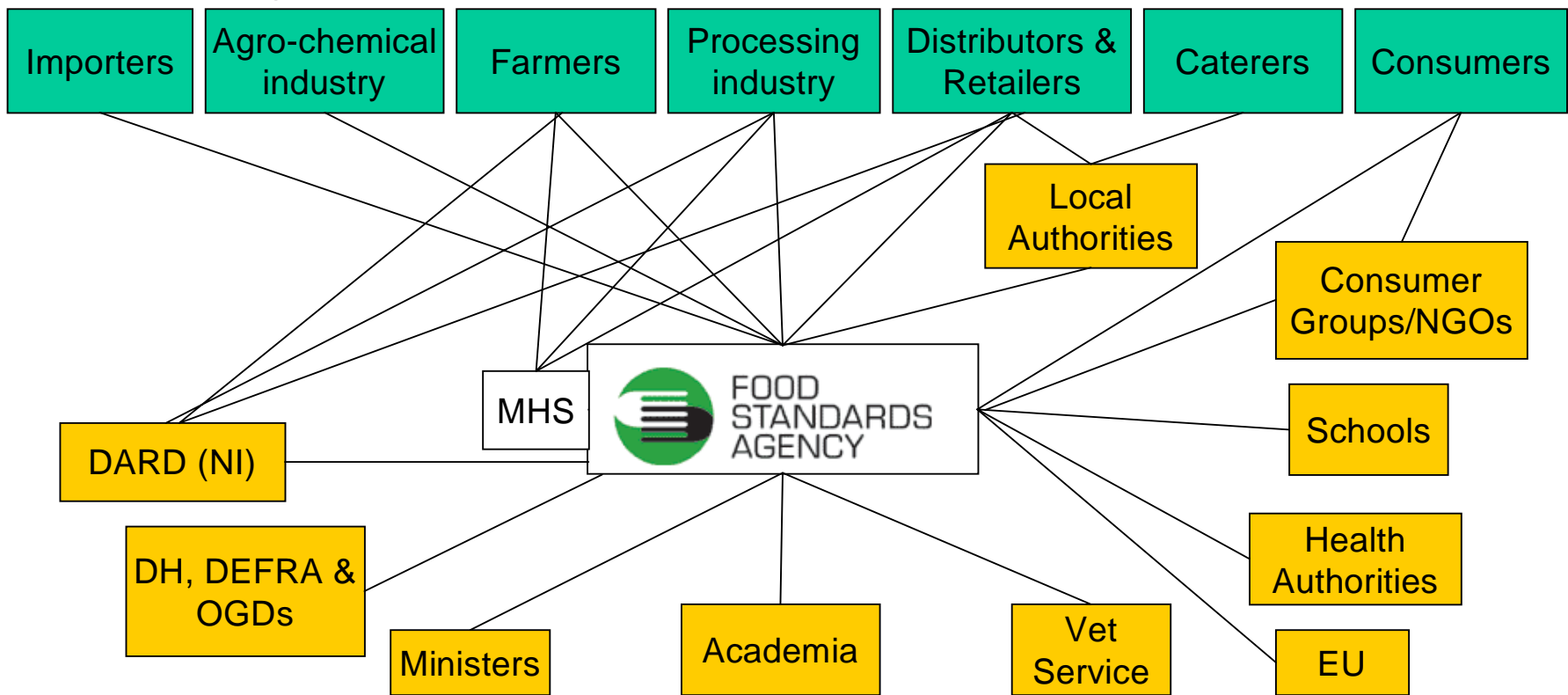
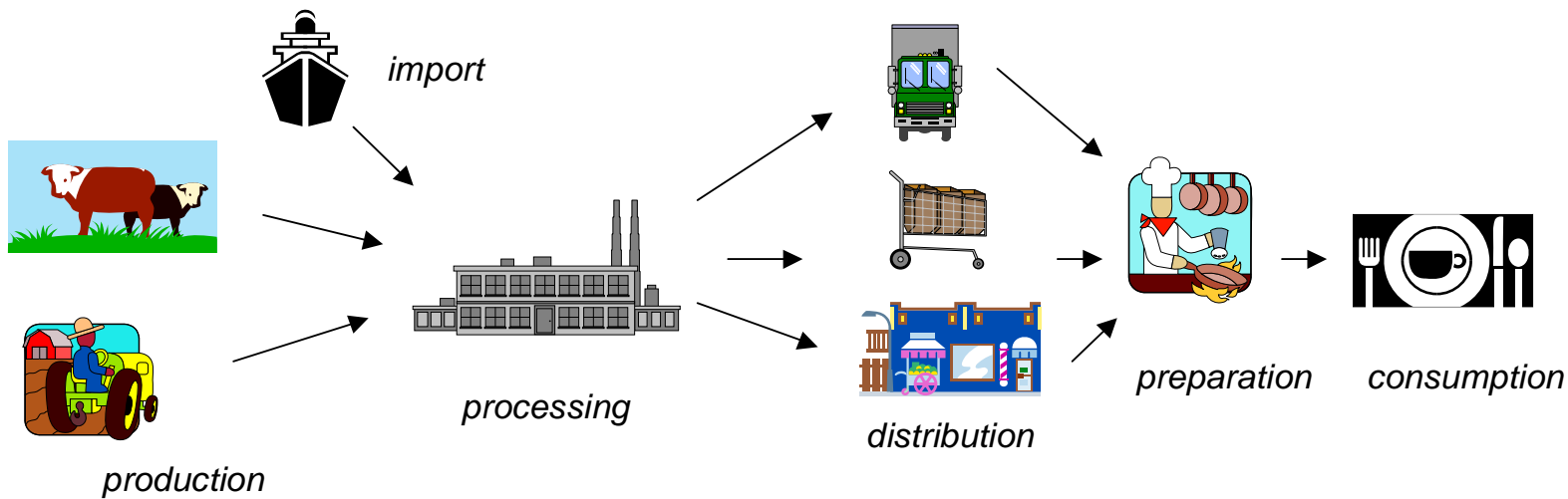


