

Microbiological Criteria – Don't Panic!

Kaarin Goodburn MBE
Chilled Food Association
cfa@chilledfood.org

freshly made every day



freshly made every day



Menu

- **UK retail chilled prepared food industry & CFA**
- **Micro Criteria Regulations 2073/2005**
- ***Listeria monocytogenes* and listeriosis**
- **Highest risk foods**
- **Controls used by professionals and their efficacy**
- **Conclusions**
- **Guidance available**

UK Retail Chilled Prepared Food Industry

Year	Market (£m)
1989	550
1999	4550
2005	7357
2010	9163
2011	9755
2012	10306
2013	11356
2014	12280

Source: TNS/Kantar WorldPanel, CFA:
www.chilledfood.org/market

Chilled foods' unique position

- Retail brand dominance, although brands now emerging
- No manufacturer contracts
- Unpreserved
- Just in time
- HACCP from the outset
- Exacting microbiological standards
- Significant annual churn
- Predominantly made in the UK

freshly made every day



Chilled Food Association

- **Who are we?**
 - Represent professional manufacturers supplying UK market
- **What is our Mission?**
 - To promote and defend the reputation and value of the professional chilled food industry through the development and communication of standards of excellence in the production and distribution of chilled food
- **With whom do we work?**



CFA – Our Partnerships



Samworth Brothers
QUALITY FOODS



Public Health
England







UK Chilled Prepared Food Ranges

- Entrées (some RTE)
- Dressed salads
- Leafy salads
- Prepared vegetables
- Prepared fruit
- Delicatessen products
- Sandwiches, rolls & wraps
- Sandwich fillings
- Savoury pastries & quiches
- Dips & dressings
- Stir fry kits
- Pizza
- Recipe dishes/kits (ready meals)
- Meal Accompaniments
- Sushi
- Filled and plain fresh Pasta
- Soups (some RTE)
- Sauces (some RTE)
- Desserts

Items in green = ready to eat

EU Micro Criteria Rules (2073/2005 apply)

Ready to Eat Food = ?

Defined in Regulation 2073/2005 as:

“food intended by the producer or the manufacturer for direct human consumption

without the need for cooking or other processing effective to reduce to an acceptable level or eliminate microorganisms of concern.”

freshly made every day



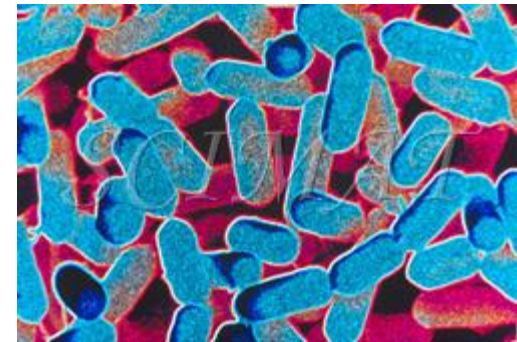
Not included in CFA's scope:

- **Meat, e.g.**
 - Raw or air-dried
 - Cooked or cured
- **Dairy products, e.g.**
 - Milk (fresh or fermented)
 - Cheese
- **Fish, e.g.**
 - Unprocessed raw whole/fillets

BUT... chilled prepared foods may include these ingredients

Listeria monocytogenes (Lm)

- One of 6 spp of *Listeria* (mono, innocua, welshimeri, seeligeri, ivanovii, grayi)
- Gram-positive rod-shaped bacterium
- Most strains pathogenic
- Most heat resistant vegetative pathogen (6D = 70°C/2 mins)
- Facultative anaerobe
- Relatively cold tolerant
- Relatively salt tolerant
- Only Lm is specifically legislated for

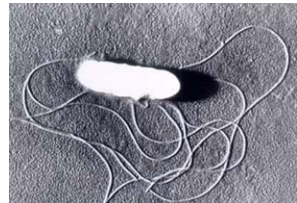


Lm ecology

Factor	Growth			Survival
	Lower Limit	Optimum	Upper Limit	
Temperature (°C)	-1.5 to 3.0	30-37	45	-18
pH	4.2-4.3	7	9.4-9.5	3.3-4.2
aW	0.90-0.93	0.99	>0.99	<0.90
NaCl (%)	<0.5	0.7	12-16	>20
Atmosphere	Facultative anaerobe – survives in presence or absence of oxygen			

