

*Status: Point in time view as at 31/01/2020.*

*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	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
		h	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	[ <sup>F4</sup> EN ISO 4833-1]	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	[ <sup>F4</sup> EN ISO 4833-2]	Carcasses after dressing but before chilling	Improvements in slaughter hygiene and review of process controls
2.1.2	Aerobic colony count of pig <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	[ <sup>F4</sup> EN ISO 4833-1]	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>	[ <sup>F4</sup> EN ISO 4833-2]	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> spp. Carcases of cattle, sheep, goats and horses	10 <sup>e</sup>	2 <sup>f</sup>	[ <sup>F4</sup> Not detected] in the area tested per carcass		[ <sup>F4</sup> EN ISO 6579-1]	Carcases after dressing but before chilling	Improvements in slaughter hygiene, review of process controls and of origin of animals
[ <sup>F5</sup> 2.1.4	<i>Salmonella</i> spp. Carcases of pigs	10 <sup>e</sup>	3 <sup>f</sup>	[ <sup>F4</sup> Not detected] in the area tested per carcass		[ <sup>F4</sup> EN ISO 6579-1]	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]
[ <sup>F6</sup> 2.1.5	<i>Salmonella</i> spp. Poultry carcasses of broilers and turkeys	10 <sup>e</sup> ( <sup>5</sup> )	7 ( <sup>6</sup> ) From 1.1.2012 c = 5 for broilers From 1.1.2013 c = 5 for turkeys	[ <sup>F4</sup> Not detected] in 25 g of a pooled sample of neck skin		[ <sup>F4</sup> EN ISO 6579-1]	Carcases after chilling	Improvement 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	[ <sup>F4</sup> EN ISO 4833-1]	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	[ <sup>F4</sup> EN ISO 4833-1]	End of the manufacturing process	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
[ <sup>F7</sup> 2.1.9	<i>Campylobacter</i> spp. Carcases of broilers	50	c = 20 From 1.1.2020 c = 15; From 1.1.2025 c = 10	1 000 cfu/g		EN ISO 10272-2	Carcases after chilling	Improvements in slaughter hygiene, review of process controls, of animals' origin and of the biosecurity measures in the farms of origin]

**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 2.1.3-2.1.5 and 2.1.9 m = M.]

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

**d** 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.

**e** The 50 samples shall be derived from 10 consecutive sampling sessions in accordance with the sampling rules and frequencies laid down in this Regulation.

**f** 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.

**g** This criterion shall not apply to minced meat produced at retail level when the shelf-life of the product is less than 24 hours.

**h** *E. coli* is used here as an indicator of faecal contamination.

**i** 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.

**j** [<sup>F3</sup>]<sup>F4</sup>Where *Salmonella* spp. is found, the isolates shall be further serotyped for *Salmonella* Typhimurium and *Salmonella* Enteritidis in order to verify compliance with the microbiological criterion set out in Row 1.28 of Chapter 1.]

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### Textual Amendments

- F2** Substituted by Commission Regulation (EU) 2017/1495 of 23 August 2017 amending Regulation (EC) No 2073/2005 as regards *Campylobacter* in broiler carcasses (Text with EEA relevance).
- F3** Inserted by Commission Regulation (EU) No 1086/2011 of 27 October 2011 amending Annex II to Regulation (EC) No 2160/2003 of the European Parliament and of the Council and Annex I to Commission Regulation (EC) No 2073/2005 as regards salmonella in fresh poultry meat (Text with EEA relevance).
- F4** Substituted by Commission Regulation (EU) 2019/229 of 7 February 2019 amending Regulation (EC) No 2073/2005 on microbiological criteria for foodstuffs as regards certain methods, the food safety criterion for *Listeria monocytogenes* in sprouted seeds, and the process hygiene criterion and food safety criterion for unpasteurised fruit and vegetable juices (ready-to-eat) (Text with EEA relevance).
- F5** Substituted by Commission Regulation (EU) No 217/2014 of 7 March 2014 amending Regulation (EC) No 2073/2005 as regards Salmonella in pig carcasses (Text with EEA relevance).
- F6** Substituted by Commission Regulation (EU) No 1086/2011 of 27 October 2011 amending Annex II to Regulation (EC) No 2160/2003 of the European Parliament and of the Council and Annex I to Commission Regulation (EC) No 2073/2005 as regards salmonella in fresh poultry meat (Text with EEA relevance).
- F7** Inserted by Commission Regulation (EU) 2017/1495 of 23 August 2017 amending Regulation (EC) No 2073/2005 as regards *Campylobacter* in broiler carcasses (Text with EEA relevance).

