Regulation (EC) No 2073/2005 on Microbiological criteria for foodstuffs

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Microbiological criteria

Main objectives

• To **ensure** a high level of human health protection
  ➞ Reduction of human cases of foodborne diseases

• To **verify** the HACCP measures

• To **harmonise** microbiological criteria in the EU
  ➞ Uniform rules within the EU and for the import
A microbiological criterion for food

defines the acceptability of a product or a food lot, based on the absence or presence, or number of microorganisms including parasites, and/or quantity of their toxins/metabolites, per unit(s) of mass, volume area or lot.
Establishment of Community criteria

Criteria should
- enhance food safety
- be feasible in practice
- Be based on the scientific risk assessment
Scientific opinions, e.g.

- **SCVPH opinions**
  (http://ec.europa.eu/food/fs/sc/oldcomm4/previous_en.html)
  - *Listeria monocytogenes* 1999 (+SCF 2000)
  - *Vibrio vulnificus* and *V. parahaemolyticus* 2001
  - Norwalk-like viruses 2002
  - Gelatine 2002
  - Verotoxigenic *E. coli* 2003
  - *Salmonella* 2003
  - Staphylococcal enterotoxins in milk products 2003

- **EFSA opinion** (www.efsa.europa.eu)
  - Microbiological risks in baby formulae and follow-on formulae 2004
Components of a microbiological criterion

- Micro-organism of concern
- Analytical method
- Sampling plan
  - Number of sample units
  - Size of the analytical unit
- Microbiological limits
- The foodstuff
- The point of the food chain where the limit applies
- Actions to be taken when unsatisfactory results
Responsibility of FBOs

• To demonstrate the compliance with MC
  - Food safety criteria throughout the shelf-life
  - Durability, challenge studies (Annex II)
• To establish a sampling and testing scheme based on risk (HACCP)
• To respond in case of non-compliance
• To follow and assess trends
Process hygiene criteria

- Indicate the acceptable functioning of production process
- Stage: during the process, not when placed on the market
- Actions when unsatisfactory results
  = Corrective actions defined in HACCP programme
    - Improvement of production hygiene
    - Selection of raw materials
Commission Regulation (EC) No 2073/2005

microbiological criteria

- Operator can choose frequency and method
  - based on risk
  - in the context of HACCP
- Fixed frequency of sampling
- Once weekly                 forthnightly sampling
- Reduced frequency for small establishments
Process hygiene criteria

Examples:

- **Salmonella**
  - Carcases

- **Aerobic colony count and Enterobacteriaceae**
  - Carcases

- **E. coli**
  - Minced meat, meat preparations, butter and cream made from raw milk, precut fruit and vegetables

- **Coagulase positive staphylococci**
  - Certain dairy products

- **Enterobacteriaceae**
  - Dried infant formulae
<table>
<thead>
<tr>
<th>Food category</th>
<th>Micro-organisms</th>
<th>Sampling plan(^1)</th>
<th>Limits(^2)</th>
<th>Analytical reference method(^3)</th>
<th>Stage where the criterion applies</th>
<th>Action in case of unsatisfactory results</th>
</tr>
</thead>
<tbody>
<tr>
<td>2.2.3 Cheeses made from raw milk</td>
<td>Coagulas e-positive staphylococci</td>
<td>5 2</td>
<td>10(^4) cfu/g</td>
<td>10(^5) cfu/g</td>
<td>EN/ISO 6888-2</td>
<td>Improvements in production hygiene and selection of raw materials. If values &gt;10(^5) cfu/g are detected, the cheese batch has to be tested for staphylococcal enterotoxins.</td>
</tr>
</tbody>
</table>
Commission Regulation (EC) No 2073/2005

microbiological criteria

Food safety criteria

• Defines the acceptability of the product/batch
• Stage: products placed on the market
• Actions when unsatisfactory results
  – Withdrawal or recall
  – Further processing (not yet at retail level)
  – Other corrective actions based on HACCP programme
Food safety criteria

- **Listeria monocytogenes**
  - All ready-to-eat foods

- **Salmonella**
  - Certain ready-to-eat foods
  - Minced meat, meat preparations, meat products

- **Staphylococcal enterotoxins**
  - Certain dairy products

- **E. sakazakii**
  - Dried infant formulae

- **E. coli**
  - Live bivalve molluscs

- **Histamine**
  - Fishery products from certain fish species
Target: Reduction of human listeriosis

- Although the disease is relatively rare, listeriosis is a significant public health concern.
  - Clinical severity and high mortality (20-30%)

- 1048 listeriosis cases reported in the EU and Norway
  (EU Zoonosis report 2003)
<table>
<thead>
<tr>
<th>Food category</th>
<th>Microorganisms / their toxins, metabolites</th>
<th>Sampling-plan</th>
<th>Limits</th>
<th>Analytical reference method</th>
<th>Stage where the criterion applies</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>n  c  m  M</td>
<td></td>
<td>EN/ISO 11290-1</td>
<td>Products placed on the market during their shelf-life</td>
</tr>
<tr>
<td>1.1 Ready-to-eat foods intended for infants and ready-to-eat foods for special medical purposes</td>
<td><em>Listeria monocytogenes</em></td>
<td>10  0</td>
<td>Absence in 25 g</td>
<td></td>
<td></td>
</tr>
<tr>
<td>1.2 Ready-to-eat foods able to support the growth of <em>L. monocytogenes</em>, other than those intended for infants and for special medical purposes</td>
<td><em>Listeria monocytogenes</em></td>
<td>5  0</td>
<td>100 cfu/g</td>
<td>EN/ISO 11290-26</td>
<td>Products placed on the market during their shelf-life</td>
</tr>
<tr>
<td></td>
<td></td>
<td>5  0</td>
<td>Absence in 25 g</td>
<td>EN/ISO 11290-1</td>
<td>Before the food has left the immediate control of the food business operator, who has produced it</td>
</tr>
</tbody>
</table>
Salmonella
Food safety criteria