Lm ecology

- Occurs naturally in soil, sewage, silage, gut of many animals, raw meats
- Estimated that 10% of healthy adults carry in gut
- Transmission from
 - infected food
 - the environment
 - mother to foetus
- Major transmission route into humans is through contaminated foodstuffs

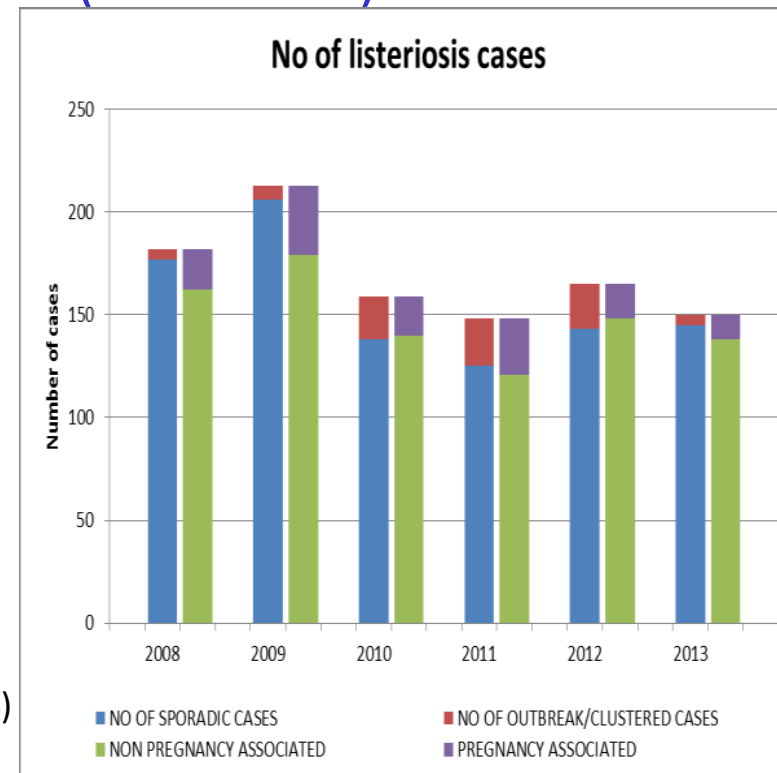


Lm ecology

- Lm enters from workers, raw materials etc
- Drains are hotspot unless special measures taken
- Spreads onto equipment (e.g. screw threads, cable duct, imperfect joins), becomes persistent
- Persistent strains mostly isolated from final products
- Lm can adhere to equipment materials commonly used in the food industry, and form biofilms
 - Cleaning and disinfection
 - Quaternary ammonium compounds (quats) particularly effective against Gram positive organisms such as Lm

Listeriosis – Epidemiology

- Long incubation period: 70+ days
- Changes
 - Mainly in 60+ group (65%), especially those with underlying conditions/taking specific medication
 - Bacteraemia without CNS infection (79% cases)
- Cannot be explained by
 - Recognised outbreaks
 - Regional differences
 - Age
 - Gender (54% male)
 - A predominant *Lm* subtype



Figures relate to England & Wales 2008-2013 (ACM1135, Jan 2014)

Listeriosis

The biggest cause of foodborne illness deaths in the UK & EU

Disease	Number of confirmed human cases	Hospitalisation		Deaths	
		Reported hospitalised cases	Rate (%)	Reported deaths	Case-fatality rate (%)
Campylobacteriosis	214,779	11,922	43.6	56	0.05
Salmonellosis	82,694	7,841	36.0	59	0.14
Yersiniosis	6,471	481	48.4	2	0.05
VTEC infections	6,043	922	37.1	13	0.36
Listeriosis	1,763	735	99.1	191	15.6

