

Microbiological Criteria

Implementing the EU criteria 2073/2005 in practice

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Don't panic

What is the EU Micro Criteria Regulation
2073/2005 (as amended) all about?

HACCP

What is its scope?

- Food production and retail including catering
 - but NOT all foods
 - Excludes agriculture except sprouted seeds, shellfish
- Food Safety Criteria
- Process Hygiene Criteria

Scope – Food Safety Criteria

**Define micro food safety. Require action under 178/2002 (EU General Food Law):
reporting and potentially recalls on exceedances**

- *E coli*
 - Live bivalve molluscs and echinoderms, tunicates and gastropods
- **Histamine**
 - Fishery products from fish species associated with high histidine
- *Listeria monocytogenes*
 - RTE foods (with exceptions)
 - 100 cfu/g max unless cannot be shown that will not exceed this, otherwise zero applies, as for RTE foods intended for infants and RTE food for special medical purposes
- *E sakazakii*
 - Dried infant formulae and dried foods for special medical purposes intended for infants <6m
- **Salmonella**
 - Butter, cream and cheese from raw/non-pasteurised milk
 - Cooked crustaceans and molluscan shellfish
 - Egg products (except where processed to eliminate risk)
 - Follow-on formulae
 - Gelatine and collagen
 - Ice cream (except where processed to eliminate risk)
 - Live bivalve molluscs, echinoderms, tunicates and gastropods
 - Milk and whey powder
 - Meat products, Mechanically Separated Meat, minced meat and meat preparations
 - RTE sprouted seeds, pre-cut fruit and vegetables, unpasteurised fruit and vegetable juices

Scope – Process Hygiene Criteria

Quality-related, no reporting required under 178/2002, but corrective action required in terms of process, raw material chain

- **Salmonella (not zero tolerance)**
 - Carcasses of cattle, sheep, goats, pigs and horses
 - Poultry carcasses of broilers and turkeys
- **Bacillus cereus (presumptive)**
 - Dried infant formulae
- **Aerobic Colony Count**
 - Carcasses of cattle, sheep, goats, pigs and horses
 - Minced meat, MSM
- **Staphylococcal enterotoxin**
 - Shelled and shucked products of cooked crustaceans and molluscan shellfish
 - Cheese from raw/non-pasteurised milk
 - Unripened cheese made from pasteurised milk
 - Milk powder and whey powder
- **E. coli**
 - Cheeses made from milk or whey that has undergone heat treatment
 - Meat preparations, MSM
 - Pre-cut fruit and veg, unpasteurised fruit and vegetable juices
 - Shelled and shucked products of cooked crustaceans and molluscan shellfish
- **Enterobacteriaceae**
 - Carcasses of cattle, sheep, goats, pigs and horses
 - Egg products
 - Ice cream & frozen dairy desserts
 - Infant formulae
 - Follow-on formulae
 - Milk powder and whey powder
 - Pasteurised milk and other pasteurised liquid dairy products

Not in the Scope

- Non-RTE non-meat products
- Primary agriculture - except sprouted seeds and shellfish
- Certain pathogens
 - Bacillus cereus
 - EFSA: no point in setting criterion but: infant formulae
 - Campylobacter – may come in the future (non-thermal CCP = ?)
 - Clostridia – may come in the future (worthwhile??)
 - Protozoa – may come in the future (detection??)
 - Viruses – may come in the future (detection??)
 - VTEC – SCVPH: no point in setting criterion
- Spoilage/Quality
 - Coliforms
 - Lactic Acid Bacteria
 - Moulds
 - Pseudomonads
 - Yeasts

What's it NOT about – Myths (1)

- Increased sampling of foods
 - NO! - no change to current HACCP-based approaches
 - BUT specified sampling frequency for minced meat/preps etc
- *Listeria monocytogenes* zero tolerance in adult RTE foods
 - NO! – limit of 100/g applies throughout allocated shelf life
- Every batch has to be tested
 - NO! - frequency is HACCP-based, determined by manufacturer
- 5 samples need to be tested *per batch* (e.g. RTE foods)
 - NO! - compositing is allowed for between comparable lots
- Positive release is required
 - NO! – using functioning HACCP-based systems is required