EU Regulation on Microbiological Criteria for Foodstuffs



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Microbiological Criteria

- Overview regulation development
- Explain food safety criteria
- Describe process criteria
- Discuss compliance
- Reference and Alternative test methods



The EU Regulation on Microbiological Criteria

Reg. (EC) No. 2073/2005 amended No. 1441/2007)



- **Supports the Food Hygiene Regulations**
- **Guidance on the acceptability of food and production process**
- **Reviews and consolidates previous criteria**
- **Open to review**

legal framework - 1

- ✓ Regulation (EC) No 178/2002 - General food law
- ✓ Regulation (EC) No 852/2004 - Hygiene of foodstuffs
- ✓ Regulation (EC) No 853/2004 - Hygiene rules for food of animal origin
- ✓ Regulation (EC) No 854/2004 - Official controls (meat inspection)
- ✓ Regulation (EC) No 882/2004 - Official Feed & Food Controls

legal framework - 2

- ✓ **Council Directive 2002/99/EC - Animal health**
- ✓ **Directive 2004/41/EC - repealing 17 Directives**
- ✓ **Implementing Regulations of the hygiene package**
- ✓ **Regulation (EC) No 1831/2003 - Hygiene of feedstuffs**



The EU Regulation on Microbiological Criteria

(Reg. (EC) No. 2073/2005 revised No. 1441/2007)

Supports the Food Hygiene Regulations

- **The use of microbiological criteria should form an integral part of the implementation of HACCP-based procedures and other hygiene control measures**
- **Preventative approach, risk based**
- **Article 4 Regulation (EC) No 852/2004**
- **MC can be used in validation and verification of HACCP procedures and GHP**



scientific opinions: **SCVPH 1999**

- ***old criteria***
 - not based on risk assessment or int. approved principles
 - cover a limited number of microbes for certain foodstuffs of animal origin
- ***proposal***
 - MC should be relevant and effective: human health protection
 - MC should be harmonised
 - consider existing problems of *Salmonella*, *Campylobacter*, VTEC, *Listeria*



