Project: Technical assistance to improve implementation of food safety standards and disease crisis preparedness

Activity 1.1.17: Training on topics relevant to food chain safety including processed food of non-animal origin and composite food

Module: **Microbiological criteria for foodstuffs**

- **EU Legislation on microbiological criteria**

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Place: Nicosia, Cyprus

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EU regulation on Microbiological Criteria

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COMMISSION REGULATION (EC) No 2073/2005

of 15 November 2005

on microbiological criteria for foodstuffs

(Text with EEA relevance)

(OJ L 338, 22.12.2005, p. 1)

Amended by:

		Official Journal		
		No	page	date
►M1	Commission Regulation (EC) No 1441/2007 of 5 December 2007	L 322	12	7.12.2007
►M2	Commission Regulation (EU) No 365/2010 of 28 April 2010	L 107	9	29.4.2010
►M3	Commission Regulation (EU) No 1086/2011 of 27 October 2011	L 281	7	28.10.2011
►M4	Commission Regulation (EU) No 209/2013 of 11 March 2013	L 68	19	12.3.2013
►M5	Commission Regulation (EU) No 1019/2013 of 23 October 2013	L 282	46	24.10.2013
►M6	Commission Regulation (EU) No 217/2014 of 7 March 2014	L 69	93	8.3.2014

Corrected by:

►C1	Corrigendum, OJ L 278, 10.10.2006, p. 32 (2073/2005)
►C2	Corrigendum, OJ L 283, 14.10.2006, p. 62 (2073/2005)

EU Regulation on Microbiological Criteria

Reg. (EC) No. 2073/2005 as amended 1441/2007, 365/2010 1086/2011, 209/2013,1019,2013, 217/2014

Main objectives

- **To ensure a high level of human health protection**

  Reduction of human salmonellosis and listeriosis

- **To harmonise microbiological criteria**

  Uniform rules for food business operators

EU Regulation on Microbiological Criteria

Reg. (EC) No. 2073/2005 as amended 1441/2007, 365/2010 1086/2011, 209/2013,217/2014

Implementing measure - 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 Good Hygiene Practice

(Not CCP)

EU Regulation 2073/2005

Microbiological criteria in foodstuffs

Criteria established in support of Food Hygiene Legislation.

Criteria apply to Food Business Operators (FBO) however the limits apply to samples taken for official control (Reg 625/2017) to verify the criteria have been met.

FBO's should use the criteria to validate and verify the correct functioning of their food safety management procedures based on HACCP principles and GMP.

Concept of Microbiological Criteria (Codex Alimentarius)

1. Micro-organism of concern
2. Analytical method
3. Sampling plan
   - Number of sample units
   - Size of the analytical unit
4. Microbiological limits
5. Foodstuff
6. Point of the food chain where the limit applies
7. Actions when results are unsatisfactory

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 (Article 6)

Food Safety Criteria:
assess the acceptability
of a product
or batch of foods
market restrictions

Process Hygiene Criteria:
Indication of the performance
of the food production proces
No market restrictions

Why do we need microbiological criteria?

- Because of legal requirements
- It is important for food safety
- Microbiological hazards in foodstuffs form a major source of foodborne diseases in humans
- They can be used in validation and verification of
  - HACCP procedures
  - other hygiene control measures.

Whom the Regulation 2073/2005 is addressed to?

- All food business operators at each stage of food production, processing and distribution, including retail.
- Competent authority for official control purposes (eg. verification of the conformity of food and their production process with the provisions contained the Regulation 2073/2005).

<u>Regulation 852/2002 (Art. 4):</u>

3. Food business operators shall, as appropriate, adopt the following specific hygiene measures:

*(a) compliance with **microbiological criteria** for foodstuffs;*

(e) sampling and analysis.

Microbiological criteria

Microbiological criteria can be generally classified as:

- **standard**: included in the legislation and mandatory for FBOs
- **guidance criteria** or target values: (recommended to FBOs): are used to assess the hygiene of the process and for separating acceptability from deviation;
- **specification**: limits agreed between suppliers and purchasers of foodstuffs and formalized in contracts.