What's it NOT about – Myths (2)

- Challenge testing to demonstrate safe shelf life
 - NO! - hierarchy of approaches is set out in the Regulation
- Testing emphasised over control, diverting resources
 - NO! – having functioning HACCP-based systems is the key legal requirement
- It all means extra work for labs
 - NO! – no change if sampling is already HACCP-driven

Nothing Fundamentally New

... according to the European Commission:

“The Regulations do not bring any new obligations or new administrative requirements for food businesses and do not cause additional costs for food businesses”

Legal Basis

Regulation 852/2004 (general EU Hygiene Regs)

i.e. HACCP (control) is king!

- Breaching the criteria is not itself against the law
- Not taking action specified in the Regulation is, i.e. must
 - Use the criteria in the context of food safety management systems based on HACCP principles to help show correct functioning
 - Notify/withdraw if NOT within direct control of the producer if safety criteria exceeded (EU General Food Law 178/2002)
 - Take internal corrective action (process/raw material) if process hygiene criteria exceeded

What about National Criteria?

- Where not set in the Regulation, Member States may keep national micro criteria providing
 - they are scientifically justified and
 - do not pose barriers to intra-Community trade
- Member States were to scientifically justify to the EC by 1/1/06 any rules they wished to keep in place
- National rules rejected by the EC cannot be used for imports into the EU, but can still be used for internal trade



What do manufacturers have to do?

- Implement GMP & HACCP: EU hygiene 852/2004 etc
- Sample for HACCP verification and monitoring, compositing across lots
- Carry out environmental swabbing:
 - *Lm* (RTE food) – *Listeria* spp as indicator
 - *Cronobacter* (*Enterobacter sakazakii* - baby food/for medical purposes) – Enteros as indicator

What do manufacturers have to do?

- Test 5 samples of 1 minced meat/meat preparation etc per week per producer
- Set relevant RTE products' shelf lives so *Lm* does not exceed 100/g
- Report confirmed exceedances of safety criteria to Competent Authorities (via brand owner if own label)
- React to exceedances of Process Hygiene Criteria: trend, investigate, carry out relevant corrective action

What DON'T manufacturers have to do?

- Test 5 samples of every batch
- Challenge test products vs *Listeria monocytogenes*
- Use specified test methods (as long as recognised validated methods are used)
- Report exceedances of Process Hygiene Criteria

Emphasis on Testing?

Food Standards Agency guidance:

“In many cases current practices may be sufficient to demonstrate compliance with the Regulation, as it is not intended that there should be increased emphasis on microbiological testing where food safety management procedures based on HACCP principles and good hygiene practices are in place and appropriate verification is carried out.”

i.e. do HACCP and use criteria in monitoring (inc trends), as now

HACCP: non-negotiable legal requirement

1. Carry out hazard analysis
2. Identify CCPs
3. Establish critical limits
4. Monitor the process to maintain control
5. Establish corrective actions
6. Document
7. Verify that the HACCP system is working correctly

Key point

Food safety is neither guaranteed nor controlled by micro testing

- Testing is not a control measure
- Micro testing of final product alone cannot be relied upon to demonstrate product safety and may be insufficient to demonstrate due diligence
- Key is to be able to demonstrate functioning HACCP-based systems

How should enforcers use the Reg?

Food Standards Agency guidance:

"Food Business Operators will be required to provide evidence that the necessary food safety management procedures are in place to ensure all relevant criteria are met"

i.e. FBOs must have properly functioning HACCP-based systems

.... and have a sound basis for the shelf life

Testing Frequency?

