Shelf life of ready to eat food in relation to *L. monocytogenes* - Guidance for food business operators



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The information contained herein is to assist with implementation of the shelf life aspects of the EC Regulation on Microbiological Criteria for Foodstuffs in relation to* Listeria monocytogenes*. It is not a definitive interpretation of the law which only the courts can provide. Information and opinion herein are not substitutes for specific legal or other professional advice.

1. INTRODUCTION

Listeria monocytogenes (*L. monocytogenes*) may cause serious disease in humans and is typically transmitted via food. It is frequently present in nature and may be found in any food environment. *L. monocytogenes* can grow or survive even in chilled conditions. It is therefore important to manage hygiene and limit the shelf life of ready to eat (RTE) ingredients and finished products.

This shelf life guidance is designed for use by manufacturers and retailers of RTE food that might support the growth of *L. monocytogenes*. This guidance is designed to meet the needs of all levels of expertise, from small businesses and individuals to technical managers in large enterprises. It is also designed to help Competent Authorities and food law enforcement officers (hereafter referred to as enforcement officer(s)) to carry out their enforcement duties.

This UK good practice guidance, which is endorsed by the FSA, has been produced by a stakeholder drafting group chaired by the BRC, comprising representatives from the following organisations:

Organisation	Representative
Bakkavör	Bridgette Clarke
British Meat Processors Association	Elizabeth Andoh-Kesson
British Retail Consortium	Sally Barber
British Sandwich Association	Sally Higgins
Campden BRI	Roy Betts, Phil Voysey
Chilled Food Association	Kaarin Goodburn
Chartered Institute of Environmental Health	Jenny Morris
Food Solutions	Bob Salmon
Food Standards Agency	David Alexander
Greencore	Frances Swallow
Iceland Frozen Foods	Summer Rimmington
LACORS	David Lock
Marks & Spencer	Jenny Hopwood
Northern Foods plc	Fiona Brookes
Provision Trade Federation	Diana Axby
Sainsbury's Supermarkets	Juliette Jahaj
Specialist Cheesemakers Association	Paul Neaves
Tesco	Sam Kirk
The Co-operative Group	Neil Linford
Waitrose	Karen Sims

A representative from the UK National Reference Laboratory Services for Food Microbiology (Health Protection Agency, Christine Little) participated in the drafting group as an observer.

Comments were gratefully received from FSA officials.

This guidance will be updated as required in light of practical experience. Comments are welcomed, to be sent to the publishers.

The Microbiological Criteria for Foodstuffs Regulation (EC) No. 2073/2005 (as amended) provides for further criteria to be added in the future and businesses must ensure that they are aware of any changes.

The issuing organisations seek to ensure the information and guidance they provide is correct, but accept no liability in respect thereof. Such information and guidance are not substitutes for specific legal or other professional advice.

2. GUIDANCE AIMS AND SCOPE

This document aims to provide guidance for Food Business Operators (FBOs) and enforcement officers on practical implementation of the European Commission staff working document *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[1].

Regulation (EC) No. 2073/2005 (as amended, referred to hereafter as 'the Regulation') includes limits for the number of *L. monocytogenes* in RTE food and requires you to be able to demonstrate these are not exceeded. *L. monocytogenes* must be absent in RTE food intended for consumption by infants or for special medical purposes.

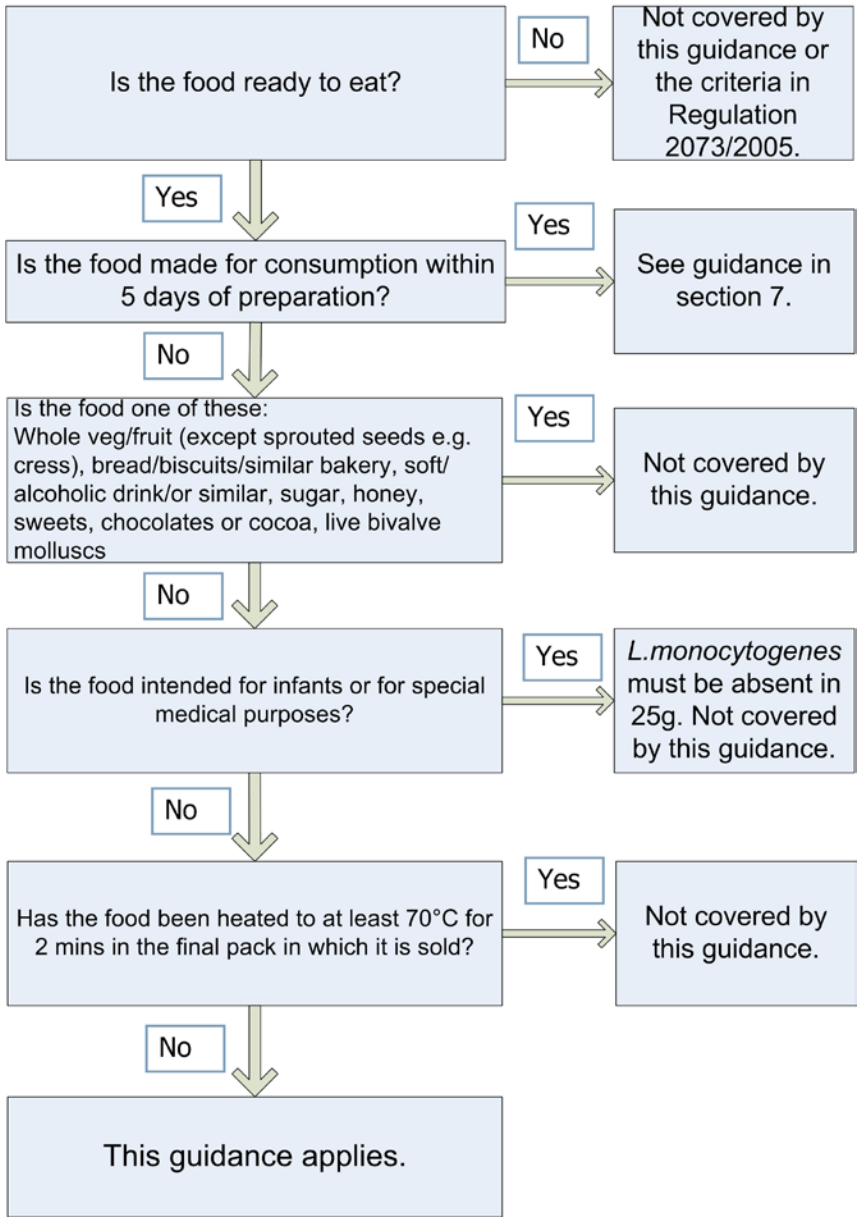
Under the Regulation a RTE food or ingredient with a shelf life of less than 5 days is considered to be unable to support the growth of *L. monocytogenes*. However, in practice since such foods may contain ingredients that support growth of *L. monocytogenes* you must in these cases have evidence to demonstrate that the limit of 100 cfu/g will not be exceeded, otherwise *L. monocytogenes* must be absent. Key compliance advice is given in section 6.

In addition, Article 14 of Regulation (EC) No. 178/2002 on '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". Setting shelf life requires taking into full consideration all chemical parameters, all microorganisms in addition to *L. monocytogenes*, and the intended consumer.

If you do not have the relevant technical expertise to make ready-to-eat foods safely then you are strongly recommended to seek relevant expert advice.

