Official control of food safety, European Union reference laboratories (EURL) to national reference laboratories (NRL)

Implementation for Milk and Milk products

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Main topics of the conference

- Quick reminder of European regulations
- EURL Organisation for official control
- European to National organisation for control of milk and milk products
In the aftermath of the BSE crisis and several other food scandals, the EU decided to have an action plan for a pro-active new food policy. It has developed a “Farm to Fork” approach covering all sectors of the food and feed chain.
Key elements in the new approach:
- the establishment of a framework regulation,
- the creation of a framework for harmonized food controls,
- the development of specific food and feed safety legislation including a major overhaul of the existing hygiene legislation,
- the establishment of an independent body providing scientific advice to the legislators.
In January 2002, the EU adopted the framework legislation in Regulation(EC) No.178/2002 laying down the general principles and requirements of EU food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety.
In April 2004, the EU adopted the three basic Acts forming the core of the so-called "Food Hygiene Package"

The „hygiene package“ is a body of EU law laying down hygiene rules for foodstuffs produced in the EU and non-EU countries exporting to the EU, and includes the following acts:
Regulation (EC) No. 852/2004 on the hygiene of foodstuffs

Regulation (EC) No. 853/2004 laying down specific hygiene rules for food of animal origin in order to guarantee a high level of food safety and public health

Regulation (EC) No. 854/2004 putting in place a Community framework of official controls on products of animal origin intended for human consumption

Regulation (EC) No. 882/2004 on official controls performed to ensure verification of compliance with feed and food law, animal health and animal welfare rules,

Regulation (EC) No. 183/2005 laying down requirements for feed hygiene
The „hygiene package“ is supplemented by other EU legislation on food hygiene

Regulation (EC) 2073/2005 on microbiological criteria for foodstuffs
Food Hygiene package principles

• Food safety ensured throughout the food chain, starting with primary production
• General implementation of procedures based on the HACCP principles and application of basic common hygiene requirements;
  • Primary responsibility of food business operators
  • Traceability at all stages of the production, processing and distribution
  • Food risk analysis, precautionary principle
• Member States shall ensure the implementation of the food law, and monitor and verify the compliance by food business operators of the legislation.
FOOD LAW EC Reg 178/2002

Feedstuffs
- EC Reg 183/2005

Foodstuffs
- EC Reg 852/2004
  - retailing included

Foods from animal origin
- EC Reg 853/2004

Operators

Competent Authorities
- EC Reg 882/2004
  - Official controls

EC Reg 854/2004

MICROBIOLOGICAL CRITERIA
EC Reg 2073/2005
EURL Organisation for official control
3 ways to harmonize official controls

2 - Criteria: Safety criteria, Process hygiene criteria

1 - Competent laboratories

3 - Analytical standards, reference methods
Regulation (EC) No. 882/2004 on official controls performed to ensure verification of compliance with feed and food law, animal health and animal welfare rules,

Article 12: official laboratories
Article 32 European Union Reference Laboratories (EU-RL)
Article 33: National Reference Laboratories (NRL)

Implementation of an official network of competent laboratories in various areas of expertise required by Food law
21 EU Reference Laboratories for food and feed

- Biological hazard
  - Salmonella, Listeria monocytogenes, Coagulase positive *Staphylococci*, including *Staphylococcus aureus*, Verotoxigenic E. coli (VTEC), *Campylobacter*, parasites, antimicrobial resistance, transmissible spongiform encephalopathies (TSEs)

- Chemical hazard
  - Marine biotoxins, residues of veterinary medicines and contaminants, material intended to come into contact with foodstuffs, residues of pesticides, heavy metals, mycotoxins, Polycyclic Aromatic Hydrocarbons (PAH), dioxins and PCBs

- Food sector
  - Milk and milk products, viral and bacteriological contamination of bivalve molluscs, animal proteins in feedingstuffs, additives for use in animal nutrition, genetically modified organisms (GMOs),
EURL for residues of pesticides
Food of animal origin and commodities with high fat content
Chemisches und Veterinäruntersuchungsamt (CVUA)
Freiburg Germany

EURL for Escherichia coli, including Verotoxigenic E. coli (VTEC)
Istituto Superiore di Sanità (ISS)
Roma Italy

EURL for milk and milk products
ANSES — Laboratoire de sécurité des aliments
Maisons-Alfort France

EURL for the monitoring of marine biotoxins
Agencia Española de Seguridad Alimentaria (AESA)
Vigo Spain
Role of RL

• Activities of a reference laboratory

1. Coordination of laboratory networks
   • Networks of
     – Of NRLs (as EURL)
     – Of national laboratories approved for official control (as NRL)
   a) Organisation of regular workshops
   b) Organisation of proficiency testing trials
   c) Organisation of theoretical/practical training sessions
   d) Scientific & technical assistance upon request

