

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

BRITISH **RETAIL** CONSORTIUM
for successful and responsible retailing



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Enquiries concerning reproduction should be sent to:

Chilled Food Association Ltd
P.O. Box 6434
Kettering
NN15 5XT
UK
cfa@chilledfood.org
www.chilledfood.org

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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:

<u>Organisation</u>	<u>Representative</u>
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 foodstuffs¹.

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.

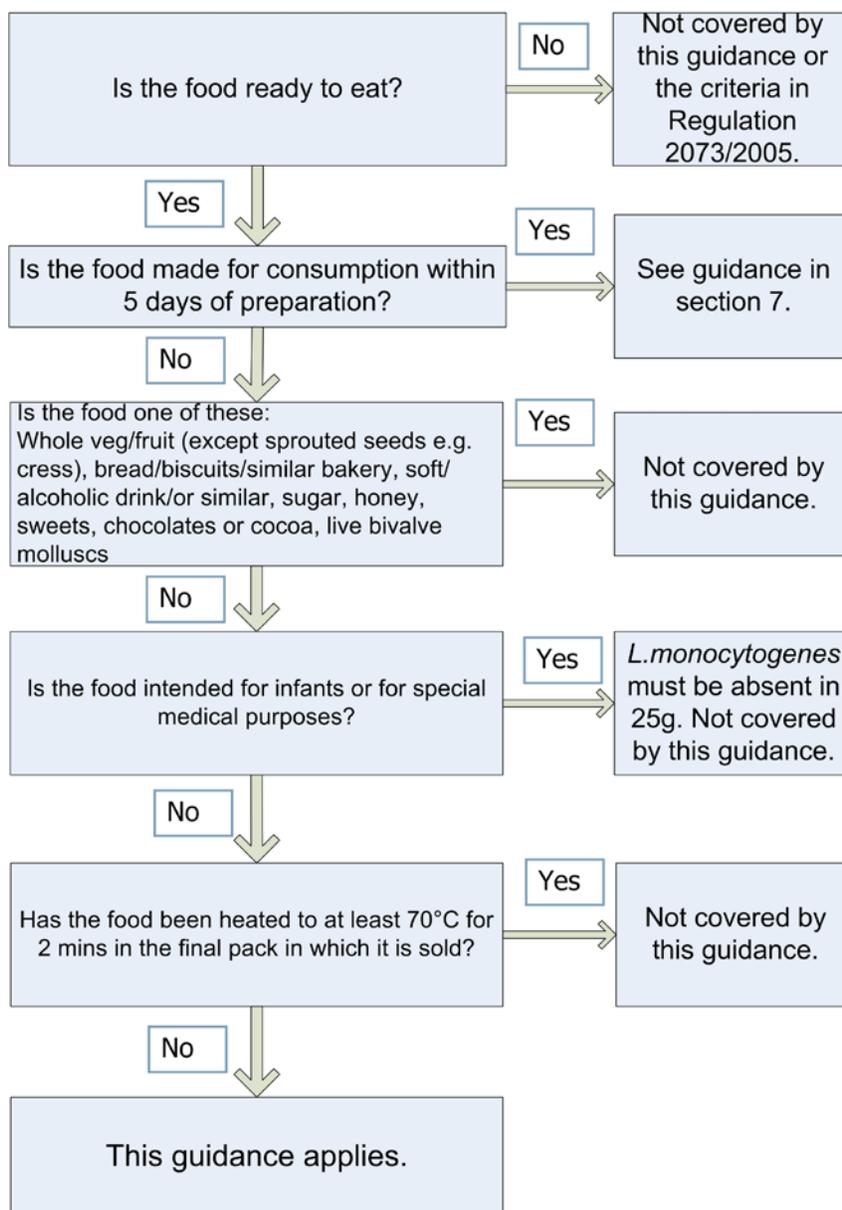
Under the Regulation a RTE food or ingredient with a shelf life of less than 5 days is considered to be unable to support the growth of *L. monocytogenes*. However, in practice since such foods may contain ingredients that support growth of *L. monocytogenes* you must in these cases have evidence to 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.