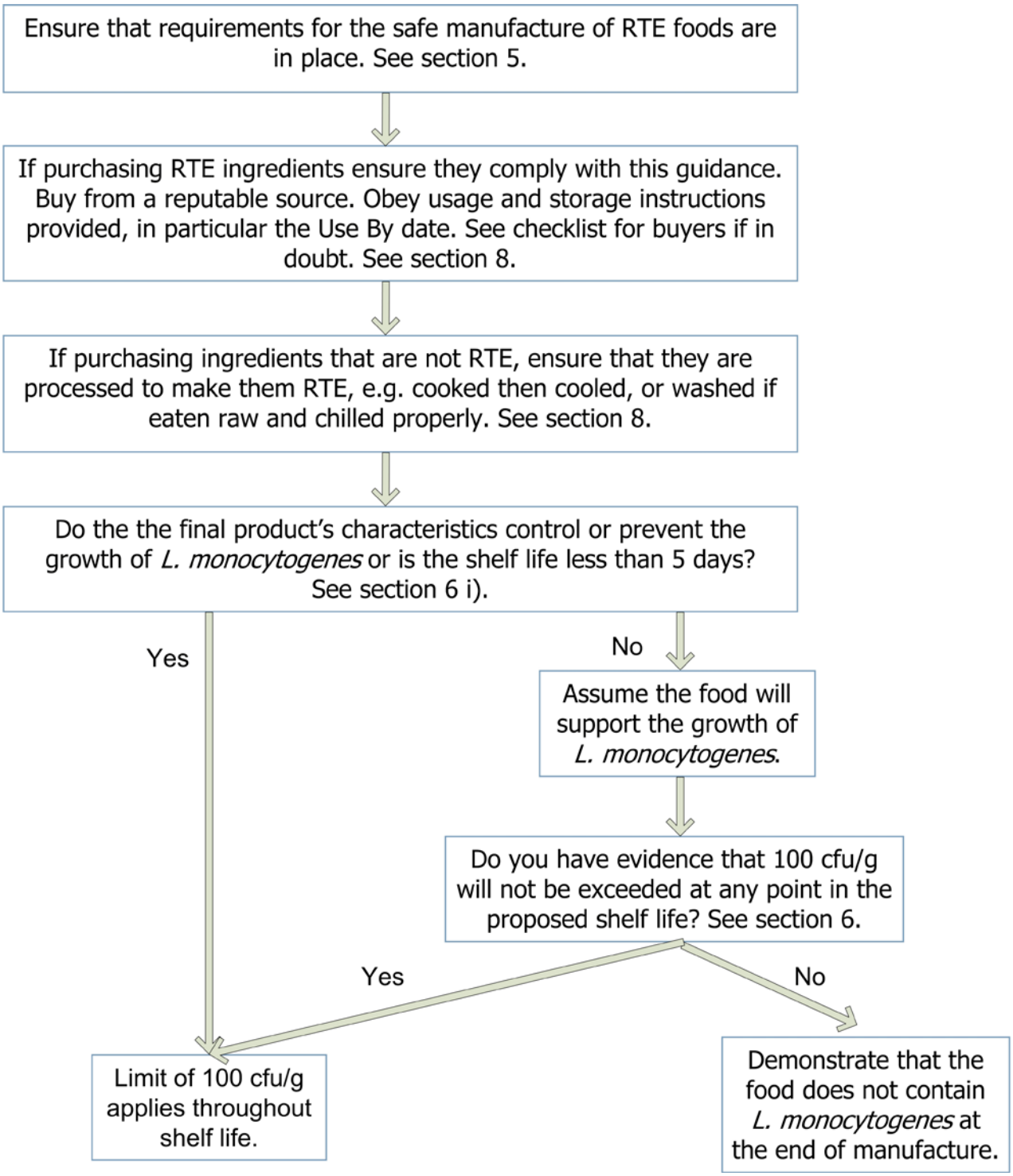
3. WHO NEEDS TO USE THIS GUIDANCE?

Figure 1: Decision Tree – Does this Guidance Apply to You?



4. GUIDANCE SUMMARY

Figure 2: Key Guidance Points



5. REQUIREMENTS FOR THE SAFE MANUFACTURE OF RTE FOOD

The manufacture of RTE food requires a particularly high standard of hygienic preparation.

The following prerequisites must be in place and followed:

1. Good Manufacturing Practices (GMP) and hygiene including:

    - Effective equipment cleaning and disinfection systems
    - Premises hygiene
    - A high standard of personal hygiene
    - Ingredients from reputable suppliers (see section 8)

2. Procedures based on Hazard Analysis & Critical Control Point (HACCP) principles, including separation between RTE and non-RTE food (e.g. cooked meat and raw meat) and associated equipment and personnel.

A system must be in place to check and review the effectiveness of HACCP based procedures and hygiene, and records kept of these data.

Relevant guidance and Industry Guides will provide further information (see section 11.3).

6. ESTABLISHING SHELF LIFE

The Regulation says that RTE foods must not exceed the limit of 100 cfu/g for *L. monocytogenes* at any point during their shelf life (except those intended for infants or particular medical purposes, which must not contain *L. monocytogenes*). Otherwise *L. monocytogenes* must be absent at the point of manufacture. If you apply the 100 cfu/g limit you must have evidence for each product to show that *L. monocytogenes* does not exceed 100 cfu/g throughout the shelf life.

This evidence must be based upon shelf life studies which should initially consist of information on the specific composition for your own product (i.e. physical and chemical characteristics, including packaging) and consultation with relevant scientific literature.

If the results of these studies give sufficient confidence that *L. monocytogenes* will not grow in your product no further studies are needed. However, if your results do not give sufficient confidence additional studies will be necessary. Such studies may include one or more of the following:

i) Historical data,
ii) Predictive microbiology,
iii) Specific laboratory shelf life studies, i.e. durability studies, challenge testing

FBOs can collaborate in conducting these studies.

FBOs must keep documentation of shelf life studies and verification as part of GMP and HACCP procedures.

Taking each of the above in turn:

a) Product characteristics and scientific literature and research data

Product characteristics such as pH, a_w (water activity), salt concentration and/or concentration of chemical preservatives affect *L. monocytogenes* survival and growth within a food, as does the way that these products are packed, and the time and temperature of storage.

You must establish these characteristics for your product as these are important factors in influencing the survival and growth of *L. monocytogenes*. This must be done under the conditions in which your product is normally produced, packed and stored. If you do not have access to your own in-house expertise for this then you should contact research organisations and/or laboratories that can help you understand and gather the necessary information (see section 11.1).

It is important to understand the formulation of your food. In the case of a multicomponent food such as a quiche the highest pH and a_w value within the food must be known throughout its shelf life.

Another consideration is whether the food is an emulsion, e.g. mayonnaise, margarine, butter. For these types of foods, a_w and pH measurements will be difficult to measure and will vary throughout the food. Where necessary seek specific expert advice.

Determining the characteristics of your product will then allow you to determine whether *L. monocytogenes* will grow in your product.

Foods are not considered to support the growth of *L. monocytogenes* if:

- pH is less than or equal to 4.4, or
- a_w is less than or equal to 0.92, or
- pH is less than or equal to 5.0 with the a_w being less than or equal to 0.94

If these parameters are used to demonstrate that the food will not support the growth of *L. monocytogenes* then

- these are critical control points and must be monitored as part of HACCP, and
- further shelf life studies are not required in relation to *L. monocytogenes*

If there is clear scientific evidence that your food cannot support the growth of *L. monocytogenes* the legislated limit of 100 cfu/g throughout shelf life applies.

If scientific evidence is not available, further evidence as set out in the following sections will be necessary to justify the shelf life.

However, the FBO is responsible for the production of safe food under EU law.

b) Historical data

FBOs have a legal obligation under food safety legislation to maintain key records including the safety of foods placed on the market.

Historical data comprise records specific to your premises and your foods, built up over a period of time.

Historical data (including end product testing on the day of production and/or end of life) can be used as evidence that a food will not exceed the limit of 100 cfu/g during its shelf life.

Historical data on levels of *L. monocytogenes* in existing RTE foods at the start and/or end of shelf life can be used to assess its growth potential and confirm that the assigned shelf life is appropriate. It can also be applied to similar RTE foods with comparable intrinsic characteristics (pH, a_w, microflora, etc.) produced under practically identical conditions. These should be specific to your premises and your foods; however collaboration between FBOs is acceptable under certain circumstances (see section 6 v 'collaboration between food businesses').

Data should include:

- Information from HACCP and monitoring checks, including:
    - Process validation, verification and monitoring (e.g. temperature, time, pH and a_w)
    - Ingredients traceability and microbiological quality testing including for hygiene indicator organisms and/or *L. monocytogenes*
    - Sampling for *Listeria* species and appropriate hygiene indicator organisms from processing areas and equipment (to demonstrate the efficacy of factory hygiene and cleaning regimes)
    - Final product testing for *L. monocytogenes* for example on the day of production and/or at the end of shelf life to verify effective functioning of the HACCP system and durability verification
- Shelf life evaluation

Detection of *Listeria* species from ingredients, the product or the environment, particularly food contact surfaces after cleaning, requires documented investigation and follow-up remedial hygienic action carried out and documented.

Protocols for shelf life evaluation (e.g. Evaluation of Product Shelf life for Chilled Foods[3]) are available which provide a basis for historical data sets.

Historical data can provide the best evidence to demonstrate consistent control of the level of *L. monocytogenes* in a particular food.

If there are insufficient historical data, carrying out additional actions as set out in the following sections will be necessary to justify shelf life, otherwise you must demonstrate that *L. monocytogenes* is absent at the end of manufacture until such data have been gathered.

The level of confidence increases with the size of the data set, i.e. the more product units that have been tested the more reliable the historical data becomes. However, it is not possible to recommend a specific amount of data since this will be a risk-based approach dependent on the varying manufacturing processes and the nature of the food.

c) Predictive microbiology (modelling)

Where additional studies are needed, predictive microbiological modelling is expected to be the most commonly used approach to confirm the assigned shelf life.

By inputting key physicochemical factors of your food (e.g. pH, a_w/salt) and historical data into a predictive microbiological model (computer programme) it is possible to obtain an indication of potential growth of certain key organisms including *L. monocytogenes*.

Predictive microbiological models are freely available on the internet, e.g. ComBase (http://www.combase.cc). These are useful tools to provide additional confidence in the assigned shelf life. However, they have limitations (e.g. lack of uniformity throughout foods) and must therefore be used with caution and only used by trained and experienced personnel who can help you interpret the results.

d) Specific laboratory shelf life studies

There are microbiological procedures used for determining the growth of *L. monocytogenes* using durability studies and/or challenge tests. Both methods have limitations as described below.

i) Durability Studies

Durability studies evaluate the growth of *L. monocytogenes* in a naturally contaminated food during its storage under reasonably foreseeable conditions.