CODEX 1997	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"
Regulation 2073/2005	microbiological criterion means a criterion defining **the acceptability of a product, a batch of foodstuffs or a process**, based on the absence, presence or number of micro-organisms, and/or on the quantity of their toxins/metabolites, per unit(s) of mass, volume, area or batch.

Microbiological Criteria Annex 1

Chapter 1 Food Safety Criteria

Chapter 2 Process Hygiene Criteria

Chapter 3 Rules for sampling and preparation of test samples

Microbiological criteria

Food category	Microorganism/their toxins metabolites	Sampling plan		Limits (maximum values for sample)		Analytic reference methods	Stages where the criterion applies	Action in case of unsatisfactory results
Detailed description	Specific and general	n= number of units	c= number of sample units giving values over m or between m and M	m	M	EN/ISO method	shelf-life; before/after chilling	withdrawal/recall; corrective measures

Food Safety Criteria

Chapter 1. Food safety criteria

	Food category	Micro-organisms/their toxins, metabolites	Sampling plan (1)		Limits (2)		Analytical reference method (3)	Stage where the criterion applies
			n	c	m	M		
1.1	Ready-to-eat foods intended for infants and ready-to-eat foods for special medical purposes (4)	*Listeria monocytogenes*	10	0	Absence in 25 g		EN/ISO 11290-1	Products placed on the market during their shelf-life
1.2	Ready-to-eat foods able to support the growth of *L. monocytogenes*, other than those intended for infants and for special medical purposes	*Listeria monocytogenes*	5	0	100 cfu/g (5)		EN/ISO 11290-2 (6)	Products placed on the market during their shelf-life
			5	0	Absence in 25 g (7)		EN/ISO 11290-1	Before the food has left the immediate control of the food business operator, who has produced it
1.3	Ready-to-eat foods unable to support the growth of *L. monocytogenes*, other than those intended for infants and for special medical purposes (4) (8)	*Listeria monocytogenes*	5	0	100 cfu/g		EN/ISO 11290-2 (6)	Products placed on the market during their shelf-life
1.4	Minced meat and meat preparations intended to be eaten raw	*Salmonella*	5	0	Absence in 25 g		EN/ISO 6579	Products placed on the market during their shelf-life
▼M2								
1.5	Minced meat and meat preparations made from poultry meat intended to be eaten cooked	*Salmonella*	5	0	Absence in 25 g		EN/ISO 6579	Products placed on the market during their shelf-life
▼M1								
1.6	Minced meat and meat preparations made from other species than poultry intended to be eaten cooked	*Salmonella*	5	0	Absence in 10 g		EN/ISO 6579	Products placed on the market during their shelf-life
1.7	Mechanically separated meat (MSM) (9)	*Salmonella*	5	0	Absence in 10 g		EN/ISO 6579	Products placed on the market during their shelf-life
1.8	Meat products intended to be eaten raw, excluding products where the manufacturing process or the composition of the product will eliminate the salmonella risk	*Salmonella*	5	0	Absence in 25 g		EN/ISO 6579	Products placed on the market during their shelf-life