13 food-borne outbreaks reported by 7 MS and 1 non-MS. 3 outbreaks implicated seafood

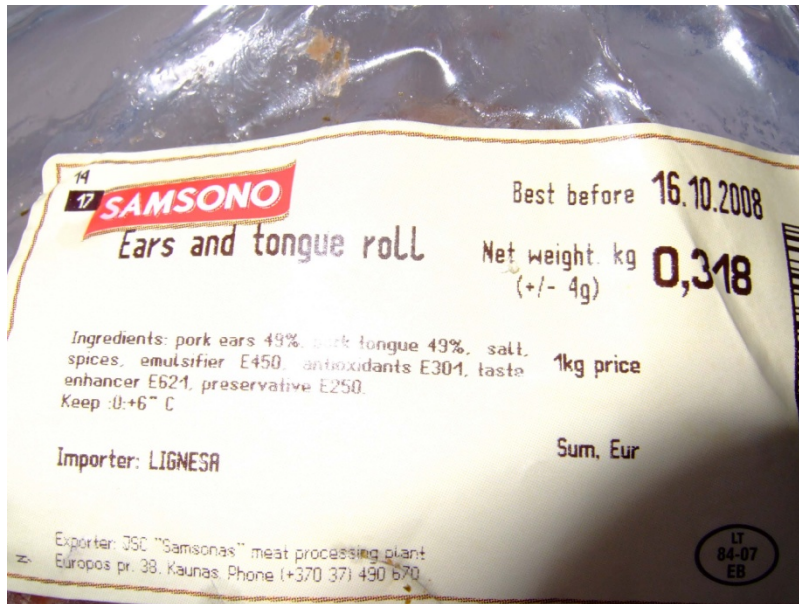
Listeriosis - Risk Factors

- **More likely to report consumption of:**
 - cooked meats (beef and ham/pork; not poultry)
 - cooked fish (i.e. (cold??) smoked salmon) & shellfish (prawns)
 - dairy products (i.e. milk but also certain cheeses)
 - ‘mixed salads’
- **More likely to be bought from:**
 - convenience stores & local shops (bakers, butchers, fishmongers and greengrocers)
- **Incidence higher in most deprived areas**
 - Observed in patients aged 60+
 - More marked for pregnancy-associated cases
- **Pregnancy-associated cases increasingly ‘ethnic’**
 - 16.7% to 57.9% from 2001-8, most marked 2006-8
 - 12.7% from 2008-2013