The EC has defined a protocol for durability studies (EC, 2008). However, since this protocol requires low levels of *L. monocytogenes* to be naturally and consistently present in batches of the food being studied, the number of foods to which this can be applied is limited.

ii) Challenge Tests

Challenge testing is in practice only used if other methods of assessing safety/stability of the food as follows have not been or cannot be carried out:

- Data on product characteristics
- Historical data
- Predictive microbiology
- Specific laboratory shelf life studies, i.e. durability studies

Challenge tests aim to provide information on the behaviour of *L. monocytogenes* artificially introduced into a food before storage under given conditions in a laboratory environment.

The EC has defined a protocol for challenge testing (EC, 2008). This protocol involves inoculating the food with a specific cocktail of *L. monocytogenes* to a defined level within the food and measuring any subsequent changes in this level over the anticipated shelf life under worst case chilled conditions. Because of the complexity of the procedure this protocol demands specialist laboratory expertise.

Other protocols may be acceptable to UK enforcement officers, but their applicability to the intracommunity trade will need to be established with the recipient EU country before conducting a trial.

iii) Shelf Life Evaluation

Shelf-life evaluation is a practical approach which can be carried out using established protocols, e.g. CCFRA (now Campden BRI) (2004) which does not require pathogens to be present.

These protocols give useful guidance on the major considerations to be taken into account before launching a new or reformulated product onto the market.

As these tests do not involve inoculation of the foods they rarely isolate pathogens.

Data and information generated from such protocols contribute to historical data.

e) Collaboration between food businesses

Each FBO needs to validate that growth data they are using is applicable to their own product and process. Caution should be taken if sharing environmental data.

With the provisos set out below FBOs may collaborate in conducting the studies set out in section 6, either between different sites within the same company or different companies, e.g. through a trade association.

The FBO should be able to demonstrate to an enforcement officer that the products and the processing of the products for which the data are being shared are similar. For example:

- For these studies to be valid the products being compared should have the same characteristics (pH, a_w, salt content, concentration of preservatives, type of packaging, associated microflora or any other characteristic important for the survival and growth of *L. monocytogenes*), and;

- The production process and storage conditions of the products should be similar.

It must be noted that different production areas will have different potential for contamination; however products may have the same potential for growth of *L. monocytogenes* if contaminated.

If the products are not similar, the FBO should be able to show how they are different and what effect those differences have on the survival and growth of *L. monocytogenes.*

7. PRACTICAL APPLICATION OF SHELF LIFE

7.1. NEW START-UP (NEW FOOD PRODUCTION FACILITY)

Recommendations:

a) Ensure that requirements for the safe manufacture of RTE foods (see section 5) are in place.

b) Purchase ingredients from a reputable source, obeying usage and storage instructions provided, in particular the Use By date. See checklist for buying ingredients (section 8) if in doubt.

c) Review the ingredients and determine the control for *L. monocytogenes* in place for each (including shelf life), using the supplier's information as necessary. Note that data are product-specific and are only valid for the supplier from which they are gathered. **If there is no further processing of ingredients then shelf life of the finished product must not exceed that of the shortest shelf life ingredient incorporated**, e.g. where a product contains ingredients that have a shelf life of between 5 and 10 days the shelf life of the product must be no more than 5 days.

d) Consider any changes to the ingredients that may occur when they are mixed or assembled, i.e. changes to the individual ingredient characteristics, and determine whether this impacts on the continuing efficacy of *L. monocytogenes* controls, which may change the usable shelf life. This may require expert guidance. Consider any changes to the microbial loading or characteristics of the ingredients that may occur when they are handled, processed, mixed or assembled, i.e. cooking, heating, cooling, freezing, thawing and any potential cross contamination.

e) Set up a system to monitor the controls on raw materials, **focusing on high risk ingredients**.

f) Start an environmental microbiological monitoring programme for the production area, as a minimum check for *Listeria* species, swabbing areas that have the greatest risk of contamination, e.g. slicing equipment.

g) Ensure that any detection of *Listeria* species in the food or environment is investigated and follow-up remedial action carried out and documented.

h) Set up a system to monitor *L. monocytogenes* in the finished product, to verify effective functioning of the HACCP system and for durability verification to demonstrate that 100 cfu/g is not exceeded during the shelf life.

i) Gather data to substantiate that the limit of 100 cfu/g is unlikely to be exceeded at the end of shelf life. Whilst building up such data collect data to demonstrate that you have implemented effective HACCP-based procedures and that *L. monocytogenes* is unlikely to be present at the end of manufacture. See section 6. If you have any doubt as to the validity of this data seek expert advice.

j) Review collated raw material, finished product and environmental data on an ongoing basis to ensure controls are in place.

7.2 NEW PRODUCT (PRODUCED IN AN EXISTING FACILITY WITH GMP & GHP)

Recommendations:

a) Ensure that any changes in raw materials, product characteristics, suppliers, equipment or processes are fully considered through the HACCP plan.

b) Implement points above as per a new start-up.

c) Historical data (e.g. environmental monitoring) gathered from existing production of similar products with comparable intrinsic characteristics (e.g. pH, a_w) may now assist in demonstrating the efficacy of controls and shelf life.

8. CHECKLIST FOR BUYING RTE INGREDIENTS

When buying RTE ingredients from a reputable supplier it may be assumed that shelf life has been established appropriately. If you are unsure, it is your responsibility to ensure that the supplier has implemented this guidance and has established the shelf life appropriately, otherwise you should change to another supplier that can demonstrate correct implementation of this guidance or you will need to do so yourself.

The following are suggested questions to ask suppliers when buying ingredients from them:

- What hygiene-/HACCP-related accreditations/certifications does the supplier have, e.g. British Retail Consortium Global Food standard, SALSA?
- Can the supplier provide a written specification which includes appropriate limits for *L. monocytogenes*?
- What microbiological criteria for *L. monocytogenes* are they using? (Regulation (EC) No. 2073/2005 (as amended) applies).
- Do the results of microbiological testing show that the ingredients comply with the Regulation?
- Can the supplier provide a Certificate of Compliance or Certificate of Analysis for the ingredient?
- What type of process has the ingredient been through, e.g. what heating temperature and for how long?
- What type of packaging is the ingredient in, e.g. vacuum packed chilled foods have a limit of 10 days shelf life unless treated as required by 'FSA guidance on the safety and shelf-life of vacuum and modified atmosphere packed chilled foods with respect to non-proteolytic *Clostridium botulinum*'[2]?
- Is the business supplying the ingredient part of a larger group and able to use its technical support?

In all cases you must have information on the following:

- Whether the ingredient is suitable for its intended use, e.g. ready to eat.
- How is/has the ingredient been stored – what temperature and for how long
- Has the ingredient been cooked (a time/temperature combination of 70°C for 2 minutes or equivalent is required to eliminate *L. monocytogenes*).
- How much shelf life there is on the ingredient as delivered to you

9. QUESTIONS AND ANSWERS

a) <u>What do I do if *L. monocytogenes* is detected at a low level in an ingredient/food before the end of shelf life?</u>

If *L. monocytogenes* is detected in a RTE product before the end of shelf life at a low level, e.g. less than 10 or 20 cfu/g (depending on the test method used), then you must have evidence, e.g. end of life data on the same food made under practically identical conditions, which shows levels will not exceed 100 cfu/g. The product therefore remains within the *L. monocytogenes* food safety criteria set out in Regulation (EC) No. 2073/2005 over its shelf life.

Under such circumstances, a low level (e.g. less than 10 or 20 cfu/g) detection during shelf life will mean that the product may not need to be withdrawn or recalled. However, the source of *L. monocytogenes*, particularly in a cooked product, will require investigation and any relevant corrective actions implemented.

The product's shelf life must be reduced if it cannot be demonstrated that the level of 100 cfu/g will not be compromised. Careful consideration must be given to any subsequent manufacture where the potential reason(s) for the positive counts can not be established and corrected.

If you do not have such evidence that 100 cfu/g will not be compromised it will be necessary to withdraw or recall the product and notify the Competent Authorities.

Any detection of *Listeria* species in the food or environment must be investigated and follow-up remedial action carried out and documented, reviewing and verifying controls and re-establishing their efficacy.

Article 14 of Regulation (EC) No. 178/2002 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." This requires taking into full consideration the intended consumer.

See section 5 for prerequisites.

b) How do you measure pH, a_w?

These are routine tests that many laboratories can carry out. It is strongly recommended that you obtain expert advice to help interpret the test results if you do not have the relevant in-house expertise.

c) How much historical data is appropriate?

Safety is dependent on functioning HACCP.

Data gathering supports HACCP and is an ongoing process. Adverse results must be investigated and actioned to ensure continuing improvement.

Data should be sufficient to provide confidence in the safety of the product.

It is not possible to indicate precisely how much historical data is needed to set shelf life but the level of confidence in the shelf life being appropriate increases with the size of the data set corroborating it, i.e. the more product units that have been tested the more reliable the historical data becomes.

You may wish to set a shorter shelf life while historical data is being built up, extending shelf life as more data becomes available.

d) *L. monocytogenes* is detected at more than 20 cfu/g but less than 100 cfu/g in a food with shelf life less than 5 days?

All foods with a shelf life of less than 5 days are categorised in the Regulation as being unable to support the growth of *L.monocytogenes.* However, there are instances where growth can occur so there is a risk that *L. monocytogenes* may exceed 100 cfu/g within 5 days. In these cases you must have data substantiating that 100 cfu/g will not be exceeded during the shelf life.