- The Regulations specify sampling plans, NOT frequencies
 - Except for minced meat/preparations/MSM/carcases:
 - E.g. One product per producer per week
- Sampling frequencies are otherwise driven by HACCP:
 - Risk-based frequency in practice
 - NO CHANGE to the level of testing required for foods where HACCP verification testing is already in place
- Testing will be adapted according to the company's size
 - 'more simplified rules for SMEs concerning the testing obligation'
 - definition of 'small business' is left up to national authorities

→ level playing field?

What is a Batch?

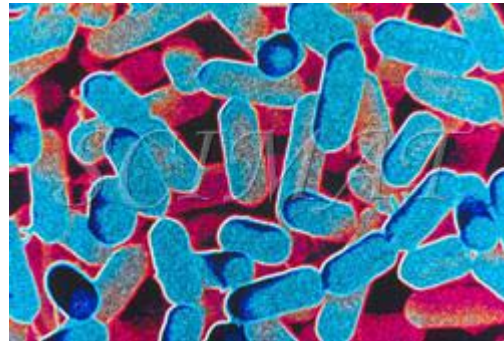
“Batch” means a group or set of identifiable products obtained from a given process under *practically* identical circumstances and produced in a given place within one defined production period

i.e. samples of the same product can be composited across different lots, as currently

Food Safety Criteria

- *Listeria monocytogenes*
- Salmonella

Listeria monocytogenes



Listeria monocytogenes

- **Applicability:**
 - 'Products placed on the market during their shelf-life', or
 - 'Before the food has left the immediate control of the FBO who has produced it' (and throughout the shelf life)
- **Sample number:**
 - n=10 (infants, particular medical uses)
 - n=5 (other foods)
- **Specified methods:**
 - Detection: EN/ISO 11290-1
 - Enumeration: EN/ISO 11290-2
 - or alternative validated using ISO 16140
- **RTE foods only**

RTE Food - Which *Lm* Criterion?

Is product RTE?

→ NO →

No specific *Lm* criterion applies

↓ YES

Is product intended for infants or for 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

Are sci/modelling, historic/etc data available to show that product won't support *Lm* growth within shelf life?

→ YES →

Limit of 100 cfu/g applies

↓ NO

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

→ YES →

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

↓ NO

Shelf life is appropriate

*default is 100/g in RTE food

Ready to Eat Food = ?

Defined in the Regulation 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





UK Chilled Prepared Food Ranges

- Dressed salads
- Leafy salads
- Prepared vegetables
- Prepared fruit
- Stir fry kits
- Sandwiches and wraps
- Sandwich fillings
- Quiche/flans
- Pizza
- Recipe dishes/kits
- Meal accompaniments
- Sushi
- Filled fresh pasta
- Soups (some RTE)
- Sauces
- Desserts

Items in green = ready to eat

Lm Zero Tolerance for RTE foods?

- NOT the intent of the EU Regulation
 - aim is to apply HACCP + appropriate shelf lives
- Has no demonstrable impact on public health protection:
 - EFSA Opinion
 - CODEX draft Lm micro criteria
 - EC SCVM scientific Opinion
 - WHO Lm Risk Assessment
 - FAO/WHO Expert Consultation - Micro Hazards in Foods:

the vast majority of cases of listeriosis is associated with the consumption of foods that do not meet current standards used for Lm, whether that standard is zero or 100/g

By eliminating higher dose levels ($>10^{3.5}$) the number of predicted cases would be reduced by >99%

i.e. HACCP/control is key to assuring safety

However

- Zero tolerance (in 25g) applies in the EU Reg
 - to RTE food able to support the growth of *Lm*
 - to those foods before they have left the immediate control of the initial FBO (and throughout shelf life)

IF

- the manufacturer is NOT able to demonstrate that growth will not exceed 100cfu/g throughout the shelf life

How does a manufacturer demonstrate this?

