[F1ANNEX 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 1.

Food safety criteria

Food category	Micro-organisms/ their toxins, metabolites	Sampling plan[a]		Limits[b]		Analytical reference method[c]	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[d]	*Listeria monocytogenes*	10	0	[F7Not detected] 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	*Listeria monocytogenes*	5	0	100 cfu/g[e]	EN/ISO 11290-2[f]	Products placed on the market during their shelf-life
			5	0	[F7Not detected] in 25 g[g]	EN/ISO 11290-1	Before the food has left the immediate control of the food business

	those intended for infants and for special medical purposes					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[dh]	*Listeria monocytogenes*	5	0	100 cfu/g	EN/ISO 11290-2[f]	Products placed on the market during their shelf-life
1.4	Minced meat and meat preparations intended to be eaten raw	*Salmonella*	5	0	[F7Not detected] in 25 g	[F7EN ISO 6579-1]	Products placed on the market during their shelf-life
[F41.5	Minced meat and meat preparations made from	*Salmonella*	5	0	[F7Not detected] in 25 g	[F7EN ISO 6579-1]	Products placed on the market during their shelf-life]

	poultry meat intended to be eaten cooked					
1.6	Minced meat and meat preparations made from other species than poultry intended to be eaten cooked	*Salmonella*	5	0	[F7Not detected] in 10 g	[F7EN ISO 6579-1]	Products placed on the market during their shelf-life
1.7	Mechanically separated meat (MSM)[i]	*Salmonella*	5	0	[F7Not detected] in 10 g	[F7EN ISO 6579-1]	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	*Salmonella*	5	0	[F7Not detected] in 25 g	[F7EN ISO 6579-1]	Products placed on the market during their shelf-life

	eliminate the salmonella risk					
[F4 1.9	Meat products made from poultry meat intended to be eaten cooked	*Salmonella*	5	0	[F7 Not detected] in 25 g	[F7 EN ISO 6579-1]	Products placed on the market during their shelf-life]
1.10	Gelatine and collagen	*Salmonella*	5	0	[F7 Not detected] in 25 g	[F7 EN ISO 6579-1]	Products placed on the market during their shelf-life
1.11	Cheeses, butter and cream made from raw milk or milk that has undergone a lower heat treatment than pasteurisation[j]	*Salmonella*	5	0	[F7 Not detected] in 25 g	[F7 EN ISO 6579-1]	Products placed on the market during their shelf-life
1.12	Milk powder and whey powder	*Salmonella*	5	0	[F7 Not detected] in 25 g	[F7 EN ISO 6579-1]	Products placed on the market during their shelf-life

1.13	Ice cream[k], excluding products where the manufacturing process or the composition of the product will eliminate the salmonella risk	*Salmonella*	5	0	[F7Not detected] in 25 g	[F7EN ISO 6579-1]	Products placed on the market during their shelf-life
1.14	Egg products, excluding products where the manufacturing process or the composition of the product will eliminate the salmonella risk	*Salmonella*	5	0	[F7Not detected] in 25 g	[F7EN ISO 6579-1]	Products placed on the market during their shelf-life
1.15	Ready-to-eat foods containing raw egg, excluding products where the	*Salmonella*	5	0	[F7Not detected] in 25 g or ml	[F7EN ISO 6579-1]	Products placed on the market during their shelf-life

	manufacturing process or the composition of the product will eliminate the salmonella risk					
1.16	Cooked crustaceans and molluscan shellfish	*Salmonella*	5	0	[F7Not detected] in 25 g	[F7EN ISO 6579-1]	Products placed on the market during their shelf-life
1.17	Live bivalve molluscs and live echinoderms, tunicates and gastropods	*Salmonella*	5	0	[F7Not detected] in 25 g	[F7EN ISO 6579-1]	Products placed on the market during their shelf-life
1.18	Sprouted seeds (ready-to-eat)[w]	*Salmonella*	5	0	[F7Not detected] in 25 g	[F7EN ISO 6579-1]	Products placed on the market during their shelf-life
1.19	Precut fruit and vegetables (ready-to-eat)	*Salmonella*	5	0	[F7Not detected] in 25 g	[F7EN ISO 6579-1]	Products placed on the market during their shelf-life
1.20	[F7Unpasteurised[x] fruit and vegetable juices	*Salmonella*	5	0	[F7Not detected] in 25 g	[F7EN ISO 6579-1]	Products placed on the market during