EUROPEAN COMMISSION
HEALTH & CONSUMER PROTECTION DIRECTORATE-GENERAL
Directorate D - Food Safety: production and distribution chain
D2 - Biological risks

Brussels 8.3.2005
SANCO/ 1252/2001 Rev. 11

DISCUSSION PAPER

**On strategy for setting
microbiological criteria for foodstuffs
in Community legislation**

Bookmarks
Pages
Attachments
Comments

The Strategy for Setting Criteria

- Clear strategy for establishing the criteria
- All criteria must be
- relevant to protection of **public health**
- **Practical** to apply
- Based on **Risk Assessment** or internationally recognised principles
- **European Food Safety Authority** must be consulted before new criteria can be included.

scientific opinions

- ***Listeria monocytogenes* (1999, 2000)**
- ***Vibrio vulnificus* and *V.parahaemolyticus* (2001)**
- **Norwalk-like viruses (2002)**
- **gelatine (2002)**
- ***Clostridium botulinum* in honey (2002)**
- **verotoxigenic *E. coli* (2003)**
- ***Salmonella* in foodstuffs (2003)**

scientific opinions

EFSA

- **Microbiological risks in baby formulae and follow-on formulae (2004)**
- ***Bacillus* spp in foodstuffs (2005)**
- **Campylobacter in animals and foodstuffs (2005)**
 - setting criteria in poultry meat at retail not cost effective
- **Enterobacteriaceae as indicators of *Salmonella* and *E. sakazakii* (2007)**

Previous Microbiological Criteria

- **Contained in EU Vertical Directives**
- **Developed 5-10 years ago**
- **Contained many inconsistencies**
- **Few standard methods**
- **Didn't take account of prevalence**



For example:
**Previous microbiological standards for
minced meat and meat preparations**

- **Salmonella criteria**
 - absence in 1g to absence in 10g
- ***E.coli* and total plate count**
- **Few standard methods/sampling procedures**
- **No scientific assessment**
- **Not consistently applied**
- **BUT established**

components of a microbiological criterion (Codex)

- 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

Who are the criteria for?

- Food business operator - own checks
- Competent Authority – official controls

Responsibility of the food business operator:

- own checks integrated with HACCP
- **👉 demonstrate compliance with MC**
 - food safety criteria throughout the shelf-life
 - durability, challenge studies (Annex II)
- **👉 establish a sampling and testing scheme based on risk (HACCP and GHP)**
- **👉 respond in case of non-compliance (Actions in HACCP and GHP)**
- **👉 follow and assess trends (HACCP)**

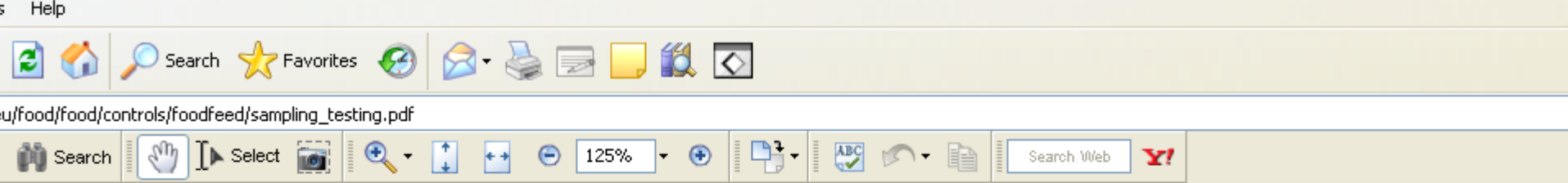
responsibility of the Competent Authority Official Controls