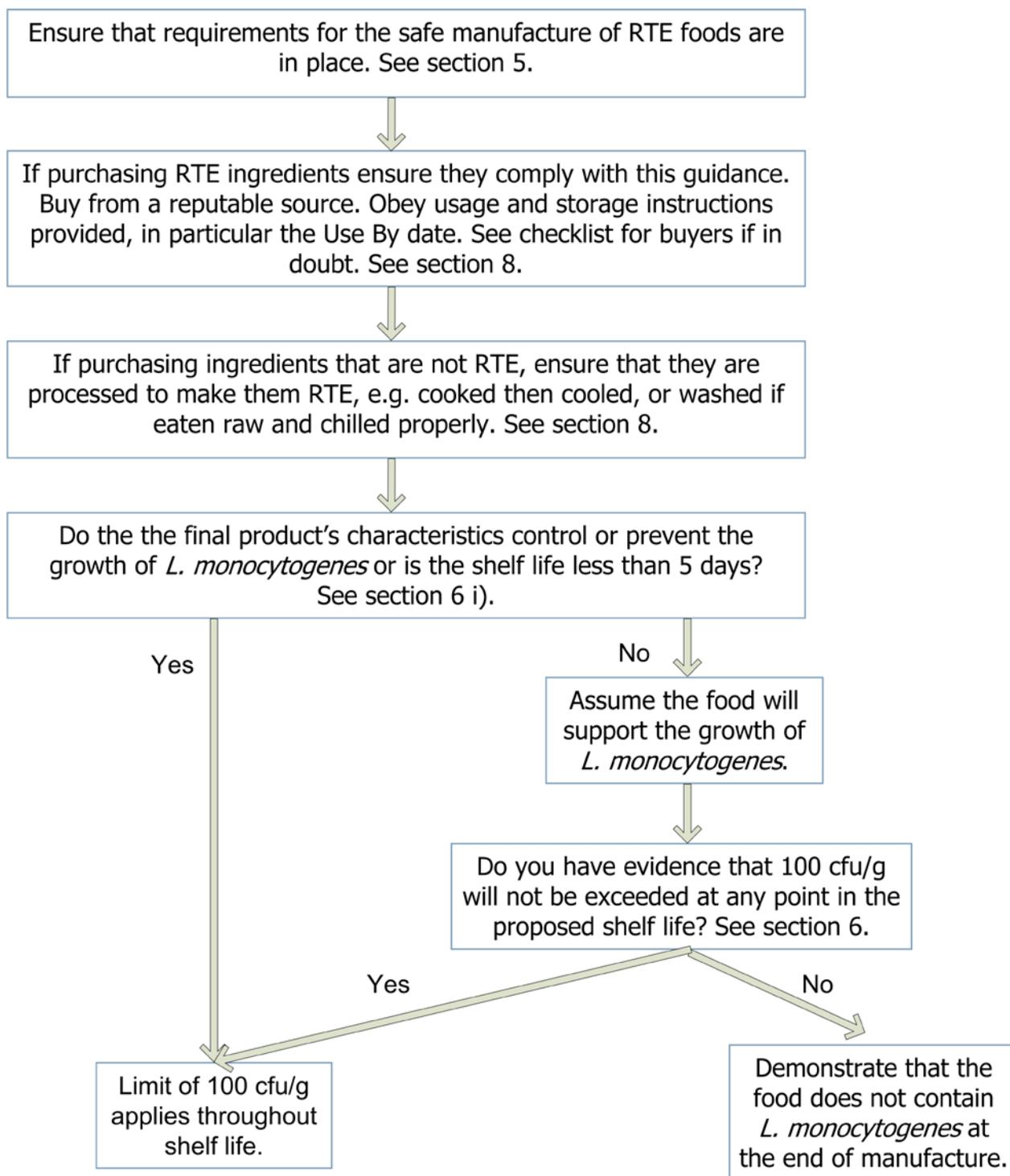
3. **WHO NEEDS TO USE THIS GUIDANCE?**

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 Foods³) 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) What do I do if *L. monocytogenes* is detected at a low level in an ingredient/food before the end of shelf life?

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/ecregquidmicrobiolcriteria.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.com

www.chilledfood.org

www.sandwich.org.uk

www.brc.org.uk

www.food-solutions.org

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