Where effective HACCP is functioning *L. monocytogenes* should only infrequently be found in raw materials, the environment and in the finished product, even at the end of life.

Any detection of *Listeria* species in the food or environment must be investigated and follow-up remedial action carried out and documented, reviewing HACCP and prerequisites and re-establishing its efficacy.

Article 14 of Regulation (EC) No. 178/2002 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." This requires taking into full consideration the intended consumer.

e) What do I do if more than 100 cfu/g are detected in a RTE food?

The product or batch of foodstuffs shall be withdrawn or recalled and Competent Authorities notified. However, products placed on the market, which are not yet at retail level and which exceed 100 cfu/g, may be submitted to further processing by a treatment eliminating the hazard. This treatment may only be carried out by food business operators other than those at retail level.

Detection of *Listeria* species from ingredients, the product or the environment, particularly food contact surfaces after cleaning, requires documented investigation and follow-up remedial hygienic action carried out and documented.

If it is determined that the exceedance had arisen because of a one-off problem that was corrected and which was not related to the growth of *L. monocytogenes* in the product then those results would not compromise historical data used to substantiate shelf life.

f) When would challenge testing be appropriate?

Challenge testing is in practice only used if other methods of assessing safety/stability of the food as follows have not been or cannot be carried out:

- Data on product characteristics
- Historical data
- Predictive microbiology
- Specific laboratory shelf life studies, i.e. durability studies

10. GLOSSARY

Batch

A batch is defined in Article 2 (e) of the Regulation for the microbiological criteria for foodstuffs (2073/2005) as a group or set of identifiable products obtained from a given process under practically identical circumstances and produced in a given place within one defined production period.

The FBO must define the batch. Batch size is a key point to consider in any risk management action.

Colony Forming Unit (cfu)

Microbial cells forming a single colony on an agar plate.

Competent Authorities

The Food Standards Agency and Environmental Health at your Local Authority.

GHP

Good hygiene practice

GMP

Good manufacturing practice

HACCP

Hazard Analysis and Critical Control Points

pH

A measure of acidity or alkalinity of a food.

Ready to Eat (RTE) Food

Food intended by the producer or the manufacturer for direct human consumption without the need for cooking or other processing effective to eliminate or reduce to an acceptable level microorganisms of concern.

Shelf Life

The shelf life is defined as the period of time for which a product remains safe and meets its quality specifications under expected storage and use. The shelf life determines the durability date and is expressed as a 'use by' or best before' date.

Shelf Life Studies

Shelf Life Studies shall demonstrate the compliance of a food with the limit of the food safety criterion (100 cfu/g) set for *L. monocytogenes* throughout its shelf life.

Water activity (a_w)

A measure of availability of water for the metabolic activity and growth of microorganisms

11. FURTHER SOURCES OF INFORMATION

a) Advice

Technical

Campden BRI: www.campden.co.uk

Chilled Food Association: www.chilledfood.org

LawLabs: www.lawlabs.com

General

Food Standards Agency: www.food.gov.uk

b) Legislation

Commission Regulation (EC) No 2073/2005 of 15 November 2005 on microbiological criteria for foodstuffs (as amended). Official Journal of the European Commission L 338/1, 22 December 2005. http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:32005R2073:en:NOT

Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety. Official Journal of the European Commission L 31/1, 1 February 2002. http://eur-lex.europa.eu/pri/en/oj/dat/2002/l_031/l_03120020201en00010024.pdf

Regulation (EC) No 852/2004 of the European Parliament and of the Council of 29 April 2004 on the hygiene of foodstuffs, Official Journal of the European Union L 139 of 30 April 2004, http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2004:139:0001:0054:EN:PDF

Regulation (EC) No 853/2004 of the European Parliament and of the Council of 29 April 2004 laying down specific hygiene rules for food of animal origin, Official Journal of the European Union L 139 of 30 April 2004, http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2004:139:0055:0205:EN:PDF

Regulation (EC) No 854/2004 of the European Parliament and of the Council of 29 April 2004 laying down specific rules for the organisation of official controls on products of animal origin intended for human consumption L 139 of 30 April 2004, http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2004:139:0206:0320:EN:PDF

Food Hygiene (England) Regulations 2006 (SI 2006/14), http://www.opsi.gov.uk/si/si2006/20060014.htm

The Food Hygiene (Scotland) Regulations 2006 (SSI 2006/3), http://www.opsi.gov.uk/legislation/scotland/ssi2006/20060003.htm

The Food Hygiene (Wales) Regulations 2006 (SI 2006/31 (W.5)), http://www.opsi.gov.uk/legislation/wales/wsi2006/wsi_20060031_mi.pdf

The Food Hygiene Regulations (Northern Ireland) 2006 (SR 2006 No 3), http://www.england-legislation.hmso.gov.uk/sr/sr2006/20060003.htm

These references are to the principle Regulations which are amended from time to time. The latest amendments are available on the Office of Public Sector Information website: http://www.opsi.gov.uk/stat.htm

c) Guidance

i) Official Guidance

[1] European Commission staff working document *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/guidoc_listeria_monocytogenes_en.pdf

[2] FSA 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

Regulation (EC) No. 2073/2005 Microbiological Criteria for Foodstuffs - General Guidance. Food Standards Agency, January 2007. http://www.food.gov.uk/multimedia/pdfs/ecregguidmicrobiolcriteria.pdf

Guidance on the Practical Implementation of the Microbiological Criteria Regulations' (2006) Chilled Food Association. ISBN 978-1-901798-12-8, www.chilledfood.org.

Guidance Notes for Food Business Operators on Food Safety, Traceability, Product Withdrawal and Recall. A guide to compliance with Articles 14, 16, 18 and 19 of General Food Law Regulation (EC) 178/2002 (2007). Food Standards Agency. http://www.food.gov.uk/multimedia/pdfs/fsa1782002guidance.pdf

ii) Industry Guidance

Best Practice Guidelines for the Production of Chilled Food. (2006). 4th Edition. Chilled Food Association. ISBN 978-1-901798-11-1, www.tsoshop.co.uk/chilledfoods

[3]*Evaluation of Product Shelf life for Chilled Foods*. (2004). Guideline No. 46. Campden BRI. ISBN 0-904942-65-5. www.campden.co.uk

Guidance on the Practical Implementation of the EC Regulation on Microbiological Criteria for Foodstuffs (2006), Chilled Food Association, ISBN 978-1-901798-13-5, www.chilledfood.org

HACCP - A Practical Guide. (2009). (4th edition). Campden BRI, Guideline G42. ISBN 978 0 907503 52 1. www.campden.co.uk

Microbiological Testing and Interpretation Guidance (2005), Chilled Food Association, ISBN 978-1-901798-10-4, www.chilledfood.org

The Specialist Cheesemakers Code of Best Practice (2007), Specialist Cheesemakers Association, www.specialistcheesemakers.co.uk

12. WORKED EXAMPLES WEBLINKS

Worked examples are available through the following websites to demonstrate the process, as set out in this document, of determining shelf life with regards to *L. monocytogenes* for specific products. This includes the considerations of ingredients, manufacturing environment and data to support (or otherwise) the assigned shelf life.

Weblinks:

www.bmpa.uk.com
www.brc.org.uk
www.chilledfood.org
www.food-solutions.org
www.sandwich.org.uk
www.specialistcheesemakers.co.uk

The data required to support the shelf life is required to be documented, but it is not a requirement for it to be held in the detailed format as set out in the worked examples.

Examples available:

New Product - Cold Smoked Salmon and Fresh Watercress Sandwich –Technical
New Product - Cold Smoked Salmon and Fresh Watercress Sandwich – Simplified

Justifying the shelf life of an existing product - Cold Smoked Salmon and Fresh Watercress Sandwich

Altering an existing recipe - Brie with Garlic and Herbs – Simplified
Altering an existing recipe - Brie with Garlic and Herbs – Technical

New Product – Simplified worked example of approach to determining the shelf life of a ready-to-eat food in relation to *Listeria monocytogenes (L. monocytogenes)*

Cold smoked salmon and fresh watercress sandwich

I wanted to extend my range of sandwiches to include ones filled with smoked salmon and chopped watercress. I had heard that smoked salmon sometimes contained *Listeria* (*L. monocytogenes*) so I thought it wise to consult my professional adviser to see what sort of a shelf life I could safely put on. If he said the life would be too short, it would not be worth going ahead as we would not have time to sell them before they went out of date.



The first question he asked me was about the ingredients we were intending to use. I said I would use the highest quality ingredients available and would obtain them from reputable suppliers. These supply a 'certificate of compliance' (to my requirements) for each batch of ingredients supplied. 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%;
- Fresh shredded watercress, supplied in 500g packs with a 7 day chilled shelf life.
- Sliced wholemeal bread, supplied in 800g bags with a 7 day ambient shelf life.
- Butter, supplied in 2kg tubs with a 6 week shelf life.

The Rules

The legislation requires that *L. monocytogenes* must not be present at more than a very low level (no more than 100 colony forming units per gram) at the end of the shelf life. So if there were any contamination to start with and the bacteria were able to grow, the shelf life must be limited.

Could there be contamination?