	(ready-to-eat)**]**					their shelf-life
1.21	Cheeses, milk powder and whey powder, as referred to in the coagulase-positive staphylococci criteria in Chapter 2.2 of this Annex	Staphylococcal enterotoxins	5	0	Not detected in 25 g	**[**[F7]EN ISO 19020**]**	Products placed on the market during their shelf-life
1.22	Dried infant formulae and dried dietary foods for special medical purposes intended for infants below six months of age	*Salmonella*	30	0	**[**[F7]Not detected**]** in 25 g	**[**[F7]EN ISO 6579-1**]**	Products placed on the market during their shelf-life
1.23	Dried follow-on formulae	*Salmonella*	30	0	**[**[F7]Not detected**]** in 25 g	**[**[F7]EN ISO 6579-1**]**	Products placed on the market during their shelf-life

[F4 1.24	Dried infant formulae and dried dietary foods for special medical purposes intended for infants below 6 months of age[n]	*Cronobacter* spp. [F3 *(Enterobacter sakazakii)*]	30	0	[F7 Not detected] in 10 g		[F7 EN ISO 22964]	Products placed on the market during their shelf-life]
[F8 1.25	Live bivalve molluscs and live echinoderms, tunicates and marine gastropods	*E. coli*[o]	5[p]	1	230 MPN/100 g of flesh and intravalvular liquid	700 MPN/100 g of flesh and intravalvular liquid	EN/ISO 16649-3	Products placed on the market during their shelf-life]
1.26	Fishery products from fish species associated with a high amount of histidine[q]	Histamine	9[r]	2	100 mg/kg	200 mg/kg	[F7 EN ISO 19343]	Products placed on the market during their shelf-life
[F2 1.27	Fishery products, except those in food category	Histamine	9[r]	2	200 mg/kg	400 mg/kg	[F7 EN ISO 19343]	Products placed on the market during their shelf-life]

	1.27a, which have undergone enzyme maturation treatment in brine, manufactured from fish species associated with a high amount of histidine[q]					
[F2[X2 1.27a	Histamine Fish sauce produced by fermentation of fishery products	1	0	400 mg/kg	[F7EN ISO 19343]	Products placed on the market during their shelf-life]]
[F9 1.28	Fresh poultry meat	[F7*Salmonella* Typhimurium[u] *Salmonella* Enteritidis]	5	0	[F7Not detected] in 25 g	[F7EN ISO 6579-1 (for detection) White-Kauffmann-Le Minor scheme (for serotyping)]	Products placed on the market during their shelf-life]
[F10 1.29	Sprouts[w]	Shiga toxin producing *E. coli* (STEC) O157, O26, O111, O103, O145 and O104:H4	5	0	[F7Not detected] in 25 grams	CEN/ ISO TS 13136[v]	Products placed on the market during their shelf-life]