verify FBO compliance with MC

- ✓ Check manufacturing process, eg time, temp, ph
- ✓ Assess shelf life assessment, durability, challenge studies (Annex II)
- ✓ verify the sampling and testing scheme is based on risk (HACCP and GHP)
- ✓ verify corrective actions are in HACCP and GHP, are appropriate and are followed in case of non compliance
- ✓ verify the FBO is following and assessing trends (HACCP)

responsibility of the Competent Authority Official Controls

- ➔ **Undertake testing against food safety criteria**
 - in surveys at retail for verification
 - border inspection posts
 - in case of suspicion



GUIDANCE DOCUMENT

on official controls, under
Regulation (EC) No 882/2004, concerning
microbiological sampling and testing of foodstuffs.

Microbiological Criteria

2073 / 2005

- Foodstuffs should not contain micro-organisms or their toxins or metabolites in quantities that present an unacceptable risk for human health
- Defines two types of criteria

Food Safety Criteria:
assess the safety
of a product
or batch of foods

Process Hygiene Criteria:
Indication of process
performance
Do not assess fitness
of food

**Commission Regulation (EC) No 2073/2005 as
amended by (EC) No 1441/2007 on
microbiological criteria for foodstuffs
ANNEX 1**

- **Chapter 1 Food safety criteria**
- **Chapter 2 Process hygiene criteria**
 - **2.1 Meat and Products thereof**
 - **2.2 Milk and Dairy products**
 - **2.3 Egg products**
 - **2.4 Fishery Products**
 - **2.5 Vegetables, fruits and products thereof**

**Commission Regulation (EC) No 2073/2005 as
amended by (EC) No 1441/2007 on
microbiological criteria for foodstuffs
ANNEX 1**

- **Chapter 3 Rules for sampling and preparation of samples**
 - **3.1 General rules for sampling and preparation of samples**
 - **3.2 Bacteriological sampling in slaughterhouses and at premises producing minced meat and meat preparations**

Chapter 3. Rules for sampling and preparation of test samples

3.1 General rules

- **In the absence of more specific rules on sampling and preparation of test samples the relevant standards of the ISO and the Codex Alimentarius shall be used as reference methods**
- **Sample size 25 g**

FBO Testing against the criteria

Validation and Verification

Frequency based on risk and use of the foodstuff
unless specified

Adapted to the size and nature of the business



Microbiological criteria in relation to hygiene control measures and HACCP

- Food safety cannot only be based on end product testing
- food safety criteria are one of several management options within GMP and HACCP
- Testing after production is only for verification of GMP and HACCP-based procedures
- Criteria in the regulation are not normally suitable as critical limits
- Monitoring must detect loss of control in real time physical and chemical parameters should be used eg time /temp profiles

Specific rules for testing and sampling

Article 5

1. Annex I : reference sampling and testing methods EN/ISO



2. sample processing areas and equipment ISO 18593

Ready to Eat Foods if *Listeria monocytogenes* risk

Dried Infant formulae , foods for special medical purposes -
if *E. sakazakii* risk monitor for Enterobacteriaceae

Specific rules for testing and sampling

Article 5

1. **Article 5 indicates that within procedures based on HACCP**
2. **samples shall be taken from processing areas and equipment used in food production**

when necessary for ensuring the criteria are met

3. **sampling of the production and processing environment can be a useful tool to identify and prevent the presence of pathogenic micro-organisms in foodstuffs**

for validation of the effectiveness of cleaning

Rapid Tests for surface cleanliness



The liquid in the left side of the Pro-test swabs changes colour from green to purple dependent on the concentration of protein residue on an environmental surface

The pad on the end of a Flash stick changes from yellow to blue when exposed to protein residues on an environmental surface





ATP detection involves the use of a luminometer to measure how much light is produced from the contamination present on an environmental surface