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

<sup>F7</sup> *Campylobacter* spp. in poultry carcasses of broilers:

- satisfactory, if a maximum of  $c/n$  values are  $> m$ ,
- unsatisfactory, if more than  $c/n$  values are  $> m$ .]

### 2.2 Milk and dairy products

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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>F8</sup> 2.2.1	Enterobacteriaceae Pasteurised milk and other pasteurised liquid dairy products <sup>d</sup>	5	0	10 cfu/ml		[ <sup>F4</sup> EN 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 batch has to be tested for
2.2.4	Coagulase positive staphylococci Cheeses made from milk that has undergone a lower heat treatment than	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 batch has to be tested for

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	pasteurisation <sup>g</sup> and ripened cheeses made from milk or whey that has undergone pasteurisation or a stronger heat treatment <sup>g</sup>							staphylococcal enterotoxins.
2.2.5	Coagulase Unripened positive staphylococci cheeses (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>c</sup> Butter and cream made from raw milk or milk that has undergone a	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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	lower heat treatment than pasteurisation							
2.2.7	Enterobacteriaceae Milk powder and whey powder <sup>d</sup>	5	0	10 cfu/g		[F4]EN 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	[F4]EN 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 purposes intended for infants	5	0	[F4]Not detected] in 10 g		[F4]EN ISO 21528-1]	End of the manufacturing process	Improvements in production hygiene to minimise contamination <sup>i</sup>



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	below six months of age						
2.2.10	Enterobacteriaceae Dried follow-on formulae	0	[ <sup>F4</sup> Not detected] in 10 g		[ <sup>F4</sup> EN ISO 21528-1]	End of the manufacturing process	Improvements in production hygiene to minimise contamination
2.2.11	Presumptive <i>Bacillus cereus</i> Dried infant formulae and dried dietary foods for special medical purposes intended for infants below six months of age	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>F8</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 [<sup>F4</sup>*Cronobacter* spp. 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 *Cronobacter* spp. It shall be the responsibility of the manufacturer to demonstrate to the satisfaction of the competent authority whether such a correlation exists between Enterobacteriaceae and *Cronobacter* spp.]

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

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### Textual Amendments

- F8** 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	[F <sup>4</sup> EN ISO 21528-2]	End of the manufacturing process	Checks on the efficiency of the heat treatment and prevention of recontamination

**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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## 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 egg products:

- 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.

## 2.4 Fishery products

[ <sup>X1</sup> 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			
2.4.1. Shelled and shucked products of cooked crustaceans and molluscan shellfish	E. coli	5	2	1 MPN/g	10 MPN/g	ISO TS 16649-3	End of the manufacturing process	Improvements in production hygiene
	Coagulase positive staphylococci	5	2	100 cfu/g	1 000 cfu/g	EN/ISO 6888-1 or 2	End of the manufacturing process	Improvements in production hygiene

**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.]

### Editorial Information

**X1** Substituted by [Corrigendum to Commission Regulation \(EC\) No 1441/2007 of 5 December 2007 amending Regulation \(EC\) No 2073/2005 on microbiological criteria for foodstuffs \(Official Journal of the European Union L 322 of 7 December 2007\)](#).

## 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 shelled and shucked products of 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.

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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> Precut 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> [ <sup>F9</sup> Unpasteurised <sup>c</sup> 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.

**c** [<sup>F9</sup>The term unpasteurised means that the juice has not been subjected to pasteurisation obtained by time-temperature combinations or to other processes validated to achieve an equivalent bactericidal effect to pasteurisation as regards its effect on *E. coli*.]

### Textual Amendments

**F9** Inserted by [Commission Regulation \(EU\) 2019/229 of 7 February 2019 amending Regulation \(EC\) No 2073/2005 on microbiological criteria for foodstuffs as regards certain methods, the food safety criterion for \*Listeria monocytogenes\* in sprouted seeds, and the process hygiene criterion and food safety criterion for unpasteurised fruit and vegetable juices \(ready-to-eat\)](#) (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.

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

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- 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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