He then explained that there was a real risk that some of these ingredients could be contaminated with *L. monocytogenes.* He said that the following points have to be considered:

- The 'heat process' used in the cold-smoking of Salmon (30°C for 16h) is 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% (McLauchlin and Nichols, 1994). Levels were generally less than 100 cfu/g with the highest count between 100 and 1000 cfu/g. This is in line with findings by the Food Standards Agency, where 1344 samples of cold smoked fish were sampled at retail during 2006. Nearly 300 (282, 20.5%) samples contained *Listeria* spp, and 236 (17.4%) *L. monocytogenes* with all levels below 100 cfu/g (http://www.food.gov.uk/multimedia/pdfs/fsis0508.pdf).

- Since *L. monocytogenes is* a relatively common bacterium in the environment, watercress might be expected to be occasionally contaminated with it. Washing the watercress in chlorinated water will help to reduce the level of *L. monocytogenes.*

  Bell & Kyriakides (2005) mention a survey of 11 samples of watercress, 2 of which were found to be contaminated with *Listeria.* (One was found to be *L. welshimeri* the other was not identified.)

- Bread has no history of being contaminated with *L. monocytogenes as* it is prevented from growing on it because appropriate nutrients are not available.

- Butter has been associated with listeriosis, but this is the exception rather than the rule, and came about as a result of incorrectly made butter. (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.)

  In an outbreak in England, testing confirmed the presence of *L. monocytogenes at* 180 cfu/g in a batch of butter although it was only detectable at low levels (less than 20 cfu/g) in other batches (ACMSF, 2003).

Would it grow?

Having established that there was a risk of *L. monocytogenes* contamination in the ingredients, my adviser then went on to show that the bacterium could grow. I knew that *L. monocytogenes* could grow at fridge temperatures or below, but he explained that unless the acidity (pH) were very low and the product is fairly dry *L. monocytogenes* would grow. He worked out for my sandwich these approximate figures.

Component	**pH**	**a_w**
Salmon	6.0	0.95 (3.5% salt)
Watercress	6.5	0.98
Bread	6.1	0.97
Butter	6.6	0.96 (aqueous phase)

NB the values used here are for illustration purposes only

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

("Bread" is one of the foods specifically mentioned as being excluded in the Regulation).

So we concluded that the pH and a_w values of the ingredients suggest that *L. monocytogenes would* grow in them if present. Although the proposed shelf life of the completed sandwich is less than 5 days, the age of one or more of the ingredients may be older than this. Now we had to determine whether any initial contamination would exceed the legal limits by the end of my proposed shelf life. So my adviser looked at the data that I had on ingredients I already used.

My test result history

Historical data show that the results of microbiological testing of supplied ingredients; sandwich-manufacturing environment; and finished product throughout shelf life could contain *L. monocytogenes.* Although information and data on *Listeria* and *L. monocytogenes is* of prime importance, other microbiological data, for example Aerobic Plate Counts, can be used to indicate if production is generally under control.

Useful information can be obtained from suppliers, such as evidence of absence of *L. monocytogenes in* the environment and ingredients they are supplying. 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. Data acquired from one supplier is not applicable to another or all potential suppliers of the same component.

Evidence of the absence of *L. monocytogenes in* ingredients where this microorganism can grow (such as Salmon and Watercress), is important to show that the sandwich produced is acceptable. Counts of *L. monocytogenes* at less than 100 cfu/g at end of life of the sandwich are useful, as is evidence that counts of *L. monocytogenes* are 'less than 10 cfu/g' or 'less than 20 cfu/g' at the start of life of the sandwich or its ingredients. This is however not evidence that *L. monocytogenes will* not grow to levels above 100 cfu/g by the end of life of the product and therefore necessitate being withdrawn from sale. It does however strongly suggest that the controls in place are working.

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

The risk is there. What should be the shelf life?

Having established that there is a real possibility that *L. monocytogenes could* be present in the sandwich at the point of sale, the task now is to be certain that the count does not exceed 100 cfu/g at the end of the proposed shelf life. My adviser explained that there are three generally accepted methods of checking this:

i. **Predictive Microbiology**

   The behaviour of *L. monocytogenes should* it be present in the sandwich ingredients, can be predicted using appropriate freely-available models such as ComBase (http://www.combase.cc). This software is designed to give an idea of how the pathogen might behave, it does not take into account factors such as: the anti-microbial effects of smoking the salmon; competing microflora in the salmon or watercress; and so on.

   The predictions for the ingredients discussed in this example indicate that if *L. monocytogenes were* present at a level of 10 cfu/g in the salmon or watercress at start of life of each component, even if they were kept at 5°C, the number is likely to

reach 100 cfu/g (2 logs) before the end of life of the ingredients and probably the sandwich made from them.

ii. Durability studies

Durability studies are generally not relevant to determining the growth of pathogens in a foodstuff, as there is no guarantee that they will be naturally present. If such a study were carried out, replicate samples would need to be taken of the ingredients and sandwich over life. The temperatures that these foodstuffs were held at would need to replicate what would happen in reality. The samples would be tested for *L. monocytogenes and* a plot of number over time would give an indication of whether this organism would grow to a level of 100 cfu/g by the end of life of the sandwich.

iii. Challenge test

A challenge test study may be used to determine the behaviour of a pathogen in a foodstuff over life. As for the durability study, the number of the relevant organism is determined over the life of the foodstuff.

The advantages of a challenge test over the other methods of shelf life determination mentioned here, is that a known number a particular species of microorganism can be added at the start of the study. And units initially inoculated at the start of the study, can be analysed at end of life.

To reflect reality, the sandwich would need to be made from the ingredients when the salmon was no more than 7 days old and the watercress no more than 4 days old – so that the shelf life of the sandwich could be taken into account.

Conclusion

If the results of these tests are satisfactory, then my adviser said it may be concluded that a three day shelf life as proposed is valid. In this case, he would still recommend that ingredients are used early in their life to minimise any potential growth of *L. monocytogenes that* might already be present.

He added that if the tests indicate that the 100 cfu/g were to be exceeded, then either the shelf life must be reduced or further precautions taken with the ingredients and processing (e.g. use ‘hot-smoked’ or ‘canned’ salmon instead of ‘cold-smoked’) to eliminate the risks during production.

The result of these discussions with my professional adviser was that I could safely put a three day shelf life on the sandwiches if I took all the precautions mentioned above. He drew my attention to several references in addition to Regulation (EC) No. 2073/2005 which defines the limits for *L. monocytogenes* at the end of shelf life assuming the sandwich was for general consumption and not for vulnerable people more susceptible or more likely to develop foodborne disease, e.g. pregnant women, the elderly, children and people with weakened immune systems...

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, 2nd Edition. Wiley-Blackwell.

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

New Product - Technical worked example of approach to determining the shelf life of a ready-to-eat food in relation to *Listeria monocytogenes* (*L. monocytogenes*)

Cold-Smoked Salmon and Fresh Watercress Sandwich



This is an example of the supporting evidence that may be gathered following the guidance document "*Shelf life of Ready to Eat food in relation to L monocytogenes – Guidance for Food Business Operators"*[1]. 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 product consists of: cold-smoked salmon; shredded watercress; sliced wholemeal bread and butter. The completed sandwich has a proposed 3 day chilled shelf life.

Box 1 Requirements for safe manufacture of Ready to Eat foods

The sandwich manufacturer (Food Business Operator (FBO)) has adopted GMP and GHP by for example, introducing and monitoring effective cleaning of equipment and staff personal hygiene. The FBO has HACCP in place for the manufacture of the sandwiches and *L. monocytogenes* is 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 supply a 'certificate of compliance' (to the FBO's requirements) for each batch of ingredients supplied. 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%
- Fresh shredded watercress, supplied in 500g packs with a 7 day chilled shelf life
- Sliced wholemeal bread, supplied in 800g bags with a 7 day ambient shelf life
- Butter, supplied in 2kg tubs with a 6 week shelf life

Box 3 Ensuring ingredients are Ready to Eat

The shredded watercress is washed in potable water prior to its use in the sandwiches by the FBO. The other ingredients are RTE as supplied.

Box 4 Final product's characteristics

The pH and water activity (a_w) of the sandwich ingredients are:

Component	pH	a_w
Salmon	6.0	0.95 (3.5% salt)
Watercress	6.5	0.98
Bread	6.1	0.97
Butter	6.6	0.96 (aqueous phase)

NB the values used here are for illustration purposes only

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

("Bread" is one of the foods specifically mentioned as being excluded in the Regulation).

The pH and a_w values of the ingredients suggest that *L. monocytogenes* would grow in them if present. Although the proposed shelf life of the completed sandwich is less than 5 days, the age of one or more of the ingredients may be older than this.

The following points have to be considered:

1. The 'heat process' used in the cold-smoking of **salmon** (30°C for 16h) is 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.

2. Cold-smoked salmon has been shown to be contaminated by *L. monocytogenes* at frequencies of 2-21% (McLauchlin and Nichols, 1994). Levels were generally less than 100 cfu/g with the highest count between 100 and 1000 cfu/g. This is in line with findings by the Food Standards Agency, where 1,344 samples of cold smoked fish were sampled at retail during 2006. Nearly 300 (282, 20.5%) of samples contained *Listeria* spp, and 236 (17.4%) *L. monocytogenes* with all levels at below 100 cfu/g (www.food.gov.uk/multimedia/pdfs/fsis0508.pdf).