Recalls from the UK Market

Ear & Tongue Roll

Lithuanian import - 2.8×10^6 cfu/g
Use by 16/10/08, Recall 22/10/08



Home Black Pudding Sausage

Polish import – 6×10^5 cfu/g
Use by 30/10/10, Recall 20/10/10



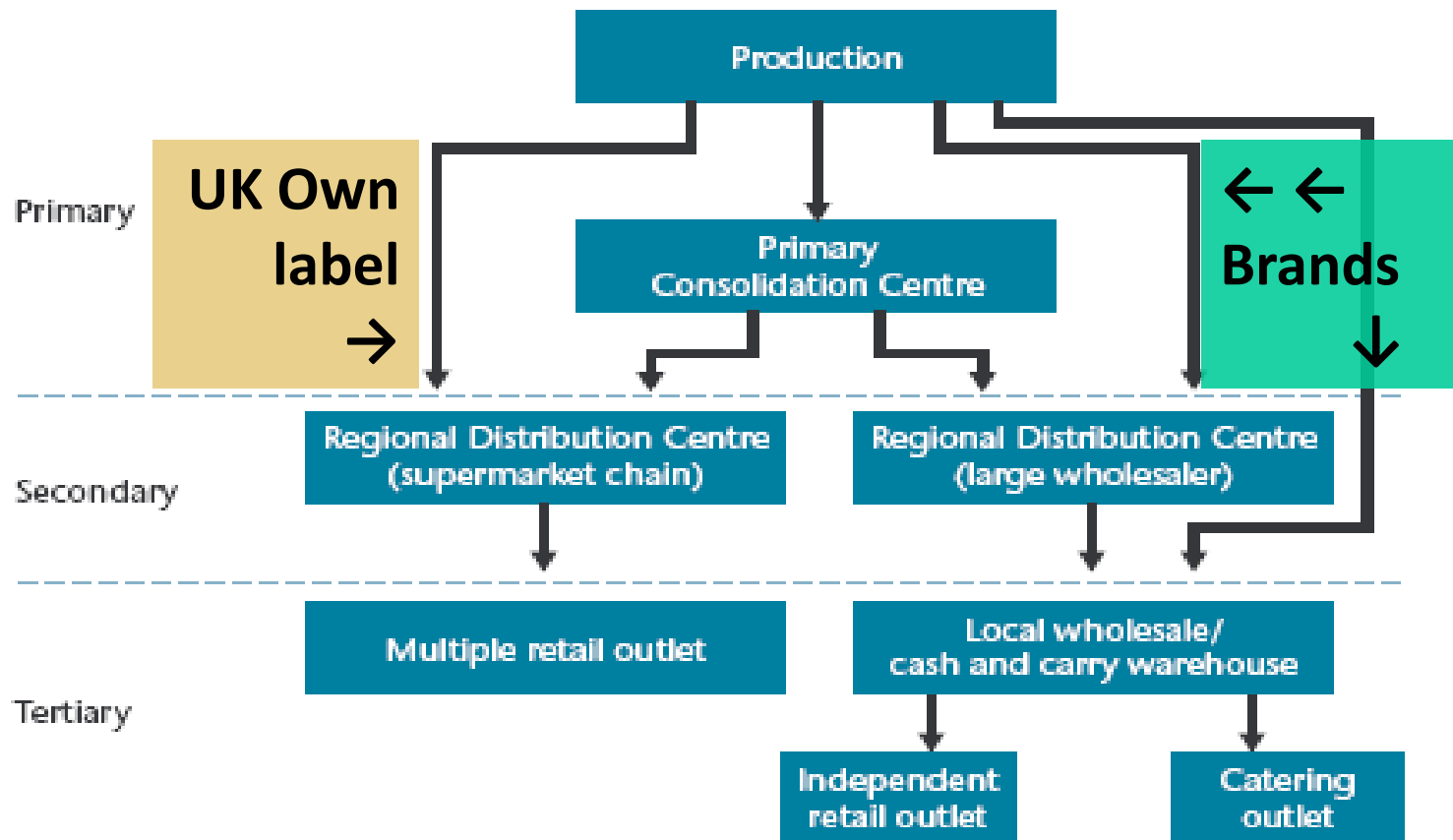
Prevalence in UK RTE Foods

- Higher prevalence in food sliced to order than pre-packed
- Greatest prevalence
 - Non-prepacked foods without clear storage/usage instructions
 - Food from sandwich bars, butchers, convenience shops, bakeries
- 'Consumer at risk' score inversely proportional to prevalence:

HPA/LACORS Survey May 2006-April 2007		
Premises type	No. samples	% samples Lm
Sandwich bar	106	6 (5.7)
Supermarket pre-packed	3820	55 (1.4)

	Mar-Sep 2007 (FSA B18024)	Apr 2012-Mar 2013 (FSA FS241042)
	Cooked sliced meat sold by SMEs & major retailers, sampled by % market share	Cooked sliced meat sold by SMEs
<i>Listeria</i> spp	2.8%	7%
Lm	1.5%	3.8%
<i>Enterobacteriaceae</i>	11.6%: $10\text{--}2.9 \times 10^5$ cfu/g	36.2%: mean 2.96 ± 1.47 log cfu/g
<i>E. coli</i>	ND	0.48%

Example structure of food distribution channels



UK Listeriosis cases/clusters

Year	Region	Cases	Vehicle
1999	NE England	4	Hospital sandwiches
2003	NE England	17	Butter
2003	NE England	18	None identified
2003	S Wales	2	Hospital sandwiches
2003	SW England	5	Hospital sandwiches
2004	E Mids	6	None identified
2004	SE England	2	Hospital sandwiches
2005	NW England	1	Sliced meat
2006	London	1	Sliced meat
2007	London	1	Hospital sandwiches
2011	Staffordshire	3	Hospital sandwiches
2012	Northern Ireland		Hospital sandwiches

What Makes Chilled Food RTE?