Process Hygiene criteria

M1

Chapter 2. Process hygiene criteria

2.1 *Meat and products thereof*

Food category	Micro-organisms	Sampling plan (1)		Limits (2)		Analytical reference method (3)	Stage where the criterion applies	Action in case of unsatisfactory results
		n	c	m	M			
2.1.1 Carcases of cattle, sheep, goats and horses (4)	Aerobic colony count			3,5 log cfu/cm² daily mean log	5,0 log cfu/cm² daily mean log	ISO 4833	Carcases after dressing but before chilling	Improvements in slaughter hygiene and review of process controls
	Enterobacteriaceae			1,5 log cfu/cm² daily mean log	2,5 log cfu/cm² daily mean log	ISO 21528-2	Carcases after dressing but before chilling	Improvements in slaughter hygiene and review of process controls
2.1.2 Carcases of pigs (4)	Aerobic colony count			4,0 log cfu/cm² daily mean log	5,0 log cfu/cm² daily mean log	ISO 4833	Carcases after dressing but before chilling	Improvements in slaughter hygiene and review of process controls
	Enterobacteriaceae			2,0 log cfu/cm² daily mean log	3,0 log cfu/cm² daily mean log	ISO 21528-2	Carcases after dressing but before chilling	Improvements in slaughter hygiene and review of process controls
2.1.3 Carcases of cattle, sheep, goats and horses	*Salmonella*	50 (5)	2 (6)	Absence in the area tested per carcase		EN/ISO 6579	Carcases after dressing but before chilling	Improvements in slaughter hygiene, review of process controls and of origin of animals
2.1.4 Carcases of pigs	*Salmonella*	50 (5)	5 (6)	Absence in the area tested per carcase		EN/ISO 6579	Carcases after dressing but before chilling	Improvements in slaughter hygiene and review of process controls, origin of animals and of the biosecurity measures in the farms of origin
2.1.5 Poultry carcases of broilers and turkeys	*Salmonella*	50 (5)	7 (6)	Absence in 25 g of a pooled sample of neck skin		EN/ISO 6579	Carcases after chilling	Improvements in slaughter hygiene and review of process controls, origin of animals and biosecurity measures in the farms of origin

Two Types of criteria

Process Hygiene

1. Applies in production, does not apply to products on the market or imports

2. Mainly indicators

3. 3 class sampling plan

Results **satisfactory**
acceptable
unsatisfactory

- Action : Improvement in production within HACCP

Food safety

1. Applies to products ready to be placed on the market and during their shelf life including imports

2. Mainly pathogens

3. 2 class sampling plan

Results **satisfactory**
unsatisfactory

- Action : Removal from the market and find the cause within HACCP

Microbiological criteria

Food safety criteria	Process hygiene criteria
1. Defines the acceptability of a product or a batch of foodstuff and is applicable to products placed on the market and during its shelf-life 2. Include pathogens and/or toxins	1. Indicates the acceptable functioning of the production process and is not applicable to products placed on the market 2. It sets an indicative contamination value above which corrective actions are required in order to maintain the hygiene of the process in compliance with legal text
Listeria monocytogens Salmonella staphylococcal enterotoxins Enterobacter sakazakii E.coli Histamine	Aerobic colony count Enterobatteriaceae Salmonella E.coli coagulase-positive Staphylococci

What to do in case of non- conformity ?

The control measures adopted by the FBO to ensure compliance with both criteria must be **documented** as part of the procedures based on **HACCP** principles and other **hygiene control procedures** and made available to the competent authority for official control.

Microbiological criteria

Food safety criteria (FSC)	Process hygiene criteria (PHC)
Actions: the FBO shall adopt the measures listed in the art. 7/ Reg. 2073/2005: • adoption of the provisions laid down in paragraphs 1, 2, 3 and 4 • adoption of the necessary corrective measures defined in their HACCP-based procedures; • adoption of other measures useful and necessary to protect the human health; • investigate the cause of the unsatisfactory results in order to prevent the recurrence of the unacceptable microbiological contamination **1. withdraw or recall** the product (Art. 19/Reg.178/2002) 2. products placed on the market, which are not yet at retail level and which do not fulfil the FSC, may be submitted to **further processing by a treatment eliminating the hazard** in question. This treatment may only be carried out by FBOs approved for such processing (other than those at retail level). 3. FBO may use the batch for purposes **<u>other</u>** than those originally intended (human or animal), provided that this use does not pose a risk and this use has been decided within the HACCP procedures and authorised by the CA. 4. a batch of MSM produced with the techniques referred to in Chapter III, paragraph 3, in Section V of Annex III to Reg. 853/2004, with unsatisfactory results in respect of the Salmonella criterion, may be used in the food chain only to manufacture **heat treated** meat products in approved establishments .	**Actions:** • No sanctions to the FBO- **reviewing the procedures and improving the hygiene of production and selection and/or origin of raw materials**. e.g: **Farmer**: Improvements in the biosecurity measures in the farms of origin; **Slaughterhouse operator**: Improvement in the slaughter hygiene and review process control; Verification of instructions for personnel and their training; Improvement of the hygiene of plant, lairage and equipment; Slaughtering of Salmonella positive animals at the end of the day; Adoption of special measures during slaughtering Salmonella positive animals; **Processing plant operators**: Improvement of processing hygiene; Improvement in selection and/or origin of raw materials