3. Since *L. monocytogenes* is a relatively common bacterium in the environment, **watercress** might be expected to be occasionally contaminated with it. Washing the watercress in chlorinated water will help to reduce the level of *L. monocytogenes*.

   Bell & Kyriakides (2005) mention a survey of 11 samples of watercress, 2 of which were found to be contaminated with *Listeria.* (One was found to be *L. welshimeri* the other was not identified.)

4. Bread has no history of being contaminated with *L. monocytogenes* as it is prevented from growing on it because appropriate nutrients are not available.

5. Butter has been associated with listeriosis, but this is the exception rather than the rule, and came about as a result of incorrectly made butter. (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.)

   In an outbreak in England, testing confirmed the presence of *L. monocytogenes* at 180 cfu/g in a batch of butter although it was only detectable at low levels (less than 20 cfu/g) in other batches (ACMSF, 2003).

Box 5 Historical testing data

Historical data show that the results of microbiological testing of supplied ingredients; sandwich-manufacturing environment; and finished product throughout shelf life could contain *L. monocytogenes.* Although information and data on *Listeria* and *L. monocytogenes* is of prime importance, other microbiological data, for example Aerobic Plate Counts, can be used to indicate if production is generally under control.

Useful information can be obtained from suppliers, such as evidence of absence of *L. monocytogenes* in the environment and ingredients they are supplying. 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. Data acquired from one supplier is not applicable to another or all potential suppliers of the same component.

Evidence of the absence of *L. monocytogenes* in ingredients where this microorganism can grow (such as salmon and watercress), is important to show that the sandwich produced is acceptable. Counts of *L. monocytogenes* at less than 100 cfu/g at end of life of the sandwich are useful, as is evidence that counts of *L. monocytogenes* are 'less than 10 cfu/g' or 'less than 20 cfu/g' at the start of life of the sandwich or its ingredients. This is however not evidence that *L. monocytogenes* will not grow to levels above 100 cfu/g by the end of life of the product and therefore necessitate being withdrawn from sale. It does however strongly suggest that the controls in place are working.

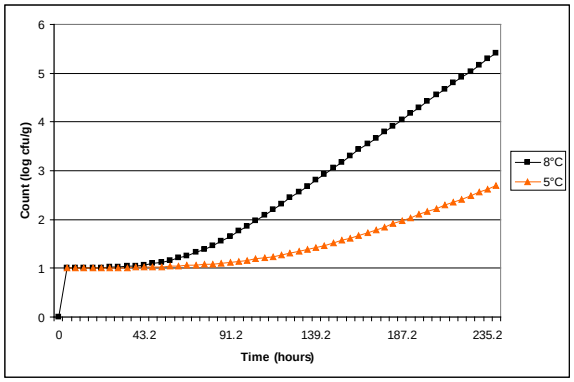
Occasional counts of *L. monocytogenes* are to be expected in this type of product, as ingredients and factory environments will be contaminated from time to time. Positive results of this sort indicate that sampling procedures and testing methods are working.

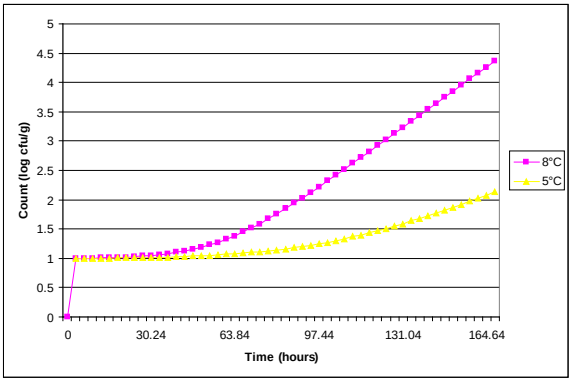
Having established that there is a real possibility that *L. monocytogenes* could be present in the sandwich at the point of sale, the task now is to be certain that the count does not exceed 100 cfu/g at the end of the proposed shelf life. There are three generally accepted methods of checking this.

Box 6 Additional data

Predictive Microbiology

The behaviour of *L. monocytogenes* should it be present in the sandwich ingredients, can be predicted using appropriate commercially-available models such as ComBase (www.combase.cc). This software is designed to give an idea of how the pathogen might behave, it does not take into account factors such as: the anti-microbial effects of smoking the salmon; competing microflora in the salmon or watercress; and so on.





Predicted behaviour of *Lm* (initial concentration of 1 log = 10 cfu/g) in (i) Salmon and (ii) Watercress over the 10 and 7 day respective shelf life of each component, and at 5 and 8°C

The predictions for the ingredients discussed in this example indicate that if *L. monocytogenes* were present at a level of 10 cfu/g in the salmon or watercress at start of life of each component, even if they were kept at 5°C, the number is likely to reach 100 cfu/g (2 logs) before the end of life of the ingredients and probably the sandwich made from them.

Durability studies

Durability studies are generally not relevant to determining the growth of pathogens in a foodstuff, as there is no guarantee that they will be naturally present. If such a study were carried out, replicate samples would need to be taken of the ingredients and sandwich over life. The temperatures that these foodstuffs were held at would need to replicate what would happen in reality. The samples would be tested for *L. monocytogenes* and a plot of number over time would give an indication of whether this organism would grow to a level of 100 cfu/g by the end of life of the sandwich.

To reflect reality, the sandwich would need to be made from the ingredients when the salmon was no more than 7 days old and the watercress no more than 4 days old – so that the 3 days shelf life of the sandwich could be taken into account.

Challenge test

A challenge test study may be used to determine the behaviour of a pathogen in a foodstuff over life. As for the durability study, the number of the relevant organism is determined over the life of the foodstuff.

The advantages of a challenge test over the other methods of shelf life determination mentioned here, is that a known number a particular species of microorganism can be added at the start of the study. And units initially inoculated at the start of the study, can be analysed at end of life.

Conclusion

If the results of these tests are satisfactory, then it may be concluded that the three day shelf life proposed is valid. If this is the case, it would still be recommended that ingredients are used early in their life to minimise any potential growth of *L. monocytogenes* that might already be present.

If the tests indicate that the 100 cfu/g were to be exceeded, then either the shelf life must be reduced or further precautions taken with the ingredients and processing (e.g. use ‘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. London, UK.

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

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

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*"[1]. 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[1].

  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 the10 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[1].

  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[1].

  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[1] 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, 2nd Edition. Wiley-Blackwell.

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

Altering an existing recipe – Simplified worked example of approach to determining the shelf life of a ready-to-eat food in relation to *Listeria monocytogenes* *(L. monocytogenes)*

Brie with Garlic and Herbs



I wanted to make a Brie type cheese with garlic and herbs. I knew how to make the cheese as I already sold a plain Brie. However, I did not know how to work out what shelf life to put on the packets. I had heard that there was a risk of *Listeria monocytogenes* (*L. monocytogenes*) contamination. My advisor asked me a series of questions and gave me the reasons behind each one of them.

The cheese would be a "ready to eat" (RTE) food as it would not be cooked to kill off bacteria before customers ate it. I must therefore be able to demonstrate that levels of harmful bacteria were low enough to keep consumers safe.

There are strict limits on the maximum allowable level of *L. monocytogenes* at the end of shelf life.

We first looked at ingredients. They are:

- Milk supplied by specified farms and delivered by a national haulier. The raw milk is pasteurised on-site at 74°C/18s, then used immediately.
- Bacterial starter culture, freeze-dried, stored frozen
- *Penicillium camemberti* ripening culture, liquid, stored chilled
- Rennet, liquid, stored chilled
- Calcium chloride, liquid, stored chilled
- Salt, solid, stored at ambient temperature (and used to prepare brine)
- Garlic, peeled, boiled and puréed, stored chilled
- Herbs, (parsley and oregano) grown organically, sun-dried and finely chopped. Purchased from a local farm

Other than the herbs and milk, all the ingredients can be supplied with specifications from multinational specialist companies. The specifications should indicate that the ingredient is of suitable quality for intended use.

Each company also can supply a certificate of analysis with each delivery, which I need to keep to show I had taken the correct precautions.

The rules

The legislation requires that *L. monocytogenes* must not be present at more than 100 colony forming units/g at the end of the shelf life. So if there were any contamination to start with and the bacteria were able to grow, the shelf life may be too short for economical production.

L. monocytogenes is one of the few harmful bacteria that can grow at fridge temperatures, so storing in the fridge may not stop a small amount of contamination from becoming large by the time the cheese is eaten.

I asked my advisor if there were any other ways of stopping *L. monocytogenes* growing.

Would it grow?

If the cheese is quite acid (pH of less than 4.4) and dry (available water (a_w) less than 0.92), *L. monocytogenes* will not grow. A high salt content also slows down growth. To find out the pH and a_w we assessed both the coating and from the inside of samples of my trial cheeses, and got the following results:

Component of the cheese	Process stage	pH	Salt-on-product (%)	Moisture (%)	Aqueous salt (%)
Coat	Despatch	6.0	1.6	45	3.6
Body	Despatch	5.2	1.6	50	3.2
Coat	End of life	7.5	1.8	40	4.5
Body	End of life	7.0	1.8	45	4.0

This meant that theoretically my cheese would support the growth of *L. monocytogenes*, so we had to look at ways to limit initial contamination and then check, if there were contamination, how long it would take to reach the critical legal limit.