a	n = number of units comprising the sample; c = number of sample units giving values between m and M.
b	**[**[F2]For points 1.1-1.25, 1.27a and 1.28 m = M.**]**
c	The most recent edition of the standard shall be used.
d	Regular testing against the criterion is not required in normal circumstances for the following ready-to-eat foods: — those which have received heat treatment or other processing effective to eliminate *L. monocytogenes*, when recontamination is not possible after this treatment (for example, products heat treated in their final package), — fresh, uncut and unprocessed vegetables and fruits,**[**[F3] excluding sprouted seeds,**]** — bread, biscuits and similar products, — bottled or packed waters, soft drinks, beer, cider, wine, spirits and similar products, — sugar, honey and confectionery, including cocoa and chocolate products, — live bivalve molluscs**[**[F4],**]** — **[**[F5]food grade salt.**]**
e	This criterion shall apply if the manufacturer is able to demonstrate, to the satisfaction of the competent authority, that the product will not exceed the limit 100 cfu/g throughout the shelf-life. The operator may fix intermediate limits during the process that must be low enough to guarantee that the limit of 100 cfu/g is not exceeded at the end of shelf-life.
f	1 ml of inoculum is plated on a Petri dish of 140 mm diameter or on three Petri dishes of 90 mm diameter.
g	This criterion shall apply to products before they have left the immediate control of the producing food business operator, when he is not able to demonstrate, to the satisfaction of the competent authority, that the product will not exceed the limit of 100 cfu/g throughout the shelf-life.
h	Products with pH ≤ 4,4 or $a_w \leq 0,92$, products with pH ≤ 5,0 and $a_w \leq 0,94$, products with a shelf-life of less than five days shall be automatically considered to belong to this category. Other categories of products can also belong to this category, subject to scientific justification.
i	This criterion shall 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	Excluding products when the manufacturer can demonstrate to the satisfaction of the competent authorities that, due to the ripening time and a_w of the product where appropriate, there is no salmonella risk.
k	Only ice creams containing milk ingredients.
l	**[**[F6]**]**
m	**[**[F3]**]**
n	Parallel testing for Enterobacteriaceae and **/**[F7]*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 must 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.**]**
o	*E. coli* is used here as an indicator of faecal contamination.
p	**[**[F8]Each sample unit comprises a minimum number of individual animals according to EN/ISO 6887-3.**]**
q	Particularly fish species of the families: *Scombridae, Clupeidae, Engraulidae, Coryfenidae, Pomatomidae, Scombresosidae*.
r	**[**[F2]Single samples may be taken at retail level. In such a case the presumption laid down in Article 14(6) of Regulation (EC) No 178/2002, according to which the whole batch should be deemed unsafe, shall not apply, unless the result is above M.**]**
s	**[**[F3]**]**
t	**[**[F9]This criterion shall apply to fresh meat from breeding flocks of *Gallus gallus*, laying hens, broilers and breeding and fattening flocks of turkeys.
u	As regards monophasic *Salmonella typhimurium* only **[**[X1]1,4,[5],12:i:-**]** is included.**]**
v	**[**[F10]Taking into account the most recent adaptation by the European Union reference laboratory for *Escherichia coli*, including Verotoxigenic *E. coli* (VTEC), for the detection of STEC O104:H4.
w	Excluding sprouts that have received a treatment effective to eliminate *Salmonella* spp. and STEC.**]**
x	**[**[F11]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 *Salmonella*.**]**

Editorial Information

X1 Substituted by Corrigendum to 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 (Official Journal of the European Union L 281 of 28 October 2011).

X2 Substituted by Corrigendum to Commission Regulation (EU) No 1019/2013 of 23 October 2013 amending Annex I to Regulation (EC) No 2073/2005 as regards histamines in fishery products (Official Journal of the European Union L 282 of 24 October 2013).

Textual Amendments

F2 Substituted by Commission Regulation (EU) No 1019/2013 of 23 October 2013 amending Annex I to Regulation (EC) No 2073/2005 as regards histamine in fishery products (Text with EEA relevance).

F3 Deleted 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).

F4 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).

F5 Inserted 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).

F6 Deleted by Commission Regulation (EU) No 209/2013 of 11 March 2013 amending Regulation (EC) No 2073/2005 as regards microbiological criteria for sprouts and the sampling rules for poultry carcases and fresh poultry meat (Text with EEA relevance).

F7 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).

F8 Substituted by Commission Regulation (EU) 2015/2285 of 8 December 2015 amending Annex II to Regulation (EC) No 854/2004 of the European Parliament and of the Council laying down specific rules for the organisation of official controls on products of animal origin intended for human consumption as regards certain requirements for live bivalve molluscs, echinoderms, tunicates and marine gastropods and Annex I to Regulation (EC) No 2073/2005 on microbiological criteria for foodstuffs (Text with EEA relevance).

F9 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).

F10 Inserted by Commission Regulation (EU) No 209/2013 of 11 March 2013 amending Regulation (EC) No 2073/2005 as regards microbiological criteria for sprouts and the sampling rules for poultry carcases and fresh poultry meat (Text with EEA relevance).

F11 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

[[F8]The limits given refer to each sample unit tested.**]**

The test results demonstrate the microbiological quality of the batch tested[(1)].

L. monocytogenes in ready-to-eat foods intended for infants and for special medical purposes:

— 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.