Controls at manufacture:

- **Manufacturer's risk assessment and product design, i.e. HACCP plan**
 - Supply QA and audits – raw materials
- **Appropriate controls**
 - Minimise potential for contamination by zoonotic organisms
 - CFA's Micro Guidance for Growers [produce]
 - CFA Best Practice Guidelines for the Production of Chilled Food
- **Hygienic preparation and packing – High Care and High Risk Areas**
 - Prevent re-/cross-contamination
- **Specified thermal processes followed by rapid chilling, e.g.**
 - Equiv. to min. 70°C/2 mins – ≤10d shelf life
 - SUSSLE Process
 - Equiv. to min. 90°C/10 mins – >10d shelf life
- **Limited shelf life**
 - Ensure peak quality
 - Minimise opportunity for microbial growth

What Makes Chilled Food RTE?

Post-Manufacture Controls

- Chilled distribution, sale and storage
 - Minimise potential for microbial growth
- Despatch and distribution to retail
 - $<5^{\circ}\text{C}$ required and monitored by UK major retailers
- Retail storage
 - $\leq 8^{\circ}\text{C}$ legally
- Consumer storage
 - Use by date
 - Usage instructions

Segregation –

GMP/LRA, High Care and High Risk Areas

- **GMP/Low Risk Area**
 - Raw material intake
 - Ready to cook foods
 - Packaged product
- **High Care Area**
 - RTE and ready to reheat food production
 - Includes non-thermally processed ('raw') ingredients having been through a decontamination process
 - Separate equipment, utensils, staff and changing areas
- **High Risk Area**
 - RTE and ready to reheat food production
 - Only thermally processed foods (minimum 70°C/2 mins)
 - Separate equipment, utensils, staff and changing areas

2073/2005 Criteria for Lm in RTE foods

Food Category	Micro-organisms	Sampling plan		Limits		Analytical Reference Method	Stage where the criterion applies
		n	c	m	M		
1.1 RTE foods intended for infants and RTE foods for special medical purposes	<i>Listeria monocytogenes</i>	10	0	Absence in 25g		EN/ISO 11290-1	Products placed on the market during their shelf life
1.2 RTE foods able to support the growth of <i>L. monocytogenes</i> other than those intended for infants and young children and ready-to eat-foods for special medical purposes ³	<i>Listeria monocytogenes</i>	5	0	100 cfu/g		EN/ISO 11290-1	Products placed on the market during their shelf-life
		5	0	Absence in 25g		EN/ISO 11290-2	Before the food has left the immediate control of the FBO who has produced it
1.3 RTE foods unable to support growth of <i>L. Monocytogenes</i> other than those intended for infants and special medical purposes	<i>Listeria monocytogenes</i>	5	0	100 cfu/g		EN/ISO 11290-1	Products placed on the market during their shelf-life

3

n = number of samples

c= number of samples units giving values between m and M.

For food safety criteria only 1 limit is provided so m=M

Footnotes are included to the Annex which assist in the interpretation/appliocation of the criteria.

Which Lm Criterion?

Is product RTE?

NO
→

No specific *Lm* criterion applies

↓YES

Is product intended for infants/special medical purposes?

YES
→

Lm absent

↓NO

Is product excluded in a footnote?

YES
→

No specific *Lm* criterion applies*

↓NO

Is $\text{pH} \leq 4.4$ or $a_w \leq 0.92$ or $\text{pH} \leq 5.0$ & $a_w \leq 0.94$ or shelf life $< 5\text{d}$ or frozen at $\leq -12^\circ\text{C}$?

YES
→

Product unable to support *Lm* growth. Limit of 100 cfu/g applies

↓NO

Do scientific/modelling/historic/etc data show growth not supported within shelf life?

