

*Status: Point in time view as at 19/05/2010.*

*Changes to legislation: There are currently no known outstanding effects for the Commission Regulation (EC) No 2073/2005, Chapter 2.. (See end of Document for details)*

## [<sup>F1</sup>ANNEX I

### Microbiological criteria for foodstuffs

#### Textual Amendments

**F1** Substituted by Commission Regulation (EC) No 1441/2007 of 5 December 2007 amending Regulation (EC) No 2073/2005 on microbiological criteria for foodstuffs (Text with EEA relevance).

#### Chapter 2.

#### Process hygiene criteria

##### 2.1 Meat and products thereof

Food category	Micro-organisms <sup>h</sup>	Sampling plan <sup>a</sup>		Limits <sup>b</sup>		Analytical reference method <sup>c</sup>	Stage where the criterion applies	Action in case of unsatisfactory results
		n	c	m	M			
2.1.1	Aerobic colony count of carcasses of cattle, sheep, goats and horses <sup>d</sup>			3,5 log cfu/cm <sup>2</sup> daily mean log	5,0 log cfu/cm <sup>2</sup> daily mean log	ISO 4833	Carcasses after dressing but before chilling	Improvements in slaughter hygiene and review of process controls
	Enterobacteriaceae			1,5 log cfu/cm <sup>2</sup> daily mean log	2,5 log cfu/cm <sup>2</sup> daily mean log	ISO 21528-2	Carcasses after dressing but before chilling	Improvements in slaughter hygiene and review of process controls
2.1.2	Aerobic colony count of pigs <sup>d</sup>			4,0 log cfu/cm <sup>2</sup> daily mean log	5,0 log cfu/cm <sup>2</sup> daily mean log	ISO 4833	Carcasses after dressing but before chilling	Improvements in slaughter hygiene and review of process controls
	Enterobacteriaceae			2,0 log cfu/cm <sup>2</sup>	3,0 log cfu/cm <sup>2</sup>	ISO 21528-2	Carcasses after	Improvements in

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				daily mean log	daily mean log		dressing but before chilling	slaughter hygiene and review of process controls
2.1.3	<i>Salmonella</i> Carcases of cattle, sheep, goats and horses	5 <sup>0</sup>	2 <sup>f</sup>	Absence in the area tested per carcass		EN/ISO 6579	Carcasses after dressing but before chilling	Improvements in slaughter hygiene, review of process controls and of origin of animals
2.1.4	<i>Salmonella</i> Carcases of pigs	5 <sup>0</sup>	5 <sup>f</sup>	Absence in the area tested per carcass		EN/ISO 6579	Carcasses 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	<i>Salmonella</i> Poultry carcasses of broilers and turkeys	5 <sup>0</sup>	7 <sup>f</sup>	Absence in 25 g of a pooled sample of neck skin		EN/ISO 6579	Carcasses after chilling	Improvements in slaughter hygiene and review of process controls, origin of animals and biosecurity measures in the

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2.1.6	Aerobic Minced meat count <sup>g</sup>	5	2	$5 \times 10^5$ cfu/g	$5 \times 10^6$ cfu/g	ISO 4833	End of the manufacturing process	farms of origin Improvements in production hygiene and improvements in selection and/or origin of raw materials
	<i>E. coli</i> <sup>h</sup>	5	2	50 cfu/g	500 cfu/ g	ISO 16649-1 or 2	End of the manufacturing process	Improvements in production hygiene and improvements in selection and/or origin of raw materials
2.1.7	Aerobic Mechanically separated meat (MSM) <sup>i</sup>	5	2	$5 \times 10^5$ cfu/g	$5 \times 10^6$ cfu/g	ISO 4833	End of the manufacturing process	farms of origin Improvements in production hygiene and improvements in selection and/or origin of raw materials
	<i>E. coli</i> <sup>h</sup>	5	2	50 cfu/g	500 cfu/ g	ISO 16649-1 or 2	End of the manufacturing process	Improvements in production hygiene and improvements in selection and/or origin of raw materials

