Microbiological criteria and shelf-life

Current legal situation

Dr. Mary Friel
Technical Executive, FSAI

- Entered into force in the EU on 1st January 2006 (amended 5th December 2007 & 28th April 2010)

- Applies to all food business operators involved in the production, processing and distribution of food

- Competent authorities must verify that food businesses are in compliance
1. Microbiological Criteria
Microbiological Criteria

Define the acceptability of....

• A foodstuff or
• A process

Based on....

• The absence, presence or the number of microorganisms or
• The quantity of their toxins/metabolites
# Type of microbiological criteria

<table>
<thead>
<tr>
<th>Type of criterion</th>
<th>1. Process hygiene</th>
<th>2. Food safety</th>
</tr>
</thead>
<tbody>
<tr>
<td>Defines</td>
<td>The acceptable functioning of the production process</td>
<td>Acceptability of a product or a batch of foodstuff</td>
</tr>
<tr>
<td>Stage when the criterion applies</td>
<td>Either during or at the end of manufacturing</td>
<td>Products placed on the market and during their shelf life</td>
</tr>
<tr>
<td>Action in case of unsatisfactory results</td>
<td>e.g. improvements in production hygiene</td>
<td>Product withdrawal or recall</td>
</tr>
</tbody>
</table>
Detail provided in a microbiological criterion

- Food concerned
- Microorganism or microbial toxin of concern
- A sampling plan (n and c)
- A microbiological limit (m and M)
- An analytical reference method

<table>
<thead>
<tr>
<th>Food</th>
<th>Microorganism</th>
<th>Sampling plan</th>
<th>Limits</th>
<th>Analytical reference method</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pre-cut fruit &amp; vegetables (RTE)</td>
<td>E. coli</td>
<td>5</td>
<td>2</td>
<td>100 cfu/g</td>
</tr>
<tr>
<td></td>
<td></td>
<td>1000 cfu/g</td>
<td></td>
<td>ISO16649-1 or 2</td>
</tr>
</tbody>
</table>
### Interpretation of results

#### 1 Limit (m=\( M \))

<table>
<thead>
<tr>
<th>Satisfactory</th>
<th>Unsatisfactory</th>
<th>2-Class plan</th>
<th>Usually used for food safety criteria</th>
</tr>
</thead>
</table>

#### 2 Limits (m & \( M \))

<table>
<thead>
<tr>
<th>Satisfactory</th>
<th>Acceptable</th>
<th>Unsatisfactory</th>
<th>3-Class plan</th>
<th>Usually used for process hygiene criteria</th>
</tr>
</thead>
</table>
1 limit ($m=M$): Two class plan

<table>
<thead>
<tr>
<th>Food</th>
<th>Micro-organism</th>
<th>Sampling plan</th>
<th>Limits (cfu/g)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sprouted seeds</td>
<td>Salmonella</td>
<td>5 0</td>
<td>Absence in 25g</td>
</tr>
</tbody>
</table>

**Satisfactory**
Salmonella is absent in 25g of all 5 samples ($n=5$)

**Unsatisfactory**
Salmonella is detected in 25g in any of the 5 samples
### 2 limits (m & M): Three class plan

<table>
<thead>
<tr>
<th>Food</th>
<th>Microorganism</th>
<th>Sampling plan</th>
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<th>Analytical Reference method</th>
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<tbody>
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<td>Pre-cut fruit &amp; vegetables (RTE)</td>
<td><em>E. coli</em></td>
<td>5</td>
<td>100 cfu/g</td>
<td>1000 cfu/g</td>
</tr>
<tr>
<td></td>
<td></td>
<td>2</td>
<td></td>
<td>ISO16649-1 or 2</td>
</tr>
</tbody>
</table>

**Satisfactory**

*E. coli* count of all 5 samples (n=5) is ≤ 100 cfu/g (m)

**Acceptable**

*E. coli* count of no more than 2 samples (c=2) are between 100 (m) and 1000 cfu/g (M) AND
*E. coli* count of the remaining samples are ≤ 100 cfu/g (m)

**Unsatisfactory**

*E. coli* count of more than 2 samples (c=2) are between 100 (m) and 1000 cfu/g (M) OR
*E. coli* count of any sample is > 1000 cfu/g (M)
Process hygiene & food safety criteria are laid down in Annex 1 of Regulation 2073/2005 for the following food categories:

1. Meat & meat products
2. Milk & dairy products
3. Fish & fishery products
4. Egg products
5. Vegetables, fruits & associated products
6. Ready-To-Eat (RTE) Foods
<table>
<thead>
<tr>
<th>Food category</th>
<th>Food description</th>
<th>Process hygiene criteria</th>
<th>Food safety criteria</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Meat</strong></td>
<td>Minced meat</td>
<td>▪ ACC</td>
<td><em>Salmonella spp.</em></td>
</tr>
<tr>
<td></td>
<td></td>
<td>▪ <em>E. coli</em></td>
<td></td>
</tr>
<tr>
<td><strong>Dairy</strong></td>
<td>Milk powder &amp; whey powder</td>
<td>▪ Enterobacteriaceae ▪ Coagulase positive staphylococci</td>
<td><em>Salmonella spp.</em></td>
</tr>
<tr>
<td><strong>Egg</strong></td>
<td>Egg products</td>
<td>Enterobacteriaceae</td>
<td><em>Salmonella spp.</em></td>
</tr>
<tr>
<td><strong>Fish</strong></td>
<td>Cooked crustaceans &amp; molluscan shellfish</td>
<td>▪ <em>E. coli</em> ▪ Coagulase positive staphylococci</td>
<td><em>Salmonella spp.</em></td>
</tr>
<tr>
<td><strong>Vegetables and fruit</strong></td>
<td>Unpasteurised fruit and vegetable juices (RTE)</td>
<td><em>E. coli</em></td>
<td><em>Salmonella spp.</em></td>
</tr>
<tr>
<td><strong>RTE foods</strong></td>
<td></td>
<td></td>
<td><em>L. monocytogenes</em></td>
</tr>
</tbody>
</table>

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<table>
<thead>
<tr>
<th>Food category</th>
<th>Sampling plan</th>
<th>Limit</th>
<th>Stage where the criterion applies</th>
</tr>
</thead>
<tbody>
<tr>
<td>RTE foods for infants &amp; for special medical purposes</td>
<td>10 0</td>
<td>Absence in 25g</td>
<td>Products placed on the market during their shelf life</td>
</tr>
<tr>
<td>RTE foods able to support the growth of <em>L. monocytogenes</em></td>
<td>5 0</td>
<td>100 cfu/g</td>
<td>Products placed on the market during their shelf life</td>
</tr>
<tr>
<td></td>
<td>5 0</td>
<td>Absence in 25g*</td>
<td>Before the food has left the immediate control of the FBO who has produced it</td>
</tr>
<tr>
<td>RTE foods unable to support the growth of <em>L. monocytogenes</em></td>
<td>5 0</td>
<td>100 cfu/g</td>
<td>Products placed on the market during their shelf life</td>
</tr>
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</table>
2. Compliance with Commission Regulation (EC) No 2073/2005 by food businesses?
Obligation on food business operators

Ensure foodstuffs comply with the relevant process hygiene and food safety criteria *

How?

Take measures as part of procedures based on GHP and HACCP principles

* foodstuffs must comply with the food safety criteria throughout their shelf life
Testing against the criteria

....when validating and verifying the correct functioning of procedures based on GHP & HACCP principles
3 Important Points

1. • Food safety is neither guaranteed nor controlled by microbiological testing alone

2. • Food safety is ensured through the implementation of a food safety management system (i.e. procedures based on GHP and HACCP)

3. • Testing against the microbiological criteria is a means of validating and verifying these procedures.
Frequency of testing

- Frequencies specified in Annex 1 of the Regulation

Carcasses, Minced meat, Meat preparations and Mechanically separated meat

- Testing to be carried out as appropriate when validating & verifying

All Other food commodities
As appropriate?
Things to consider.................

1. • Validation and verification procedures currently in place

2. • Instructions for use

3. • Nature and size of the business
When testing of **foodstuffs** is undertaken, the following should be considered........