YES
→

Limit of 100 cfu/g applies

↓NO

Will low levels of *Lm*, if present, grow to ≥ 100 cfu/g within shelf life under expected storage conditions?

YES
→

Reduce shelf life so that limit of 100 cfu/g not exceeded during shelf life

↓NO

Shelf life is appropriate

*default is 100/g in RTE food

What do manufacturers have to do?

- Implement GMP & HACCP
 - EU hygiene 852/2004 etc
- Sample for HACCP verification and monitoring, compositing across lots – batch size determined by FBO

Batch

**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**

What do manufacturers have to do?

- Implement GMP & HACCP
 - EU hygiene 852/2004 etc
- Sample for HACCP verification and monitoring, compositing across lots – batch size determined by FBO
- Carry out environmental swabbing:
 - *Lm* (RTE food) – *Listeria* spp as indicator
- Use specified/validated lab methods & certificated labs
- Set appropriate shelf life

Historical Data

- **Best indication of an organism's behaviour in a foodstuff in reality**
- **When present, *Lm* is from the environment:**
 - natural contaminants are likely to be stressed and will grow slower than those that have been grown for use in inoculation studies, i.e. in predictive models, challenge testing
- **Data on *Lm* levels present at the beginning (DOP) and at the end of shelf life (EOL) can be used to assess growth potential**
 - **FBOs should have *Lm* test results (DOP and EOL) for each RTE product**

Historical data

- Article 5.3: *"The number of sample units of the sampling plans set out in Annex I may be reduced, if the FBO can demonstrate by historical documentation, that he has effective HACCP-based procedures."*
- The more confidence you have in the FBO's procedures and efficacy of controls, the less testing is required

Confidence in HACCP systems	Testing Level
High ↓ Low	Low ↑ High

Historical data

- **For example, for raw materials FBOs should demonstrate:**
 - Understanding of microbiological hazards and risks associated with the raw material
 - Knowledge and confidence in the raw material supplier/producer
 - The risk associated with the volume of the raw material used
 - Historical data to support these points
- **Confidence can be enhanced by the FBO:**
 - Auditing their suppliers and their HACCP including their microbiological checks, and/or
 - Increasing the frequency of checks until sufficient historical data is available

Shelf life is...

- A critical parameter
- The period of time for which a product remains safe and meets its quality specifications under expected storage and use conditions.
 - Shelf life determines the durability date
 - CFA/European Chilled Food Federation protocol
 - 4h abuse at target 20-22°C (not <18°C or >24°C)
 - Store at 8°C \pm 1°C for the remainder of the study
- Setting appropriate shelf life is part of HACCP and required by law
- Very short by design for UK chilled prepared foods

Comparing chilled foods' shelf lives

	UK	Other EU	USA
Delicatessen meat	10-15 d (uncured) 15->30 d (cured) [major retailers]	14-28 d(uncured) 14-56 d(cured)	28-84 d
Sandwiches	2 d [major retailers]	≤14* d	≤ 23 d
	4 d [airline]		
	10 d [discounter]		
Cold-smoked salmon	21-24 d	≤120 d	≤120 d



Fundamentally the same food so why such different shelf lives?

Answer: Shelf life protocol variability, lack of shelf life validation, reacting to commercial demands, preservatives

* Fillings generally low a_w

Lm and RTE Shelf Life Assessment

Approach hierarchy:

- **Scientific (e.g. pH, a_w , literature)**
 - Won't support growth, growth reported to be limited
- **Historical or other data**
 - Levels found in reality, i.e. when HACCP functioning (DOP, EOL)
 - Safety record of the product
- **Model outputs (e.g. ComBase, Growth Predictor)**
 - Won't support growth, growth reported to be limited with the given shelf life under expected storage conditions

Predictive modelling: <http://ComBase.cc>

Growth Model

Prediction Uncertainty

[Static | Dynamic]

[Aw | NaCl]