Limit contamination

Although it is rare for raw milk to be contaminated with *L. monocytogenes* it will be killed by proper pasteurisation (time/temperature treatment of 74°C for 18 seconds). *L. monocytogenes* is almost everywhere, so we looked carefully at the plate cooler, transfer tubes and holding tanks. Contamination often gets in from dust, the drains, chiller units, maturation shelves, improper use of hoses and moisture in the atmosphere. We looked at the additives where we were fairly confident as, apart from the herbs, they had been supplied with test results.

My test result history

Then we looked at my existing test results. Any contaminations indicate that if other bacteria could get in, so could *L. monocytogenes*. The dairy has had a contract with a local accredited microbiological laboratory which processes environmental samples and product samples taken by the dairy. The microbiological sampling regime includes tests for other bacteria like Enterobacteriaceae, which would be primary indicators of the level of post process contamination, and *Staph. aureus* the presence of which might be considered to relate to handler hygiene practice or milk quality.

Sampling has been targeted to demonstrate the effectiveness of the hygiene controls on site and has contributed to defining and refining best practice on the cleaning procedures and schedules. Since the sampling plan was started 10 years ago the incidence of *Listeria* isolation in final product has dropped to around 25% of the original levels.

For existing cheeses, 200 samples had been taken of product at the point of despatch and tested for presence of *Listeria* in 25g using an enrichment technique. Of these 14 were positive for *Listeria* spp. and 7 were positive for *L. monocytogenes*. Enumeration of fellow samples from all of the positives gave results of less than 10/g, i.e. any contamination was below the level of detection by count at the start of the shelf life.

Results from samples of the same cheese taken on the last day of the shelf life showed similar historical results, which suggested that under normal circumstances the growth rate of *L. monocytogenes* in my plain brie is, at best, poor. This may be due to competition effects from the cheese cultures and the chemical hurdles such as the level of salt. The microbiological results suggest that the process is under control.

The occasional detection of *L. monocytogenes* may be expected in these types of product, as even the best designed and maintained factory environment will be contaminated from time to time. Positive results of this sort indicate that the sampling procedures and testing methods are working correctly.

The risk is there. What is the shelf life?

Given these results – that *L. monocytogenes* could grow and there was a possibility of contamination – my adviser recommended a mathematical prediction to suggest when levels might exceed the 100 cfu/g limit. This is called "Predictive Microbiology". It may be possible to use appropriate, commercially-available models such as ComBase (www.combase.cc) to predict the behaviour of *L. monocytogenes* should it be present in the maturing cheese. This software is designed to give an idea of how the pathogen might behave; however, predictive modelling may not be appropriate for some cultured foods as it does not take into account the competition that may occur between micro-organisms that can reduce the growth of *Listeria*.

These predictions suggested that if *L. monocytogenes* were present on the coat of the cheese at a level of 10 cfu/g at the start of life, when stored at 5°C, it could grow to a level of 100 cfu/g within 200 hours (8.3 days). This is too short to be economic.

Possible solution?

Using the data from plain brie where the background level of *L. monocytogenes* appears to be around 1 in 100g of product, the predictive model would suggest that at 5°C a level of 100 per gram would take 4 x 8.3 days = 33.2 days. So we assumed that the addition of the herbs may account for the increase in contamination.

The level of *L. monocytogenes* in the herb addition is not known and as there is no elimination step it can be assumed that there will be significant levels in certain batches. Further, the product specification provided by the supplier does not include a criterion for *L. monocytogenes*.

The addition of untreated herbs to the cheese mix at a level of 1% will increase the background level in a proportion of batches of cheese. The possibility that the storage temperatures within retail and the home may be higher would suggest that the proposed formulation is likely to exceed the legal maximum.

So we suggested that the herbs were subjected to a process step that would eliminate *L. monocytogenes*, such as steam treatment. Then the level of *L. monocytogenes* contamination could be reduced to the point where legally it comfortably conforms to the EC Regulations for an RTE food and so the additional loading to the cheese would not be significant. In this case we could safely extend the shelf life to 30 days.

Confirmatory testing

My adviser strongly recommended shelf life tests to verify that our *L. monocytogenes* predictions on the heat treated herbs were correct. These end of life tests, he explained, were not in themselves adequate to determine the shelf life. He said that, if they did show a high level, it would be too late to do anything about it as the product would have been consumed already. As there was the possibility that the cheese could become unsafe after the 30 day life we needed to label the packets with a “Use by” date rather than a “Best before”.

He told me that there were other techniques for determining whether *L. monocytogenes* could grow in the product like the Challenge Test system. Here a known amount of contamination is deliberately inoculated into the product. Measures are taken at intervals when different storage conditions are used. The technique is not really satisfactory for solid cheeses because it may be difficult to get an even distribution of contamination. It is better for fluids.

Conclusions

Finally my adviser told me that we had established that *L. monocytogenes* could grow in my cheese if it were present in the first place. His prediction was, given the historical data that I had, a shelf life of around 8 days would be appropriate. However, if I were to sterilise the additions of herbs, the initial contaminations would be reduced and I could safely quote a shelf life of 30 days using the historical data I have for the plain brie at the end of its shelf life. All this would only be possible if I were to continue to do all my process monitoring and insist with my staff that a very high level of hygiene is maintained. I am pleased to report that I have not had a test result since we started full scale production that would indicate that our conclusions were wrong.

Altering an existing recipe – Technical worked example of an approach to determining the shelf life of a ready-to-eat food in relation to *Listeria monocytogenes (L. monocytogenes)*

Brie with Garlic and Herbs

Background

A small, specialist, farm based dairy has been producing a plain brie cheese for around 15 years and wishes to develop its range to include brie with additives. A market review has indicated that a garlic and herb variant has reasonable sales potential.

The dairy structure is sound and fit for purpose; process equipment was installed as a complete project by a multinational equipment supplier who provides ongoing maintenance to a defined schedule. A specialist chemical company supplies all the requisites for hygiene & cleaning and there are defined schedules and procedures for cleaning the plant and fabric. The dairy has been accredited under the SALSA scheme for around 6 months.

1. Product characteristics and scientific literature

The existing product is a **Ripening Brie cheese**



Milk is supplied by specified farms and delivered by a national haulier. The raw milk is pasteurised on-site at 74°C/18s, then used immediately.

The following processing aids / ingredients are supplied with specifications from a multinational specialist companies. Each company also supplies a certificate of analysis with each delivery.

- Bacterial starter culture, freeze-dried, stored frozen
- *Penicillium camemberti* ripening culture, liquid, stored chilled
- Rennet, liquid, stored chilled
- Calcium chloride, liquid, stored chilled
- Salt, solid, stored at ambient temperature (and used to prepare brine)

There is a system in place to ensure all product is stored as per the manufacturers' recommendations, durability dates are respected and the dairy keeps a record of codes used in each batch of product.

The shelf life of this product from the end of the on site maturation process was originally set at 30 days based largely upon sensory characteristics, the optimum maturity if stored at 5 to 7°C being achieved at 25 days and the product remaining acceptable to 30 days, beyond which it was considered over ripe. As the product could not be guaranteed to be free from *L. monocytogenes* it carries the warning 'not suitable for pregnant women'.

The pH and aqueous salt content of the cheese are:

Component of the cheese	Process stage	pH	Salt-on-product (%)	Moisture (%)	Aqueous salt (%)
Coat	Despatch	6.0	1.6	45	3.6
Body	Despatch	5.2	1.6	50	3.2
Coat	End of life	7.5	1.8	40	4.5
Body	End of life	7.0	1.8	45	4.0

From EC Regulation 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 (= 11.90% aqueous salt), or
- pH is no more than 5.0 and the a_w is no more than 0.94 (= 9.38 % aqueous salt)
- shelf life is less than 5 days

The pH and a_w values of different parts of the finished product at the start and end of shelf life suggest that *L. monocytogenes* would grow if present.

Control of *L. monocytogenes* in the cheese is achieved by:

- correct maintenance and operation of the pasteuriser.
- use of good quality, uncontaminated ingredients.
- adopting Good Manufacturing Practice and HACCP systems in all production areas to prevent cross-contamination, especially in the cheeseroom and maturation rooms.

Having said this, the following points have to be considered:

- While *L. monocytogenes* is inactivated by the standard milk pasteurisation process of 72°C/15s, *L. monocytogenes* is a ubiquitous organism that can colonise production and maturation rooms and gain access to the milk, curd or cheese as a post-pasteurisation contaminant.
- Raw milk is considered by many to be a major source of contamination of the production environment. While raw milk supplies cannot be guaranteed to be free from *L. monocytogenes* on every occasion, the incidence of *L. monocytogenes* in raw milk is surprisingly low; in a survey of UK raw milks*. L. monocytogenes* was detected in only 5.08% of samples, more than 60% of positive samples containing less than 10 cfu/ml (O'Donnell, 1995).
- Potentially 'critical' environmental sources of *L. monocytogenes* are:
  - Brine
  - Drains
  - Chiller units
  - Maturation shelves
  - Improper use of hoses
  - Moisture in the atmosphere

2. Historical data

The dairy has had a contract with a local accredited microbiological laboratory which processes environmental samples and product samples taken by the dairy. The microbiological sampling regime includes tests for Enterobacteriaceae, which would be primary indicators of the level of post process contamination, and *Staph. aureus* the presence of which might be considered to relate to handler hygiene practice or milk quality.