Don't panic

RTE foods: *Lm* growth v. shelf life

Remember:

Shelf life (challenge) testing NOT a legal requirement

The Regulation is intended to be zero cost where HACCP applied

From the EC micro criteria Strategy:

'...there is no need to conduct durability studies for all production lines of RTE foods, as in many cases the proper shelf-life of the product can be determined without expensive durability studies.... for RTE products promoting the growth of *Listeria* and having a shelf-life <5 days there is no need to carry out durability studies."

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.
- Setting appropriate shelf life is part of HACCP and required by law
- UK chilled prepared foods' shelf life is very short, by design

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
- **Disadvantages of 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

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

Historical Data

- Best indication of an organism's behaviour in a foodstuff in reality
- When present, *Lm* is from the environment, e.g.
 - in a factory 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 and at the end of shelf life can be used to assess growth potential
- Manufacturers should have a database for *Lm* consisting of appropriate samples taken at the beginning (DOP) and end of life (EOL) for each RTE product

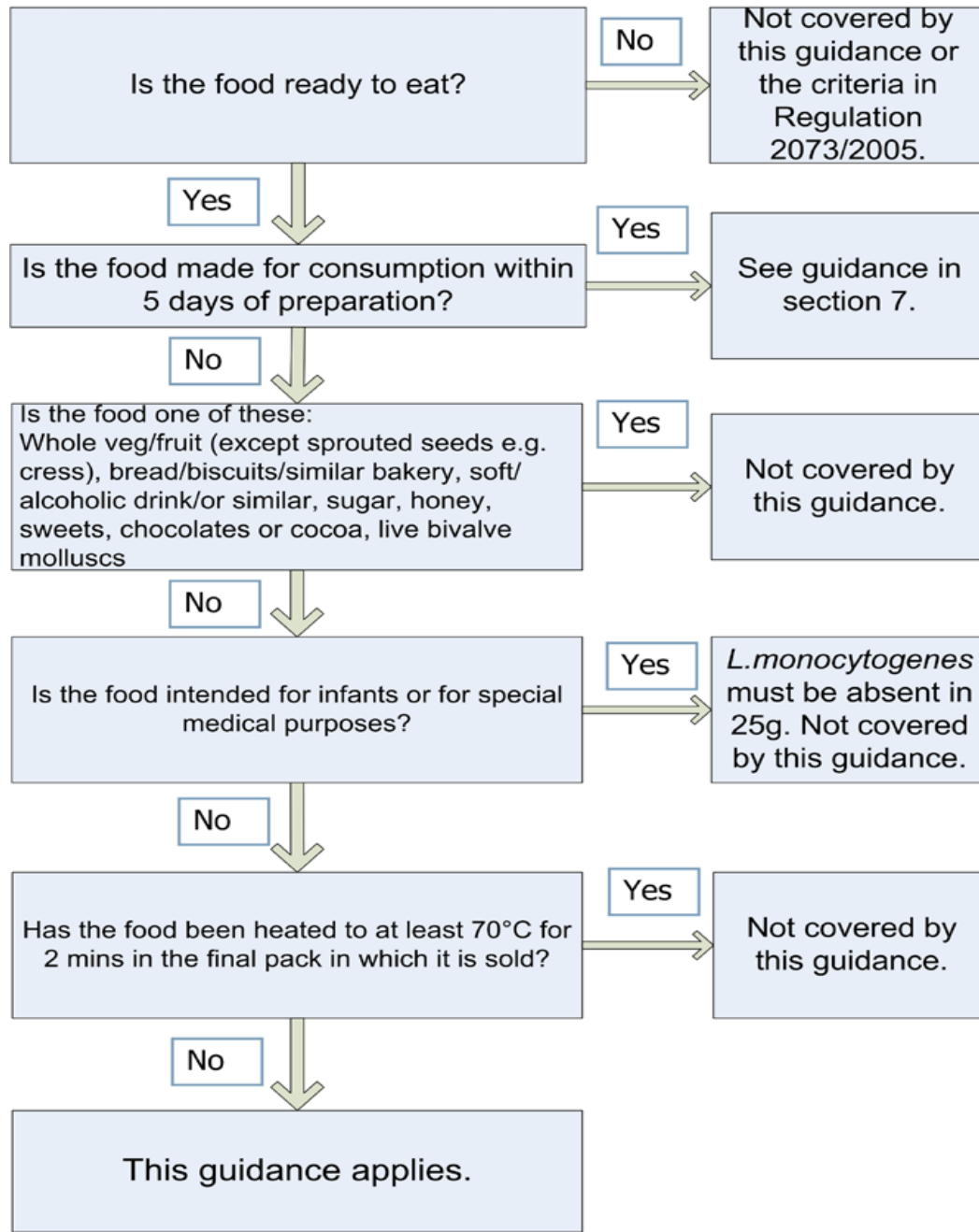
Durability Studies

- 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:
 - 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