2. Analytical development
   • To develop/update/validate reference methods for official control

3. Scientific & technical advice
   • To the French Ministry of Food & Agriculture (as NRL)
   • To the DG Health & Consumers of European Commission (as EU-RL)
Regulation (EC) No. 853/2004 laying down specific hygiene rules for food of animal origin in order to guarantee a high level of food safety and public health

Establishment of requirements for hygiene production and criteria on different food productions

For example for raw milk, (Annex III/Section IX)

I. HEALTH REQUIREMENTS FOR RAW MILK PRODUCTION (From a herd free or officially free of brucellosis and tuberculosis)

II. HYGIENE ON MILK PRODUCTION HOLDINGS (Hygiene during milking, collection and transport)

III. CRITERIA FOR RAW MILK (Criteria on total flora (TF), somatic cells (SC) in raw milk, antibiotic residues (ABR))
Article 8 Raw milk and dairy products

Member States shall ensure that official controls with respect to raw milk and dairy products take place in accordance with Annex IV.

Chapter II

Competent authority shall supervise own checks undertaken to check compliance of raw milk to regulatory sanitary criteria (TF, SC, ABR)
According to Article 4 of Regulation (EC) No 852/2004, food business operators are to comply with microbiological criteria.

Regulation (EC) No 882/2004 requires official controls performed to ensure the verification of compliance with feed and food law, animal health and animal welfare rules.

Needs for microbiological criteria
Regulation (EC) 2073/2005 on microbiological criteria for foodstuffs

2 types of criteria

- ‘food safety criteria’ means a criteria defining the acceptability of a product or a batch of foodstuff applicable to products placed on the market
- ‘process hygiene criteria’ a criteria indicating the acceptable functioning of the production process. Such a criteria is not applicable to products placed on the market.
# Chapter 1. Food safety criteria

<table>
<thead>
<tr>
<th>Food category</th>
<th>Micro-organisms/their toxins, metabolites</th>
<th>Sampling plan (n)</th>
<th>Limits (m)</th>
<th>Analytical reference method (l)</th>
<th>Stage where the criterion applies</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.12. Milk powder and whey powder</td>
<td>Salmonella</td>
<td>5</td>
<td>0</td>
<td>Absence in 25 g</td>
<td>EN/ISO 6579</td>
</tr>
</tbody>
</table>

# Chapter 2. Process hygiene criteria

<table>
<thead>
<tr>
<th>Food category</th>
<th>Micro-organisms</th>
<th>Sampling plan (n)</th>
<th>Limits (m)</th>
<th>Analytical reference method (l)</th>
<th>Stage where the criterion applies</th>
<th>Action in case of unsatisfactory results</th>
</tr>
</thead>
<tbody>
<tr>
<td>2.2.1. Pasteurised milk and other pasteurised liquid dairy products</td>
<td>Enterobacteriaceae</td>
<td>5</td>
<td>2</td>
<td>&lt;1 cfu/ml</td>
<td>ISO 21528-1</td>
<td>End of the manufacturing process</td>
</tr>
<tr>
<td>2.2.2. Cheeses made from milk or whey that has undergone heat treatment</td>
<td>E. coli</td>
<td>5</td>
<td>2</td>
<td>100 cfu/g</td>
<td>ISO 16649-1 or 2</td>
<td>At the time during the manufacturing process when the E. coli count is expected to be highest</td>
</tr>
<tr>
<td>2.2.3. Cheeses made from raw milk</td>
<td>Coagulase-positive staphylococci</td>
<td>5</td>
<td>2</td>
<td>10⁶ cfu/g</td>
<td>EN/ISO 6888-2</td>
<td>At the time during the manufacturing process when the number of staphylococci is expected to be highest</td>
</tr>
<tr>
<td>2.2.4. Cheeses made from milk that has undergone a lower heat treatment than pasteurisation and ripened cheeses made from milk or whey that has undergone pasteurisation or a stronger heat treatment</td>
<td>Coagulase-positive staphylococci</td>
<td>5</td>
<td>2</td>
<td>100 cfu/g</td>
<td>EN/ISO 6888-1 or 2</td>
<td>At the time during the manufacturing process when the number of staphylococci is expected to be highest</td>
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To summarize EURL Milk & milk products

- To coordinate analytical implementation of
  - Criteria on total flora (TF), somatic cells (SC) in raw milk, at collection stage
  - Phosphatase activity of milk & MP as pasteurization tracer
- To coordinate the network of 36 National Reference Laboratories (NRLs) MMP
  - Training
  - PT trials
  - Workshop
- To deal with analytical aspects related to the corresponding legislation:
  - Reg. 853/2004
EURL Milk & milk products

– To conduct analytical development, to develop/to improve reference methods or methods used in routine
  • Hygiene of raw milk
  • Harmonization at European level of conversion equations
  • Criteria for the validation of instrumental methods for TF & SCC
  • Development of Certified Reference Materials for SCC in raw milk

– To provide scientific & technical support to EC/DG Health
  • Upon the needs
  • Confirmatory analyses
  • Development/implementation of European legislation
  • Participation to European/international technical meetings/activities
    – Bilateral US/EU negotiations on veterinary agreement
    – CEN/ISO/IDF standardization
And also for Milk and Milk products