Microbiological criteria- position in food chain

Establishment (FBOs)		Food marketing
during production process	end of the production process (final foodstuffs ready to be dispatched)	Retail
PHC	**FSC**	**FSC**

Coffee break

Which foodstuffs are included in Regulation 2073/2005?

Mainly ready-to-eat (RTE) foodstuffs such as:

- RTE intended for infants and for special medical purposes
- RTE able to **support the growth of L. monocytogenes**, other than those intended for infants and for special medical purposes
- RTE foods **unable to support the growth of L. monocytogenes**
- Food of animal origin such:

- meats (to be consumed raw or cooked) gelatine and collagen
- milk and milk products
- RTE food containing raw eggs and eggs products
- crustaceans, bivalve mollusc, echinoderm, tunicates, gastropods and fish products

- RTE of vegetable origin

- seeds sprouted
- pre-cut fruit and vegetables

Class sampling

Sampling plans and microbiological limits should be chosen according to the severity of the health hazard and the expected conditions in which the foodstuff will be handled and consumed.

Two and three-class attribute sampling, in which unit samples are collected randomly, are the most commonly used plans for microbiological examination and are used in Regulation 2073/2005 as follows:

- **Two-class sampling**

The two-class sampling plan is used both for quantitative or qualitative (absence /presence) analytical results.
The samples analysed are divided into two categories: **satisfactory** and **unsatisfactory**, based on one limit value **'m=M'**.

Therefore:
M limit : maximum acceptable level
n=number of samples taken from the batch
c= number of sample units giving values over **m**

Class sampling

- **Three-class sampling**

In a three-class sampling plan, the samples examined are divided into three categories: **satisfactory, acceptable and unsatisfactory**. A three-class sampling plan is used if it is acceptable that some samples exceed the lower limit (m),as long as a risk contamination level (M) is not exceeded.

m limit: this limit constitutes a target level normally included in the HACCP system or GHP

M limit: maximum acceptable level

n= number of units comprising the sample

c = number of sample units giving values between **m** and **M**

Sampling of food areas and equipment

- With the application of Regulation 2073/2005, it is no longer obligatory for the areas and the equipment that come into contact with food to be submitted to microbiological exam.

- Art 5 specifies that samples shall be taken from processing areas and equipment used in food production only when such sampling is necessary for ensuring that the criteria are met.

The ISO standard 18593 shall be used as a reference method when performing the sampling (Microbiology of food and animal feeding stuffs – Horizontal methods for sampling techniques from surfaces using contact plates and swabs).

Sampling of food areas and equipment

FBO manufacturing **ready-to-eat foods**, which may **pose a Listeria monocytogenes** risk for public health, **shall sample the processing areas and equipment for Listeria monocytogenes as part of their sampling scheme**.

FBO manufacturing **dried infant formulae or dried foods for special medical purposes intended for infants** below six months which **pose an Enterobacter sakazakii** risk shall monitor the **processing areas and equipment for Enterobacteriaceae as part of their sampling scheme**.

Sampling of food areas and equipment

The FBO can continue to perform examination of the surfaces against Salmonella, E.Coli, total bacterial count, coagulase-positive staphylococci, as part of the activities to **verify** the efficiency of the **cleaning and disinfection procedures.**

Class sampling

- **Three-class sampling**

In a three-class sampling plan, the samples examined are divided into three categories: **satisfactory, acceptable and unsatisfactory**. A three-class sampling plan is used if it is acceptable that some samples exceed the lower limit (m),as long as a risk contamination level (M) is not exceeded.

m limit: this limit constitutes a target level normally included in the HACCP system or GHP

M limit: maximum acceptable level

n= number of units comprising the sample

c = number of sample units giving values between **m** and **M**

Sampling frequencies

The level of effort that Regulation 2073/2005 requires in terms of sampling frequency and type of microbiological tests links to the procedures implemented by the FBO such as GHP, GMP and HACCP.