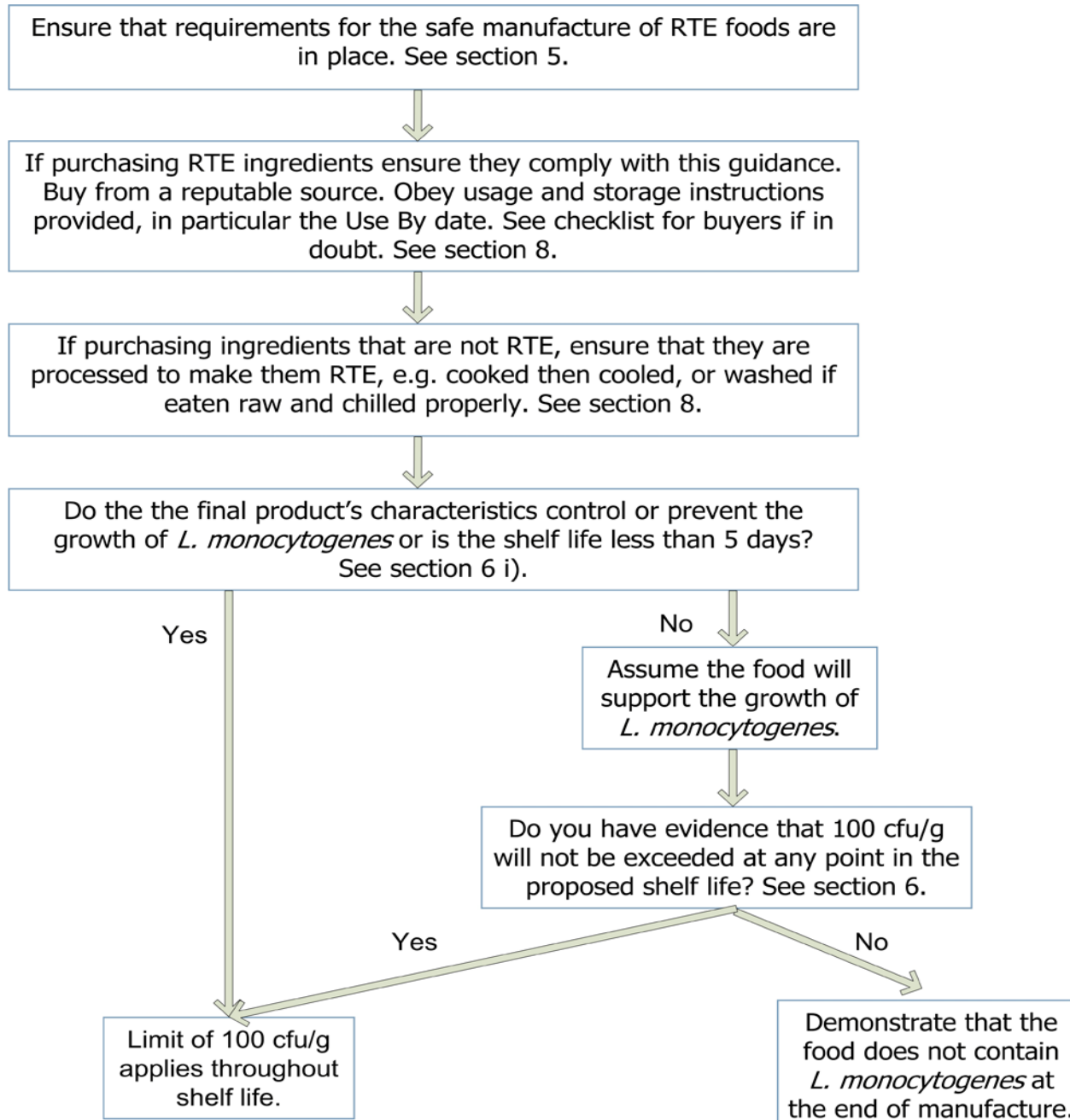
CFA/BRC Shelf Life Guidance

- Consortium of organisations inc FSA, CIEH, LACORS
- 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 Shelf Life Guidance – Does it Apply to the FBO?



CFA/BRC Shelf Life Guidance – Key Guidance Points



Example Use of *Lm* Historical Data

If *Lm* detected in a RTE product:

- at the beginning of shelf life at a level of <10 cfu/g, and
- data on a representative sample from the same batch at end of life showed levels remained 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 (<10 cfu/g) detection during shelf life should not need to be withdrawn

CFA/BRC Shelf Life Guidance – Worked Examples

- The data required to support the shelf life must be documented, but it is not a requirement for it to be held in the detailed format as set out in the worked examples:
 - New Product
 - Cold Smoked Salmon and Fresh Watercress Sandwich – Technical
 - 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
 - Brie with Garlic and Herbs – Technical

Salmonella



Salmonella

- 'Products placed on the market' and 'during their shelf-life'
- Zero tolerance – with exceptions
- Sample number varies: e.g. n=5 or 30
- EN/ISO 6579 specified

Salmonella - Food Safety Criteria

- Apply to protein, dairy, prepared produce, infant/follow-on formulae
 - Minced meat/preparations intended to be eaten raw
 - Minced meat/preparations (non-poultry) intended to be eaten cooked
 - NOTE: derogation to 31/12/09 for 1/5 positive, thereafter zero tolerance
 - Meat products intended to be eaten raw (except where risk eliminated)
 - Milk and dairy products