1. Number of samples
2. Laboratory method
3. Analyses of trends
4. Action to be taken in the case of unsatisfactory results
## 1. Number of samples

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<td>5, 2</td>
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**Flexibility:** During routine sampling the number of sample units can be reduced if the FBO has effective HACCP based procedures in place.
## 2. Laboratory method

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</tr>
</thead>
<tbody>
<tr>
<td>Pre-cut fruit &amp; vegetables (RTE)</td>
<td><em>E. coli</em></td>
<td>n = 5, c = 2</td>
<td>m = 100 cfu/g, M = 1000 cfu/g</td>
<td>ISO 16649-1 or 2</td>
</tr>
</tbody>
</table>

**Flexibility:**  
* Alternative methods,  
* Proprietary methods &  
* Other methods
3. Analyses of trends

FBOs shall analyse the trends in the test results

Trend approaching unsatisfactory

Take appropriate action to rectify the situation and prevent the occurrence of microbiological risk
4. Action to be taken in the case of unsatisfactory results

**Process hygiene criterion**
- Improvements in production hygiene
- Review of process control
- Improvements in selection/origin of raw materials etc.

**Food safety criterion**
- Foodstuff must be withdrawn or recalled from the market in accordance with Article 19 of 178/2002
## Withdraw or Recall?

<table>
<thead>
<tr>
<th>Withdraw or recall?</th>
<th>When?</th>
<th>Who should be notified?</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Withdraw</strong></td>
<td>Food has left the immediate control of the initial food business operator</td>
<td><strong>Competent Authority</strong></td>
</tr>
<tr>
<td><strong>Recall</strong></td>
<td>Food may have reached the consumer</td>
<td>• Competent Authority • Consumers</td>
</tr>
</tbody>
</table>
How much product should be withdrawn or recalled?

- Assume that all foodstuffs in the batch are unsafe (Article 14.6 of Regulation 178/2002)

- ‘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 (Article 2(e) of Regulation 2073/2005)

- Traceability system
Traceability system

- Detailed (i.e. narrow definition of a batch)
  - Small product withdrawal/recall

- Less detailed (i.e. broader definition of a batch)
  - Larger product withdrawal/recall
Traceability can mean the difference between....
FSAI Guidance Note No. 10

Product Recall and Traceability (Revision 1)
## Environmental sampling

<table>
<thead>
<tr>
<th>Category</th>
<th>Requirements</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Mandatory</strong></td>
<td>• Premises manufacturing RTE food which may pose a risk of <em>L. monocytogenes</em></td>
</tr>
<tr>
<td></td>
<td>• Premises manufacturing dried infant formulae or dried foods for special medical purposes intended for infants below 6 months, which pose a risk of <em>E. sakazakii</em></td>
</tr>
<tr>
<td><strong>As required</strong></td>
<td>• Other premises</td>
</tr>
</tbody>
</table>

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3. Shelf Life
Why Label Foods with an Accurately Determined Shelf-Life?

All fresh last month honest!

For your customers safety and your businesses continuing prosperity!
Requirements under Commission Regulation (EC) No. 2073/2005

- The FBO responsible for the manufacture of the product shall conduct studies in order to investigate compliance with the food safety criteria throughout the shelf-life.

- In particular, this applies to ready-to-eat foods that are able to support the growth of *L. monocytogenes* and that may pose a *L. monocytogenes* risk for public health.
Basic requirements specified in Article 3.2 and Annex II of Regulation 2073/2005

More detail provided in EC Guidance documents:
1. EC Guidance document for food business operators (FBO)
2. Guidance document for laboratories conducting shelf-life studies
1) EC Guidance document for food business operators (FBO):

To assist FBO producing RTE foods:

- classify their products into RTE foods which are either able or unable to support the growth of *L. monocytogenes*

- understand the approaches available for shelf-life determination and to decide the appropriate approach for their products

- demonstrate to the satisfaction of the competent authority that the products will comply with the criteria until the end of the shelf-life
Approaches available for shelf life determination

Product characteristics and scientific literature

Historical data

Predictive microbiology

Specific laboratory studies

Durability studies

Challenge tests
2. Guidance document for laboratories conducting shelf-life studies:

- Prepared by CRL & 9 NRLs
- Technical guidance document

- The microbiological procedures described are:
  1) challenge tests
     - assessing a growth potential
     - assessing the maximum growth rate
  2) durability studies

Both guidance documents available at:
http://www.fsai.ie/legislation/food_legislation/hygiene_of_foodstuffs/microbiological_criteria.html#GN_Shelf-life
Determination of Product Shelf-Life

http://www.fsa.ie/resources_and_publications/guidance_notes.html#Directory1
THANK YOU