L. monocytogenes in ready-to-eat foods able to support the growth of *L. monocytogenes* before the food has left the immediate control of the producing food business operator when he is not able to demonstrate that the product will not exceed the limit of 100 cfu/g throughout the shelf-life:

— 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.

[[F8]*L. monocytogenes* in other ready-to-eat foods:

— satisfactory, if all the values observed are ≤ the limit,

— unsatisfactory, if any of the values are > the limit.

E. coli in live bivalve molluscs and live echinoderms, tunicates and marine gastropods:

— satisfactory, if all the five values observed are ≤ 230 MPN/100 g of flesh and intravalvular liquid or if one of the five values observed is > 230 MPN/100 g of flesh and intravalvular liquid but ≤ 700 MPN/100 g of flesh and intravalvular liquid,

— unsatisfactory, if any of the five values observed are > 700 MPN/100 g of flesh and intravalvular liquid or if at least two of the five values observed are > 230 MPN/100 g of flesh and intravalvular liquid.**]**

— satisfactory, if all the values observed are ≤ the limit,

— unsatisfactory, if any of the values are > the limit.

Salmonella in different food categories:

— 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.

Staphylococcal enterotoxins in dairy products:

— satisfactory, if in all the sample units the enterotoxins are not detected,

— unsatisfactory, if the enterotoxins are detected in any of the sample units.

[[F7]*Cronobacter* spp.**]** in dried infant formulae and dried dietary foods for special medical purposes intended for infants below 6 months of age:

— 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.

[[F2]Histamine in fishery products:

Histamine in fishery products from fish species associated with a high amount of histidine except fish sauce produced by fermentation of fishery products:

— satisfactory, if the following requirements are fulfilled:

1. the mean value observed is ≤ m
2. a maximum of c/n values observed are between m and M
3. no values observed excess the limit of M.

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

Histamine in fish sauce produced by fermentation of fishery products:

— satisfactory, if the value observed is ≤ the limit,
— unsatisfactory, if the value observed is > the limit.**]**

Chapter 2.

Process hygiene criteria

2.1 *Meat and products thereof*

Food category	**Micro-organisms**	**Sampling plan[a]**		**Limits[b]**		**Analytical reference method[c]**	**Stage where the criterion applies**	**Action in case of unsatisfactory results**
		n	**c**	**m**	**M**			
2.1.1	Aerobic colony count	5	2	3,5 log cfu/cm^2 daily mean log	5,0 log cfu/cm^2 daily mean log	**[**[F7]EN ISO 4833-1**]**	Carcases of cattle, sheep, goats and horses[d] after dressing but before chilling	Improvements in slaughter hygiene and review of process controls
	Enterobacteriaceae	5	2	1,5 log cfu/cm^2 daily mean log	2,5 log cfu/cm^2 daily mean log	**[**[F7]EN ISO 21528-2**]**	Carcases after dressing but before chilling	Improvements in slaughter hygiene and review of process controls
2.1.2	Aerobic colony count	5	2	4,0 log cfu/cm^2 daily mean log	5,0 log cfu/cm^2 daily mean log	**[**[F7]EN ISO 4833-1**]**	Carcases of pigs[d] after dressing but before chilling	Improvements in slaughter hygiene and review of process controls
	Enterobacteriaceae	5	2	2,0 log cfu/cm^2 daily mean log	3,0 log cfu/cm^2 daily mean log	**[**[F7]EN ISO 21528-2**]**	Carcases after dressing but before chilling	Improvements in slaughter hygiene and review of process controls