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2.1.8	<i>E. coli</i> <sup>h</sup> Meat preparations	5	2	500 cfu/ g or cm <sup>2</sup>	5 000 cfu/g or cm <sup>2</sup>	ISO 16649-1 or 2	End of the manufacturing process	Improvements in production hygiene and improvements in selection and/or origin of raw materials
<b>a</b>	n = number of units comprising the sample; c = number of sample units giving values between m and M.							
<b>b</b>	For points 2.1.3-2.1.5 m = M.							
<b>c</b>	The most recent edition of the standard shall be used.							
<b>d</b>	The limits (m and M) shall apply only to samples taken by the destructive method. The daily mean log shall be calculated by first taking a log value of each individual test result and then calculating the mean of these log values.							
<b>e</b>	The 50 samples shall be derived from 10 consecutive sampling sessions in accordance with the sampling rules and frequencies laid down in this Regulation.							
<b>f</b>	The number of samples where the presence of salmonella is detected. The c value is subject to review in order to take into account the progress made in reducing the salmonella prevalence. Member States or regions having low salmonella prevalence may use lower c values even before the review.							
<b>g</b>	This criterion shall not apply to minced meat produced at retail level when the shelf-life of the product is less than 24 hours.							
<b>h</b>	<i>E. coli</i> is used here as an indicator of faecal contamination.							
<b>i</b>	These criteria apply to mechanically separated meat (MSM) produced with the techniques referred to in paragraph 3 of Chapter III of Section V of Annex III to Regulation (EC) No 853/2004 of the European Parliament and of the Council.							

### Interpretation of the test results

The limits given refer to each sample unit tested, excluding testing of carcasses where the limits refer to pooled samples.

The test results demonstrate the microbiological quality of the process tested.

Enterobacteriaceae and aerobic colony count in carcasses of cattle, sheep, goats, horses and pigs:

- satisfactory, if the daily mean log is  $\leq m$ ,
- acceptable, if the daily mean log is between m and M,
- unsatisfactory, if the daily mean log is  $> M$ .

*Salmonella* in carcasses:

- satisfactory, if the presence of *Salmonella* is detected in a maximum of c/n samples,
- unsatisfactory, if the presence of *Salmonella* is detected in more than c/n samples.

After each sampling session, the results of the last ten sampling sessions shall be assessed in order to obtain the n number of samples.

*E. coli* and aerobic colony count in minced meat, meat preparations and mechanically separated meat (MSM):

- satisfactory, if all the values observed are  $\leq m$ ,
- acceptable, if a maximum of c/n values are between m and M, and the rest of the values observed are  $\leq m$ ,

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— unsatisfactory, if one or more of the values observed are > M or more than c/n values are between m and M.

## 2.2 Milk and dairy products

Food category	Micro-organisms	Sampling plan <sup>a</sup>		Limits <sup>b</sup>		Analytical reference method <sup>c</sup>	Stage where the criterion applies	Action in case of unsatisfactory results
		n	c	m	M			
[ <sup>F2</sup> 2.2.1	Enterobacteriaceae Pasteurised milk and other pasteurised liquid dairy products <sup>d</sup>	5	0	10 cfu/ml		ISO 21528-2	End of the manufacturing process	Check on the efficiency of heat-treatment and prevention of recontamination as well as the quality of raw materials]
2.2.2	<i>E. coli</i> <sup>e</sup> Cheeses made from milk or whey that has undergone heat treatment	5	2	100 cfu/g	1 000 cfu/g	ISO 16649-1 or 2	At the time during the manufacturing process when the <i>E. coli</i> count is expected to be highest <sup>f</sup>	Improvements in production hygiene and selection of raw materials
2.2.3	Coagulase positive staphylococci Cheeses made from raw milk	5	2	10 <sup>4</sup> cfu/g	10 <sup>5</sup> cfu/g	EN/ISO 6888-2	At the time during the manufacturing process when the number of staphylococci is expected to be highest	Improvements in production hygiene and selection of raw materials. If values > 10 <sup>5</sup> cfu/g are detected, the cheese
2.2.4	Coagulase positive staphylococci Cheeses made from milk that has undergone a	5	2	100 cfu/g	1 000 cfu/g	EN/ISO 6888-1 or 2	At the time during the manufacturing process when the number of staphylococci is expected to be highest	Improvements in production hygiene and selection of raw materials. If values > 10 <sup>5</sup> cfu/g are detected, the cheese