Specific rules for testing and sampling

Article 5

- 3. Number of sample units can be reduced -
historical documentation effective HACCP**
- 4. Assess acceptability of a batch or process -
sampling as in Annex I**

Specific rules for testing and sampling

Article 5

- **FBO can use other sampling and testing**
 - **if equivalent guarantees (sampling sites and trends)**
- **Testing can be for other micro-organisms or analytes –**
 - **only process hygiene criteria**
 - **example E.coli on pig carcasses instead of enterobacteriaceae**

Specific rules for testing and sampling

Article 5

- **Testing can be using Alternative methods**
 - if validated against ref method according to EN/ISO 16140 (for the scope of the criterion) **AND**
 - if commercial (e.g. kit or proprietary media) certified according to EN/ISO16140
 - Other methods (not validated to 16140) can be used if validated and **CA approved**
- **Official controls**
 - reference method highly recommended



What happens if the criteria are not met?

- To fully comply with the Regulation FBOs must carry out corrective action if a food exceeds the relevant criteria.
- **SAFETY CRITERIA** - the product must not be placed on the market or must be withdrawn/recalled from the market
- **HYGIENE CRITERIA** - proposes corrective action for improved production.
- In both cases a review of the food safety management procedures.



Testing against the Criteria unsatisfactory results Art 7

What happens when results fail?

Food safety criteria

Product or batch must be:

- withdrawn or recalled Art 19 Reg 178/2002
- submitted for further processing (if not at retail) by FBO not retail
- divert to other use which poses no risk.

Procedure within HACCP CA authorise



Testing against the Criteria unsatisfactory results Art 7

What happens when results fail?

Food safety criteria

Find the cause – prevent re occurrence

- production hygiene
- selection and/or origin materials
- Review procedures based on HACCP



Testing against the Criteria unsatisfactory results Art 7



What happens when results fail?

Process hygiene criteria

Improve:

- production hygiene
- selection and/or origin materials
- Prevent re occurrence
- Review procedures based on HACCP

Chapter 1 Food Safety Criteria 1.1 -1.27

Micro-organisms/their toxins, metabolites

- **Food Category** **Ready to eat foods – specific foods**
- **Sampling plan *1** **n = number of units comprising the sample; c= number of sample units giving values between m and M**
- **Limits *2** **For points 1.1-1.25 $m = M$**
- **Stage where the criterion applies**
- **Analytical reference method *3** **the most recent edition of the standard shall be used EN/ISO**

Food Safety Criteria

- **Listeria**
 - ready to eat food
- **Salmonella**
 - certain ready to eat food, some raw processed meat
- **Staphylococcal enterotoxins**
 - certain dairy products
- **E. sakazakii (Cronobacter)**
 - baby food
- **E.coli**
 - bivalve molluscs
- **Histamine**
 - certain fish species

Chapter 2 Process Hygiene Criteria

2.1 - 2.5 Micro-organisms

- **Food Category** **Specific foods**
- **Sampling plan *1** **n = number of units comprising the sample;**
 c = number of sample units giving values between m and M
- **Limits** **m and M or $m = M$ *2**
- **Stage where the criterion applies**
- **Analytical reference method * 2 or 3 the most recent edition of the standard shall be used EN/ISO**
- **Action in case of unsatisfactory results**

Process Hygiene Criteria

- **Salmonella**
 - meat carcasses
- **Enterobacteriaceae**
 - Meat carcasses, dried infant formulae
- **E.coli**
 - processed meat, cheeses and cream made from raw milk, precut fruit and vegetables
- **Coagulase positive Staphylococcus**
 - Certain dairy products
- **Bacillus cereus**
 - Certain dairy products
- **Aerobic colony count**
 - carcasses, minced meat

National criteria

-  **Not permitted to have food safety national criteria**

Regulation 2073/2005 has harmonised criteria


-  **Can have other or stricter process hygiene criteria applicable to national production.**

Cannot apply to imports

in the absence of Community criteria

-  **interpretation of results**

Article 14 of the GFL:

- **unsafe food products must not be placed on the market**
-  **enforcement actions by the CA should be proportionate and based on scientific evidence**

Food business operator - obligation is compliance

- Testing is only an element of compliance
- Compliance can be achieved without testing against the criteria
- Exception is minimum requirements for testing, for carcasses and processed meat .
- Other types of testing can be used to assess if testing against the criteria is required
- Should not mean increased reliance on end product testing or positive release.
- Flexibility to adjust sampling requirements according to the nature and size of the business

Competent Authority - obligation is verification

- Verification of FBO compliance
 - Inspection of FBO controls and any results of testing
- Verification of compliance at the national level
 - Surveys at specific points in the food chain
 - Collection and analysis of FBO data over time


Food Safety - From the Farm to the Fork

Microbiological Criteria

Foodstuffs of animal and plant origin may present intrinsic hazards, due to microbiological contamination. Microbiological criteria are tools that can be used in assessing the safety and quality of foods. Due to reasons related to sampling, methodology and uneven distribution of micro-organisms microbiological testing of finished food products done alone is however insufficient to guarantee the safety of a foodstuff tested. The safety of the foodstuffs must principally be ensured by a more preventative approach, such as product and process design and the application of Good Hygiene and Manufacturing Practices (GHP, GMP) and the Hazard Analysis Critical Control Point (HACCP) principles.


The Community microbiological criteria for foodstuffs have been revised and certain important new criteria have also been set down. [Commission Regulation \(EC\) No 2073/2005](#) on microbiological criteria for foodstuffs, applicable from 1 January 2006, lays down **food safety criteria** for certain important foodborne bacteria, their toxins and metabolites, such as Salmonella, Listeria monocytogenes, Enterobacter sakazakii, staphylococcal enterotoxins and histamine in specific foodstuffs. These criteria are applicable to products placed on the market during their entire shelf-life. In addition, the Regulation sets down certain **process hygiene criteria** to indicate the correct functioning of the production process.

The microbiological criteria have been developed in accordance with internationally recognised principles, such as those of [Codex Alimentarius](#)

[Discussion paper on strategy for setting microbiological criteria for foodstuffs in Community legislation \(document in Annex 1\)](#) (710 Kb)  describes the Community strategy to set and revise microbiological criteria for foodstuffs in Community legislation. The strategy includes the principles for development and application of the criteria, and proposals for measures to be taken.

[Guidance Document](#) on official controls, under regulation (EC) no 882/2004, concerning microbiological sampling and testing of foodstuffs 

[Guidance Document](#)  on *Listeria monocytogenes* shelf-life studies for ready-to-eat foods, under Regulation (EC) No 2073/2005 of 15 November 2005 on microbiological criteria for foodstuffs. This document is mainly directed at Food Business Operators who produce ready-to-eat foods and conduct *Listeria monocytogenes* shelf-life studies for them in accordance with Article 3(2) and Annex II of Regulation (EC) No 2073/2005 of 15 November 2005 on microbiological criteria for foodstuffs.

[Technical Guidance Document](#)  on shelf-life laboratory durability and challenge studies for *Listeria monocytogenes* in ready-to-eat foods. This technical guidance document is intended for laboratories conducting shelf-life studies for *L. monocytogenes* in RTE foods, in collaboration with the FBO's. It provides recommendation on how to select the test(s), to implement and how to perform them.

[Scientific Advice](#) on matters relating to microbiological risks in food was given by the Scientific Committee on Food and the Scientific Committee on Veterinary Measures relating to Public Health and is now provided by the European Food Safety Authority (EFSA).

Topics

- [Introduction](#)
- [Legislation](#)
- [Implementation of the Directive](#)
- [Implementation of the Regulation](#)
- [Other legislative activities](#)
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 **FOOD AND FEED SAFETY**

 **ANIMAL HEALTH AND WELFARE**

Hope all is clear?