2.1.3	*Salmonella*	Carcases of cattle, sheep, goats and horses	50[e]	2[f]	[F7]Not detected] in the area tested per carcase		[F7]EN ISO 6579-1]	Carcases after dressing but before chilling	Improvements in slaughter hygiene, review of process controls and of origin of animals
[F13]2.1.4	*Salmonella*	Carcases of pigs	50[e]	3[f]	[F7]Not detected] in the area tested per carcase		[F7]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]
[F14]2.1.5	*Salmonella* spp.	Poultry carcases of broilers and turkeys	50 ([5])	7 ([6]) From 1.1.2012 c = 5 for broilers From 1.1.2013 c = 5 for turkeys	[F7]Not detected] in 25 g of a pooled sample of neck skin		[F7]EN ISO 6579-1]	Carcases after chilling	Improvement in slaughter hygiene and review of process controls, origin of animals and biosecurity measures in the farms of origin]
2.1.6	Aerobic colony count[g]	Minced meat	5	2	5×10^5 cfu/g	5×10^6 cfu/g	[F7]EN ISO 4833-1]	End of the manufacturing process	Improvements in production hygiene and

								improvements in selection and/or origin of raw materials
	E. coli[h]	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	Mechanically separated meat (MSM)[i]	Aerobic colony count	5	2	5×10^5 cfu/g	5×10^6 cfu/g	[F7EN ISO 4833-1]	End of the manufacturing process	Improvements in production hygiene and improvements in selection and/or origin of raw materials
		E. coli[h]	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
2.1.8	Meat preparations	*E. coli*[h]	5	2	500 cfu/g or cm^2	5 000 cfu/g or cm^2	ISO 16649-1 or 2	End of the manufacturing process	Improvements in production hygiene and improvements in selection

								and/or origin of raw materials
[F15 2.1.9	Carcases of broilers	*Campylobacter* spp.	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	[F12For 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 then 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	[F9[F7Where *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.]]

Textual Amendments

F12 Substituted by Commission Regulation (EU) 2017/1495 of 23 August 2017 amending Regulation (EC) No 2073/2005 as regards Campylobacter in broiler carcases (Text with EEA relevance).

F13 Substituted by Commission Regulation (EU) No 217/2014 of 7 March 2014 amending Regulation (EC) No 2073/2005 as regards Salmonella in pig carcases (Text with EEA relevance).

F14 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).

F15 Inserted by Commission Regulation (EU) 2017/1495 of 23 August 2017 amending Regulation (EC) No 2073/2005 as regards Campylobacter in broiler carcases (Text with EEA relevance).

Interpretation of the test results

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

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

Enterobacteriaceae and aerobic colony count in carcases of cattle, sheep, goats, horses and pigs:
— satisfactory, if the daily mean log is ≤ m,
— acceptable, if the daily mean log is between m and M,
— unsatisfactory, if the daily mean log is > M.

Salmonella in carcases:
— 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 ≤ m,
— acceptable, if a maximum of c/n values are between m and M, and the rest of the values observed are ≤ m,
— unsatisfactory, if one or more of the values observed are > M or more than c/n values are between m and M.

[*F15**Campylobacter* spp. in poultry carcases 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*

Food category	Micro-organisms	Sampling plan[a]		Limits[b]		Analytical reference method[c]	Stage where the criterion applies	Action in case of unsatisfactory results
		n	c	m	M			
[F4]2.2.1 Pasteurised milk and other pasteurised liquid dairy products[d]	Entero-bacteriaceae	5	0	10 cfu/ml		[F7]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	*E. coli*[e] 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 *E. coli* count is expected to be highest[f]	Improvements in production hygiene and selection of raw materials
2.2.3	Coagulase-positive staphylococci Cheeses made from raw milk	5	2	10^4 cfu/g	10^5 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 > 10^5 cfu/g are detected, the cheese batch has to be tested for staphylococcal enterotoxins.
2.2.4	Coagulase-positive staphylococci Cheeses made from milk that has undergone a lower heat treatment than pasteurisation[g] and ripened cheeses made from milk or whey that has undergone pasteurisation or a stronger	5	2	100 cfu/g	1 000 cfu/g	EN/ISO 6888-1 or 2		