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	lower heat treatment than pasteurisation <sup>g</sup> and ripened cheeses made from milk or whey that has undergone pasteurisation or a stronger heat treatment <sup>g</sup>							batch has to be tested for staphylococcal enterotoxins.
2.2.5	Coagulase positive staphylococci (fresh cheeses) made from milk or whey that has undergone pasteurisation or a stronger heat treatment <sup>g</sup>	5	2	10 cfu/g	100 cfu/g	EN/ISO 6888-1 or 2	End of the manufacturing process	Improvements in production hygiene. If values > 10 <sup>5</sup> cfu/g are detected, the cheese batch has to be tested for staphylococcal enterotoxins.
2.2.6	<i>E. coli</i> <sup>e</sup> Butter and cream made from raw milk or milk	5	2	10 cfu/g	100 cfu/g	ISO 16649-1 or 2	End of the manufacturing process	Improvements in production hygiene and selection of raw materials

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	that has undergone a lower heat treatment than pasteurisation							
2.2.7	Enterobacteriaceae Milk powder and whey powder <sup>d</sup>	5	0	10 cfu/g		ISO 21528-2	End of the manufacturing process	Check on the efficiency of heat treatment and prevention of recontamination
	Coagulase positive staphylococci	5	2	10 cfu/g	100 cfu/g	EN/ISO 6888-1 or 2	End of the manufacturing process	Improvements in production hygiene. If values > 10 <sup>5</sup> cfu/g are detected, the batch has to be tested for staphylococcal enterotoxins.
2.2.8	Enterobacteriaceae Ice cream <sup>h</sup> and frozen dairy desserts	5	2	10 cfu/g	100 cfu/g	ISO 21528-2	End of the manufacturing process	Improvements in production hygiene
2.2.9	Enterobacteriaceae Dried infant formulae and dried dietary foods for special medical	5	0	Absence in 10 g		ISO 21528-1	End of the manufacturing process	Improvements in production hygiene to minimise contamination <sup>i</sup>

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	purposes intended for infants below six months of age							
2.2.10	Enterobacteriaceae Dried follow-on formulae	5	0	Absence in 10 g		ISO 21528-1	End of the manufacturing process	Improvements in production hygiene to minimise contamination
2.2.11	Presumptive Dried infant formulae and dried dietary foods for special medical purposes intended for infants below six months of age <i>Bacillus cereus</i>	5	1	50 cfu/g	500 cfu/g	EN/ISO 7932 <sup>j</sup>	End of the manufacturing process	Improvements in production hygiene. Prevention of recontamination. Selection of raw material.

**a** n = number of units comprising the sample; c = number of sample units giving values between m and M.

**b** [<sup>F2</sup>For points 2.2.1, 2.2.7, 2.2.9 and 2.2.10 m=M.]

**c** The most recent edition of the standard shall be used.

**d** The criterion shall not apply to products intended for further processing in the food industry.

**e** E. coli is used here as an indicator for the level of hygiene.

**f** For cheeses which are not able to support the growth of E. coli, the E. coli count is usually the highest at the beginning of the ripening period, and for cheeses which are able to support the growth of E. coli, it is normally at the end of the ripening period.

**g** Excluding cheeses where the manufacturer can demonstrate, to the satisfaction of the competent authorities, that the product does not pose a risk of staphylococcal enterotoxins.

**h** Only ice creams containing milk ingredients.

**i** Parallel testing for Enterobacteriaceae and E. sakazakii shall be conducted, unless a correlation between these micro-organisms has been established at an individual plant level. If Enterobacteriaceae are detected in any of the product samples tested in such a plant, the batch has to be tested for E. sakazakii. It shall be the responsibility of the manufacturer



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to demonstrate to the satisfaction of the competent authority whether such a correlation exists between Enterobacteriaceae and *E. sakazakii*.

**j** 1 ml of inoculum is plated on a Petri dish of 140 mm diameter or on three Petri dishes of 90 mm diameter.

### Textual Amendments

**F2** Substituted by [Commission Regulation \(EU\) No 365/2010 of 28 April 2010 amending Regulation \(EC\) No 2073/2005 on microbiological criteria for foodstuffs as regards Enterobacteriaceae in pasteurised milk and other pasteurised liquid dairy products and \*Listeria monocytogenes\* in food grade salt \(Text with EEA relevance\)](#).