Listeria monocytogenes/innocua

Init. level 0.3
Phys.state 2.1e-2
Temp (°C) 5
pH 7
Aw 0.997



Listeria monocytogenes/innocua

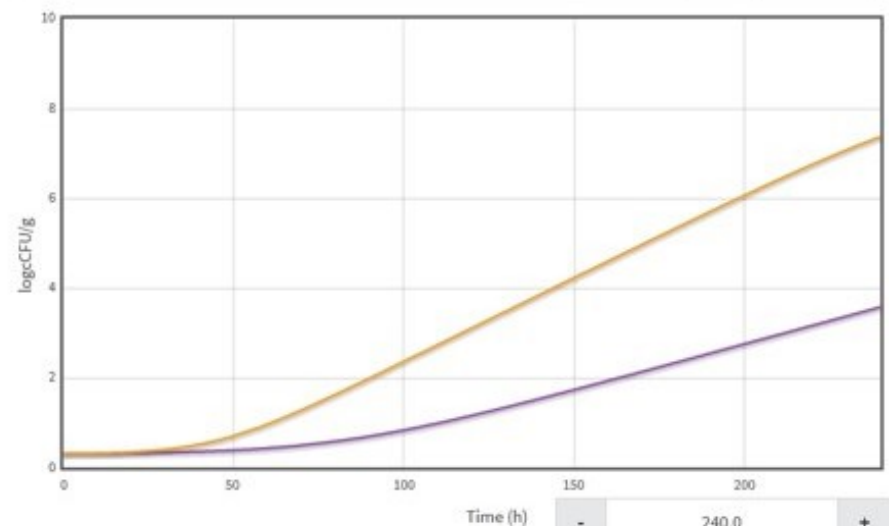
Init. level 0.3
Phys.state 2.1e-2
Temp (°C) 8
pH 7
Aw 0.997



[Add prediction]



Chart Data points



[Plot custom points]

Lm and RTE Shelf Life Assessment

Approach hierarchy:

- **Scientific (e.g. pH, a_w , literature)**
 - Won't support growth, growth reported to be limited
- **Historical or other data**
 - Levels found in reality, i.e. when HACCP functioning (DOP, EOL)
 - Safety record of the product
- **Model outputs (e.g. ComBase, Growth Predictor)**
 - Won't support growth, growth reported to be limited with the given shelf life under expected storage conditions
- **Shared industry data on any of the above**

Example Use of *Lm* Historical Data

If *Lm* detected in a RTE product:

- Before the end of shelf life at a level of e.g. <20 cfu/g, **and**
- Data on a representative sample from the same batch at end of life shows levels remain below 100 cfu/g

Then...

- The data help demonstrate that the product remains within the *Lm* criteria over its shelf life
- Under such circumstances, a low level (e.g. <20 cfu/g) detection during shelf life should not need to be withdrawn

Lm and RTE Shelf Life Assessment

Approach hierarchy:

- **Scientific (e.g. pH, a_w , literature)**
 - Won't support growth, growth reported to be limited
- **Historical or other data**
 - Levels found in reality, i.e. when HACCP functioning (DOP, EOL)
 - Safety record of the product
- **Model outputs (e.g. ComBase, Growth Predictor)**
 - Won't support growth, growth reported to be limited with the given shelf life under expected storage conditions
- **Shared industry data on any of the above**
- **If none of this available then consider shelf life or challenge test studies**

Lm Challenge Testing

- **No legal requirement to do this**
 - If there are GMP, HACCP + supporting systems and the shelf life approach is followed it is not expected to challenge test
- **Issues with challenge testing:**
 - Neither quick nor simple
 - Does not reflect either actual contamination levels nor the physical state of organisms which may be expected to be present
 - Relates only to that specific product formulation/process combination
 - Costly

**The safety/stability of a product should instead be satisfactorily addressed during new product development
i.e. use HACCP in NPD**