For food safety criteria → EURL Lm
→ EURL Salmonella

For process hygiene criteria → EURL CPS
→ EURL E. Coli

For monitoring chemical residue → EURL Pesticides
→ EURL Heavy

metals
EURL → NRL
Control of dairy production from farm to fork
From European to National organisation

EURL Milk and Milk products
Anses, Food safety laboratory

NRL Milk and Milk products
Anses, Food safety laboratory

17 recognized laboratories for milk paiement
CNIEL network of laboratories
Recognized laboratories for milk payment according to its sanitary quality
• Guarantees of confidentiality, independence and impartiality;
• Accredited laboratories by COFRAC;
• Recognition of laboratories by the ministry for the analysis of Regulation n° 853/2004 criteria (plate count at 30°C, somatic cells and antibiotic residues);
• Supervision by national reference laboratories which are also under EU reference laboratory supervision.
Regulation (CE) n° 853/2004

Requirements for raw milk primary production:

- From animals in a good general state of health, no symptoms of infectious diseases
- No unauthorised substances or products
- From a herd free or officially free of brucellosis and tuberculosis

Requirements for premises and equipment:

- Hygiene during milking, collection and transport
- Staff hygiene
- Criteria for plate count, somatic cell count or antibiotic residues

Plate count at 30°C (per mL) ≤ 100 000
Somatic cell count (per mL) ≤ 400 000
Inspection of holdings by competent authorities

● « vétérinaire sanitaire » mandatory
● Officially free of TB and brucellosis
● Holding register mandatory (analysis, vet prescriptions, treatments, audit, etc.)
● Regular controls animal identification, animal welfare, milking practices
● Control plans
Payment of milk according to quality and safety

Bonuses / Malus system to promote the best quality milk

Mandatory criteria:
- Somatic cells
- Total germs
- Drug residues
- Proteins
- Fats
- Freezing point

Others possible criteria
Regular sampling of raw milk on farm

- Done by truck drivers
- Mandatory training
- Samples taken at each collect
- Random analysis of samples

Minimum frequency defined in the national legislation:

<table>
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<th>Parameter</th>
<th>Frequency</th>
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<tr>
<td>Fats</td>
<td>3 times/month</td>
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<td>Proteins</td>
<td>3 times/month</td>
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<tr>
<td>Freezing point</td>
<td>3 times/month</td>
</tr>
<tr>
<td>Germs</td>
<td>Twice/month</td>
</tr>
<tr>
<td>Somatic cells</td>
<td>Once/month</td>
</tr>
<tr>
<td>Antibiotic</td>
<td>3 times/month</td>
</tr>
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At milk processing establishments level

Regulation (CE) n° 853/2004

Requirement for dairy products

- Temperature
- Preparation of pasteurised milk and Ultra High Temperature (UHT) milk
- Wrapping and packaging to protect milk and/or milk products from harmful effects of external origin.
- Labelling must clearly show the characteristics of the product.
Official controls at milk processing

• During an inspection, vet services check that the FBO:
  – Has validated his risk analysis and control measures;
  – Apply correctly his « sanitary control plan »;
  – Verifies the efficiency of this plan;
  – Sampling and analysis are a part of this verification process, but not systematic;
• Analysis carried out by approved laboratories.
Regulation 2073/2005 on microbiological criteria for foodstuffs

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<td>acceptability of food, applicable throughout the shelf-life of the products</td>
<td>acceptability of the supply, handling and processing of raw materials and foodstuffs</td>
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Official Monitoring and control programs

• Control program $\rightarrow$ non-compliance or fraud.

**Targeted sampling**

• Monitoring program $\rightarrow$ estimation of the prevalence, evaluation of consumers exposure to a hazard.

**Random sampling**

• In case of a non-conform result:
  – Investigation, withdraw, recall of the production
  – Oriented control
  – Re-enforced control $\rightarrow$ consignment of the production
Control programs

- Analyses in approved laboratories
- On raw milk
- Chemical residues
  - prohibited substances (e.g. chloramphenicol)
  - Residues of Veterinary drugs (antibiotic, anti-inflammatory drugs)
  - Contaminants (pesticides, dioxin, polychlorinated biphenyls, heavy metals)
  - Mycotoxins (Aflatoxins M1)
Monitoring programs

Annual programmation, done by official services sampling and analysis

- 2012: *Listeria monocytogenes* and *E. coli* β-glucuronidase positive in cheese at production level
- 2014: STEC in cheese at production level
- 2015: pesticides in butter
Antibiotics and vet medecines monitoring

3 levels of control

- 1 = farm level, sampling in the tank at each delivery, analyses at least 3 times / month
  - 2 millions of analyses / year (cow)
- 2 = plant level, sampling in each truck, before unloading, systematic analyses
- 3 = national level, through control programs, sampling by official services and analyses in the NRL
  - More than 1000 analyses planned for 2015