If these procedures are correctly and constantly implemented, validated and verified, it is not necessary to intensify microbiological tests.

The minimal sampling frequencies is specified in **Annex I chapters 1 and 2 of Regulation 2073/2004** (specific sampling frequencies such as carcases, minced meat and meat preparations and separated mechanically meat).

Sampling frequencies

For the rest, the FBOs must properly define for they own products and in line with HACCP principles taking into consideration: **potential hazard** (microbiological, chemical and physical) and **risks** associated to the raw materials; **destination** of the final product and instructions for their use (ex. ready-to-eat product or products to be cooked prior consumption); **nature and dimension** of the business activity; risks associated to the production **volume**; **historical data** (frequency of controls); **confidence** of the producer/provider of raw materials (audit).

The FBO must know:

The physical-chemical parameters of the foodstuffs like:

- a_W
- pH
- Temperature/time profile
- Packaging technique
- Possibility for contamination.

Two Types of criteria

- ***Process Hygiene***

1. Applies in production, does not apply to products on the market or imports

2. Mainly indicators

3. 3 class sampling plan

- *Results* ***satisfactory***
  - ***acceptable***
  - ***unsatisfactory***
- *Action :- Improvement in production within HACCP*

- ***Food safety***

1. Applies to products ready to be placed on the market and during their shelf life including imports

2. Mainly pathogens

3. 2 class sampling plan

- *Results* ***satisfactory***
  - ***unsatisfactory***
- *Action :- Removal from the market and find the cause within HACCP*

Chapter 1 Food Safety Criteria

1.1 -1.27 Micro-organisms/their toxins/ metabolites

1. Food Category	*Ready to eat foods – specific foods*
2. Microorganism	*Pathogen (Listeria) – indicator (E.coli)- toxin (enterotoxin)- metabolite (histamine)*
*3. Sampling plan *1*	*n = number of sample units* *c= number of sample units giving values between m and M*
*4. Limits *2*	*M and m for counts* *For points 1.1-1.25 m = M (2 Class attribute)* *Absence in x gms* *Results : **satisfactory**/**unsatisfactory***

Chapter 1 Food Safety Criteria

1.1 -1.27 Micro-organisms/their toxins/ metabolites

5. Analytical reference method	*EN/ISO - *3 the most recent edition of the standard shall be used*
6. Stage where the criterion applies	*-products placed on the market and during their shelf life .* *-before the food has left the immediate control of the FBO who produced it* *point 1.2 only*

Chapter 2 Process Hygiene Criteria

2.1 - 2.5 Micro-organisms

1. Food Category	*Specific foods /physical characteristics*
2. Microorganism	*Indicator organisms – pathogens (Salmonella)*
*3. Sampling plan *1*	*n = number of sample units* *c= number of sample units giving values between m and M*
*4. Limits *2*	*m and M or m = M for counts 3 class attribute* *Absence in x gms* *Results :* ***satisfactory*** ***acceptable*** ***unsatisfactory***

Chapter 2 Process Hygiene Criteria

2.1 - 2.5 Micro-organisms

5. Analytical reference method	*EN/ISO * 3 the most recent edition of the standard*
6. Stage where the criterion applies	*before the market*
7. Action in case of unsatisfactory results	*HACCP* *production hygiene , selection of raw materials*

What happens if the criteria limits are not met?

- FBOs must carry out corrective action if a food exceeds the relevant criteria limit.
- The food cannot be consumed and the food will not be placed on the market or will be removed from the market (withdrawn/recalled).
- The food cannot be consumed, but it can be processed, treated, or other corrective actions, as allowed under the HACCP framework and authorized by a competent authority, can be taken.
- Batches that exceed the criterion limit have to have a penalty.

Obligations for the FBO

- **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)**

Obligations for Competent Authority

- **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)**

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