Sampling has been targeted to demonstrate the effectiveness of the hygiene controls on site and has contributed to defining and refining best practice on the cleaning procedures and schedules. Since the sampling plan was started 10 years ago the incidence of *Listeria* isolation in final product has dropped to around 25% of the original incidence.

Taking the last 2 years of data with respect to *Listeria* species, *Listeria* spp. have been found in 15% (of which one third were *Lm*) of drain samples and 2% (of which half were *Lm*) of food contact surfaces prior to cleaning. Post cleaning samples & brine samples all gave negative results.

Start of life testing

200 samples were taken of product at the point of despatch and tested for presence of *Listeria* in 25g using an enrichment technique; of these 14 were positive for *Listeria* spp. and 7 were positive for *L. monocytogenes*. Enumeration of fellow samples from all of the positives gave results of less than 10/g, i.e. any contamination was below the level of detection by count.

End of life testing

Over the same period 50 samples were tested 30 days after the date of despatch; these included fellow samples from all of the *Listeria* positives batches found above. The enrichment technique found 10 samples positive in 25g for *Listeria* spp. of which 6 were confirmed as *L. monocytogenes*. The enumeration technique found one single sample with a count of 400 *L. monocytogenes*/g; this was on a product which previously had been found to be absent in 25g at the start of life. All other samples were below the level of detection (i.e. less than 10/g).

It is important to note that detection of *Listeria* species from ingredients, the product or the environment, particularly food contact surfaces after cleaning, requires documented investigation and follow-up remedial hygienic action carried out and documented.

If the limit of 100 *L. monocytogenes* cfu/g is compromised during shelf life it will be necessary to withdraw or recall the product.

The pattern of *Listeria* isolation:

- **Suggests** an endemic low incidence of post process contamination with *Listeria* spp. including *L. monocytogenes*. Assuming a uniform contamination rate, the base level of contamination could be as high as 1 in 100g or as low 1 in 1,000g. That there is potential for growth of *Listeria* in the product is suggested by the increase the proportion of positive samples from start to end of shelf life and in the single detection of 400/g on one enumeration at end of life. However it is also possible that the contamination is random and sporadic and this single sample might represent an unusually high level of contamination of the sample tested rather than actual growth. The apparent increase in detection rate at 30 days may be skewed by selection of samples from batches which initially proved positive. The situation is further complicated by the variation in pH between body and coat of the cheese over the ripening period, where the ability of *L. monocytogenes* to grow is affected by the level of acidity in its immediate environment.

- **reinforces** that positive release of product on the basis of the incidence of *L. monocytogenes* at start of life would not be an effective control measure.

Conclusions

The microbiological criterion for *L. monocytogenes* in food capable of supporting the growth of *L. monocytogenes* is absent in 25g at point of despatch, based upon n=5, c=0 in EC Regulation 2073/2005. This applies when the Food Business Operator cannot demonstrate that the criterion of 100 *L.monocytogenes*/g throughout shelf life will not be exceeded.

The data presented above suggest that the product would fail the rigour of this requirement if 5 x 25 g samples were taken on each occasion.

The historical results suggests that under normal circumstances the growth rate of *L. monocytogenes* in this product is, at best, poor, this may be due to competition effects from the cheese cultures and the chemical hurdles such as the level of salt.

Aside from the one high result at the end of life, the microbiological results suggest that the process is under control and the 30 day life given is not excessive.

Although one sample out of 50 enumerated at the target shelf life of 30 days has exhibited a count above the legal maximum for a RTE food the weight of evidence suggests that this was a rogue result and that the process is under control; however this view might change as more results are added to the data set which needs to be kept under review.

New Product Development: Ripening Brie cheese with garlic and herbs

1. Product characteristics and scientific literature

The product is a **Ripening Brie cheese with garlic and herbs**. It consists of the plain ripening brie described above with the following additions.

- Garlic (peeled, boiled and puréed, stored chilled)
- Herbs (parsley and oregano), grown organically, sun-dried and finely chopped, purchased from a local farm shop and added to curd without treatment.

The physico chemical characteristics are identical to the plain brie.

- Additive ingredients such as herbs and spices may be added to the milk, curd or fresh cheese with, or without, a treatment such as boiling that would inactivate *Listeria*, yet such commodities may be grown under conditions conducive to contamination with *Listeria*; i.e. near the ground and where there may be poor hygiene standards. Such ingredients must be considered as a potential source of *L. monocytogenes* and controls implemented to minimise this potential.

2. Historical data

The historical data for the plain brie suggests that although the physical and chemical characteristics suggest that growth of *Listeria* might be supported, in practice significant growth is not detected.

The new ingredients required careful risk assessment.

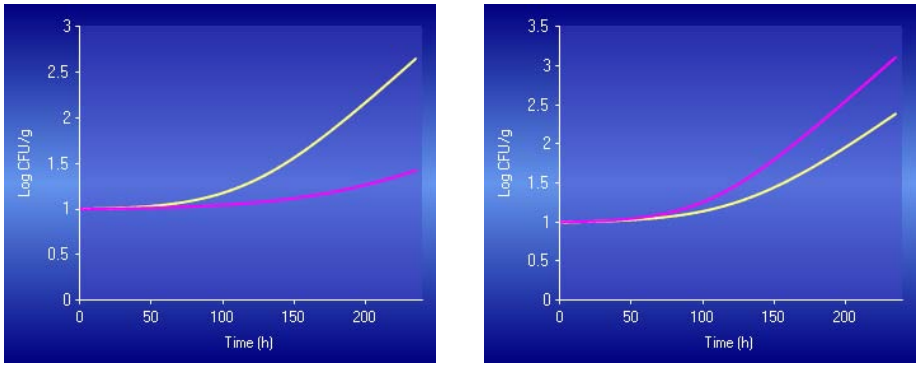
Garlic has gone through a boiling process which should eliminate *L. monocytogenes* – the product is supplied with a specification detailing the process and assures a level of absence in 25g throughout the shelf life.

The provenance of the herbs has not been tested and there is no stage in the process which would eliminate any *L. monocytogenes* (or other pathogens) naturally present. The supplier is therefore not able to guarantee that individual batches are free from contamination.

It must be assumed that *L. monocytogenes* may be present and in a vigorous condition in the herb additive and therefore if added direct into the cheese may significantly increase the loading at the start of life.

3. Predictive Microbiology

It may be possible to use appropriate, freely-available models such as ComBase (http://www.combase.cc) to predict the behaviour of *L. monocytogenes* should it be present in the maturing cheese. This software is designed to give an idea of how the pathogen might behave; however, predictive modelling may not be appropriate for some cultured foods as it does not take into account the competition that may occur between micro-organisms that can reduce the growth of *Listeria*.



(i) (ii)

Predicted behaviour of *L. monocytogenes* in Brie cheese during storage at 5°C: (i) start of life (coat, upper curve; body, lower curve), and (ii) end of life (body; upper curve; coat; lower curve).

These predictions suggest that if *L. monocytogenes* was present on the coat of the cheese at a level of 10 cfu/g at start of life, when stored at 5°C, growth to a level of 100 cfu/g might occur within 200 hours (8.3 days).

Utilising the data from the plain brie where the background level of *L. monocytogenes* appears to be around 1 in100g of product, the predictive model would suggest that at 5°C a level of 100 per gram (4 $\log_{10}$ growth) would take 4 x 8.3 days = 33.2 days.

The level of *L. monocytogenes* the herb addition is an unknown quantity and as there is no elimination step it can be assumed that there will be significant levels in certain batches. Further, the product specification provided by the supplier does not include a criterion for *L. monocytogenes*.

The addition of untreated herbs to the cheese mix at a level of 1% will increase the background level in a proportion of batches of cheese and the possibility that the storage temperatures within retail and the home may be higher would suggest that the proposed formulation is likely to exceed the legal maximum at a 30 day life.

If the herbs were subjected to a process step that would eliminate *L. monocytogenes*, such as steam treatment, then the level of *L. monocytogenes* contamination could be reduced to the point where legally it conforms to the EC Regulations for a RTE food, then the additional

loading to the cheese would not then be significant less than 1 per 100g) – this would enable a 30 day life to be applied.

4. Durability studies

Durability studies are generally not applicable to determine the growth of pathogens in a foodstuff, as there is no guarantee that the pathogen will be naturally present.

Although it would appear that there is a natural background level present in this particular product there is no real evidence of an even distribution of *Listeria* in the cheese which would guarantee its presence in a 25 g sample.

If such a study was carried out, replicate samples would need to be taken from a batch of cheese over life. The storage temperature would need to replicate what would happen in reality. The samples would be tested for *L. monocytogenes* and a plot of number over time would give an indication of whether this organism could grow to a level of 100 cfu/g by the end of life of the cheese.

Reference

O'Donnell, E T, (1995). The incidence of *Salmonella* and *Listeria* in raw milk from farm bulk tanks in England and Wales. *Journal of the Society of Dairy Technology*, 48 (1), 25-29.