 - Dried infant formulae
 - RTE foods which include raw egg
 - Cooked crustaceans and molluscs
 - Live bivalves, echinoderms, tunicates and gastropods
 - RTE produce
 - sprouted seeds
 - pre-cut fruit and vegetables
 - unpasteurised fruit and vegetable juices

Confirm before notifying!

Presumptives/unconfirmed findings
are NOT required to be notified
to the Competent Authority

- Action should only be taken on confirmed results unless there is written agreement to the contrary with the customer
- If an external laboratory is used, a written agreement must be in place covering communication of findings to the manufacturer and to any agreed third party

Summary - What FBOs have to do

- Implement GMP and HACCP
- Sample for HACCP verification & monitoring purposes
- Carry out environmental swabbing
- Test 5 samples of 1 minced meat/meat preparation a week per producer
- Quantify L_m for relevant RTE products
- Limit shelf life of relevant RTE products so $L_m \leq 100/g$
- Report confirmed safety criteria exceedances to Competent Authorities (via brand owner if own label)
- Internal corrective action on exceedance of process hygiene criteria

Don't panic

CFA Guidance Online

- Free downloads from www.chilledfood.org:
 - CFA/BRC shelf life guidance + worked examples
<http://preview.tinyurl.com/ycyyydu>
 - CFA/BRC guidance on the MCR v 1.2
<http://preview.tinyurl.com/yaxr9ss>
 - CFA Micro Testing & Interpretation Guidance v2
<http://preview.tinyurl.com/ybo2p35>
- CFA Best Practice Production Guidelines
 - www.tsoshop.co.uk/chilledfoods



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