### Interpretation of the test results

The limits given refer to each sample unit tested.

The test results demonstrate the microbiological quality of the process tested.

Enterobacteriaceae in dried infant formulae, dried dietary foods for special medical purposes intended for infants below six months of age and dried follow-on formulae:

- satisfactory, if all the values observed indicate the absence of the bacterium,
- unsatisfactory, if the presence of the bacterium is detected in any of the sample units.

*E. coli*, Enterobacteriaceae (other food categories) and coagulase-positive staphylococci:

- satisfactory, if all the values observed are  $\leq m$ ,
- acceptable, if a maximum of  $c/n$  values are between  $m$  and  $M$ , and the rest of the values observed are  $\leq m$ ,
- unsatisfactory, if one or more of the values observed are  $> M$  or more than  $c/n$  values are between  $m$  and  $M$ .

Presumptive *Bacillus cereus* in dried infant formulae and dried dietary foods for special medical purposes intended for infants below six months of age:

- satisfactory, if all the values observed are  $\leq m$ ,
- acceptable, if a maximum of  $c/n$  values are between  $m$  and  $M$ , and the rest of the values observed are  $\leq m$ ,
- unsatisfactory, if one or more of the values observed are  $> M$  or more than  $c/n$  values are between  $m$  and  $M$ .

### 2.3 Egg products

Food category	Micro-organisms	Sampling plan <sup>a</sup>		Limits		Analytical reference method <sup>b</sup>	Stage where the criterion applies	Action in case of unsatisfactory results
		n	c	m	M			
2.3.1	Enterobacteriaceae Egg products	5	2	10 cfu/g or ml	100 cfu/g or ml	ISO 21528-2	End of the manufacturing process	Checks on the efficiency of the heat treatment

**a** n = number of units comprising the sample; c = number of sample units giving values between m and M.

**b** The most recent edition of the standard shall be used.



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- unsatisfactory, if one or more of the values observed are  $> M$  or more than  $c/n$  values are between  $m$  and  $M$ .

Coagulase-positive staphylococci in shelled and cooked crustaceans and molluscan shellfish:

- satisfactory, if all the values observed are  $\leq m$ ,
- acceptable, if a maximum of  $c/n$  values are between  $m$  and  $M$ , and the rest of the values observed are  $\leq m$ ,
- unsatisfactory, if one or more of the values observed are  $> M$  or more than  $c/n$  values are between  $m$  and  $M$ .

## 2.5 Vegetables, fruits and products thereof

Food category	Micro-organisms	Sampling plan <sup>a</sup>		Limits		Analytical reference method <sup>b</sup>	Stage where the criterion applies	Action in case of unsatisfactory results
		n	c	m	M			
2.5.1	<i>E. coli</i> Pre-cut fruit and vegetables (ready-to-eat)	5	2	100 cfu/g	1 000 cfu/g	ISO 16649-1 or 2	Manufacturing process	Improvements in production hygiene, selection of raw materials
2.5.2	<i>E. coli</i> Unpasteurised fruit and vegetable juices (ready-to-eat)	5	2	100 cfu/g	1 000 cfu/g	ISO 16649-1 or 2	Manufacturing process	Improvements in production hygiene, selection of raw materials

**a** n = number of units comprising the sample; c = number of sample units giving values between  $m$  and  $M$ .

**b** The most recent edition of the standard shall be used.

### Interpretation of the test results

The limits given refer to each sample unit tested.

The test results demonstrate the microbiological quality of the process tested.

*E. coli* in pre-cut fruit and vegetables (ready-to-eat) and in unpasteurised fruit and vegetable juices (ready-to-eat):

- satisfactory, if all the values observed are  $\leq m$ ,
- acceptable, if a maximum of  $c/n$  values are between  $m$  and  $M$ , and the rest of the values observed are  $\leq m$ ,
- unsatisfactory, if one or more of the values observed are  $> M$  or more than  $c/n$  values are between  $m$  and  $M$ .]

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