the variety of distinct ingredients.

A challenge test study may be commissioned to determine the behaviour of a pathogen in a foodstuff over life. For challenge tests, *L. monocytogenes* is deliberately introduced into the ingredient and growth determined over the life of the foodstuff. Care needs to be taken with such studies to ensure that the mode of inoculation of organisms does not affect the physical nature of the product, e.g. the  $a_w$ . Results from challenge tests need expert interpretation since it is difficult to artificially inoculate the organisms in the same way that they would naturally contaminate the food

In the above scenario, this additional data from predictive microbiology, durability studies or challenge tests were not deemed necessary since there was sufficient data from the ingredient suppliers and from the sandwich FBO to support the fact that although *L. monocytogenes* can occasionally be isolated from the sandwich in low levels there was justification that these levels would not be above 100 cfu/g over the 3 day chilled life.

## Conclusion

Providing there was sufficient data from the ingredient suppliers and from the sandwich FBO to support the fact that although *L. monocytogenes* can occasionally be isolated from the sandwich in low levels (i.e. less than 10 or 20 cfu/g depending on the test method used) there was justification that these levels would not be above 100 cfu/g over the 3 day chilled life. Therefore it may be concluded that the three day shelf life proposed is valid.

If the tests had indicated that the 100 cfu/g were to be exceeded, then either the shelf life would have to be reduced, alternative suppliers sought or further precautions taken with the ingredients and processing (e.g. use of 'hot-smoked' or 'canned' salmon instead of 'cold-smoked') to eliminate the risks during production.

## References

Advisory Committee on the Microbiological Safety of Foods (ACMSF) (2003) Information paper. Recent Trends in Listeriosis in the UK. ACM/667. December. London, UK.

Bell, C and Kyriakides, A (2005) *Listeria*: a practical approach to the organism and its control in foods, 2<sup>nd</sup> Edition. Wiley-Blackwell.

McLauchlin, J and Nichols, G L (1994) *Listeria* and seafood. *PHLS Microbiology Digest* 11(3), 151-154.