- **Strict criteria**
  - minced meat, meat preparations and meat products intended to be eaten raw and cooked

- **Raw**
  - Absence in 25 g
    - n=5, c=0

- **Cooked**
  - Absence in 10 g
    - n=5, c=0
Target: Reduction of human salmonellosis

- Approximately 150,000 salmonellosis cases notified annually in EU and Norway (EU Zoonosis report 2003)

- The estimated annual cost of foodborne salmonellosis 560-2840 MEUR in the EU

- An expectation would be a decrease in salmonellosis cases by 50%
  - Implementation of the new food hygiene and zoonosis legislation and microbiological criteria.
Trend in human salmonellosis

![Graph showing the trend in human salmonellosis from 1995 to 2003. The y-axis represents the number of reported cases in the EU and the x-axis represents the years from 1995 to 2003. The graph includes data for both the EU as a whole and Germany. There is a downward trend in reported cases over the years.]
## Food Safety Criteria for fish products

<table>
<thead>
<tr>
<th>1.16</th>
<th>Cooked crustaceans and molluscan shellfish</th>
<th><em>Salmonella</em></th>
<th>5</th>
<th>0</th>
<th>Absence in 25 g</th>
<th>EN/ISO 6579</th>
<th>Products placed on the market during their shelf-life</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.17</td>
<td>Live bivalve molluscs and live echinoderms, tunicates and gastropods</td>
<td><em>Salmonella</em></td>
<td>5</td>
<td>0</td>
<td>Absence in 25g</td>
<td>EN/ISO 6579</td>
<td>Products placed on the market during their shelf-life</td>
</tr>
<tr>
<td>1.25</td>
<td>Live bivalve molluscs and live echinoderms, tunicates and gastropods</td>
<td><em>E. coli</em>&lt;sup&gt;15&lt;/sup&gt;</td>
<td>1&lt;sup&gt;(16)&lt;/sup&gt;</td>
<td>0</td>
<td>230 MPN / 100g of flesh and intra-valvular liquid</td>
<td>ISO TS 16649-3</td>
<td>Products placed on the market during their shelf-life</td>
</tr>
<tr>
<td>1.26</td>
<td>Fishery products from fish species associated with a high amount of histidine&lt;sup&gt;17&lt;/sup&gt;</td>
<td>Histamine</td>
<td>9&lt;sup&gt;(18)&lt;/sup&gt;</td>
<td>2</td>
<td>100 mg/kg</td>
<td>200 mg/kg</td>
<td>HPLC&lt;sup&gt;19&lt;/sup&gt;</td>
</tr>
<tr>
<td>1.27</td>
<td>Fishery products which have undergone enzyme maturation treatment in brine, manufactured from fish species associated with a high amount of histidine&lt;sup&gt;17&lt;/sup&gt;</td>
<td>Histamine</td>
<td>9</td>
<td>2</td>
<td>200 mg/kg</td>
<td>400 mg/kg</td>
<td>HPLC&lt;sup&gt;19&lt;/sup&gt;</td>
</tr>
</tbody>
</table>
### Food Safety Criteria for Vegetables and Fruits

<table>
<thead>
<tr>
<th>1.18</th>
<th>Sprouted seeds (ready-to-eat)¹²</th>
<th>Salmonella</th>
<th>5</th>
<th>0</th>
<th>Absence in 25 g</th>
<th>EN/ISO 6579</th>
<th>Products placed on the market during their shelf-life</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.19</td>
<td>Precut fruit and vegetables (ready-to-eat)</td>
<td>Salmonella</td>
<td>5</td>
<td>0</td>
<td>Absence in 25 g</td>
<td>EN/ISO 6579</td>
<td>Products placed on the market during their shelf-life</td>
</tr>
<tr>
<td>1.20</td>
<td>Unpasteurised fruit and vegetable juices (ready-to-eat)</td>
<td>Salmonella</td>
<td>5</td>
<td>0</td>
<td>Absence in 25 g</td>
<td>EN/ISO 6579</td>
<td>Products placed on the market during their shelf-life</td>
</tr>
</tbody>
</table>
National criteria

- Regulation (EC) No 2073/2005 harmonised the microbiological food safety and process hygiene criteria for foodstuffs in EU. From practical point of view this Regulation means that:
  - MSs cannot have other (national) microbiological food safety criteria.
  - However, Member States may have other or stricter national microbiological process hygiene criteria. These process hygiene criteria are applicable, by the definition, only during processing of the food in the particular Member State. These process hygiene criteria may not be used when product is on the market neither may they have impact on the import or intra-community trade.
Last amendments on Microcriteria


- Criteria on Enterobacteriaceae and *Salmonella* in dried follow-on formulae and *Bacillus cereus* in dried infant formulae
- The reference method for the staphylococcal enterotoxin detection
- Specifies the *Salmonella* sampling rules for carcasses of cattle, pig, sheep, goats and horses.


GUIDANCE DOCUMENT on official controls, under Regulation (EC) No 882/2004, concerning microbiological sampling and testing of foodstuffs (http://ec.europa.eu/food/food/controls/foodfeed/sampling_testing.pdf)

Thank you