Durability Studies

- **Design safety into the product during NPD**
- **Number of studies is determined by HACCP**
- **Assess**
 - Micro safety and stability: indicators + spoilage organisms
 - Organoleptic characteristics, e.g. texture, colour
 - Pathogens before factory trialling
- **Test using competent laboratory (17025):**
 - Day of production (DOP)
 - End of life (EOL)
 - In-between (if shelf life long enough)
 - Use a different sample for each test point
- **Ongoing monitoring**

CFA/BRC Shelf Life Guidance

- Consortium of organisations inc FSA, CIEH, LGR
- **Contents**
 - Who Needs to Use This Guidance?
 - Requirements for the Safe Manufacture of RTE Food
 - Establishing Shelf Life
 - **Practical Application of Shelf Life Studies**
 - **Checklist for Buying Ingredients**
 - Questions and Answers
 - Glossary
 - Further Sources of Information
 - Worked Examples Weblinks
- **Free download:**
<http://preview.tinyurl.com/ycyyydu>

CFA/BRC/FSA Shelf Life Guidance – Key Points

Ensure that requirements for safe manufacture of RTE foods are in place. See section 5.



If buying RTE ingredients ensure they comply with this guidance. Buy from a reputable source. Obey usage and storage instructions provided, in particular the Use By date. See 'Checklist for buyers' if in doubt. See section 8

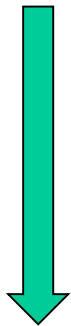


If buying ingredients that are not RTE, ensure they are processed to make them RTE, e.g. cooked then cooled. See section 8.



Do the final product's characteristics control or prevent the growth of Lm or is shelf life <5d? See section 6i.

Yes



Limit of 100 cfu/g applies throughout shelf life

No

Assume the food will support the growth of Lm. Do you have evidence 100 cfu/g will not be exceeded during the proposed shelf life? See section 6.

Yes



Demonstrate that the food does not contain Lm at the end of manufacture

No



CFA/BRC Shelf Life Guidance – Worked Examples

- Data to support shelf life must be documented
- No requirement for data to be held in the format as set out
- Worked examples
 - New Product
 - Cold Smoked Salmon & Fresh Watercress Sandwich – Simplified
 - Cold Smoked Salmon & Fresh Watercress Sandwich – Technical
 - Altering an existing recipe
 - Brie with Garlic and Herbs – Simplified
 - Brie with Garlic and Herbs – Technical
 - Justifying the shelf life of an existing product
 - Cold Smoked Salmon and Fresh Watercress Sandwich

Finding *Listeria*

- Finding >20 *Lm*/g in food is highly unusual if food safety management procedures are working, i.e.
 - *Lm* quantifiable in no more than 0.03% of samples
- If *L spp* detected in food or environment:
 - Investigate
 - Follow-up with remedial action, e.g. hygiene, ingredient suppliers, temperature control
 - Document that action
 - Review and verify controls
 - Re-establish controls' efficacy

Conclusions

- Applying GMP + HACCP, i.e. High Care/Risk Area regimes, are a **demonstrably effective** control strategy
- DOP and EOL analysis **works** as a means of demonstrating manufacturing control and shelf life appropriateness
- **Current rules and guidance need to be implemented and enforced for all RTE foods**
 - Hygiene legislation
 - Shelf life establishment
 - Micro Criteria for Foodstuffs

HACCP in Practice – CFA Guidance

- **CFA Best Practice Production Guidelines:**
 - www.tsoshop.co.uk/chilledfoods
 - Covers all chilled prepared foods
 - Integrates with BRC Global Standard and IFS
 - **20% discount code for EHPs - quote 'CFA'**
- **CFA Lm Management Guidance:**
 - Best hygiene practice, methodology, implementation
 - Hard copy available from CFA@chilledfood.org by request
- **Microbiological testing - application & interpretation:**
 - <http://preview.tinyurl.com/ybo2p35>
- **EU Microbiological Criteria Regulation 2073/2005:**
 - CFA/BRC guidance: <http://preview.tinyurl.com/yaxr9ss>
 - CFA/BRC Lm and shelf life guidance + worked examples: <http://preview.tinyurl.com/ycyyydu>



The centre of excellence for the chilled food industry

www.chilledfood.org

freshly made every day