	heat treatment[g]							
2.2.5	Unripened soft cheeses (fresh cheeses) made from milk or whey that has undergone pasteurisation or a stronger heat treatment[g]	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 > 10^5 cfu/g are detected, the cheese batch has to be tested for staphylococcal enterotoxins.
2.2.6	Butter and cream made from raw milk or milk that has undergone a lower heat treatment than pasteurisation	*E. coli*[e]	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
2.2.7	Milk powder and whey powder[d]	Enterobacteriaceae	5	0	10 cfu/g		[F7]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 > 10^5 cfu/g are detected, the batch has to be tested for staphylococcal enterotoxins.
2.2.8	Ice cream[h] and frozen dairy desserts	Enterobacteriaceae	5	2	10 cfu/g	100 cfu/g	[F7EN ISO 21528-2]	End of the manufacturing process	Improvements in production hygiene
2.2.9	Dried infant formulae and dried dietary foods for special medical purposes intended for infants below six months of age	Enterobacteriaceae	10	0	[F7Not detected] in 10 g		[F7EN ISO 21528-1]	End of the manufacturing process	Improvements in production hygiene to minimise contamination[i]
2.2.10	Dried follow-on formulae	Enterobacteriaceae	5	0	[F7Not detected] in 10 g		[F7EN ISO 21528-1]	End of the manufacturing process	Improvements in production hygiene to minimise contamination

2.2.11	Dried infant formulae and dried dietary foods for special medical purposes intended for infants below six months of age	Presumptive *Bacillus cereus*	5	1	50 cfu/g	500 cfu/g	EN/ISO 7932[j]	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	**[**[F4]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 **/**[F7]*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.

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 ≤ m,

— acceptable, if a maximum of c/n values are between m and M, and the rest of the values observed are ≤ 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 ≤ m,
— acceptable, if a maximum of c/n values are between m and M, and the rest of the values observed are ≤ 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[a]		Limits		Analytical reference method[b]	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	[F7EN 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.

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 ≤ m,
— acceptable, if a maximum of c/n values are between m and M, and the rest of the values observed are ≤ 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*

[X3Food category	Micro-organisms	Sampling plan[a]	Limits			

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.]

		n	c	m	M	Analytical reference method[b]	Stage where the criterion applies	Action in case of unsatisfactory results
2.4.1.	*E. coli* Shelled and shucked products of cooked crustaceans and molluscan shellfish	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

X3 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 ≤ m,

— acceptable, if a maximum of c/n values are between m and M, and the rest of the values observed are ≤ m,

— 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 ≤ m,

— acceptable, if a maximum of c/n values are between m and M, and the rest of the values observed are ≤ 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[a]		Limits		Analytical reference method[b]	Stage where the criterion applies	Action in case of unsatisfactory results
		n	c	m	M			
2.5.1	*E. coli* 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	*E. coli* [F7Unpasteurised[c] 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 [F11The 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*.]

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):

— satisfactory, if all the values observed are ≤ m,

— acceptable, if a maximum of c/n values are between m and M, and the rest of the values observed are ≤ m,

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

Chapter 3.

Rules for sampling and preparation of test samples

3.1 *General rules for sampling and preparation of test samples*

In the absence of more specific rules on sampling and preparation of test samples, the relevant standards of the ISO (International Organisation for Standardisation) and the guidelines of the Codex Alimentarius shall be used as reference methods.

[F14][F12]3.2 *Bacteriological sampling in slaughterhouses and at premises producing minced meat, meat preparations, mechanically separated meat and fresh meat*

Sampling rules for carcases of cattle, pigs, sheep, goats and horses

The destructive and non-destructive sampling methods, the selection of the sampling sites and the rules for storage and transport of samples to be used are set out in standard ISO 17604.

Five carcases shall be sampled at random during each sampling session. Sample sites must be selected taking into account the slaughter technology used in each plant.

When sampling for analyses of *Enterobacteriaceae* and aerobic colony counts, four sites of each carcase shall be sampled. Four tissue samples representing a total of 20 cm^2 shall be obtained by the destructive method. When using the non-destructive method for this purpose, the sampling area shall cover a minimum of 100 cm^2 (50 cm^2 for small ruminant carcases) per sampling site.

When sampling for *Salmonella* analyses, an abrasive sponge sampling method shall be used. Areas most likely to be contaminated shall be selected. The total sampling area shall cover a minimum of 400 cm^2.

When samples are taken from the different sampling sites on the carcase, they shall be pooled before examination.

Sampling rules for poultry carcases and fresh poultry meat

Slaughterhouses shall sample whole poultry carcases with neck skin for *Salmonella* and *Campylobacter* analyses. Cutting and processing establishments other than those adjacent to a slaughterhouse cutting and processing meat received only from this slaughterhouse, shall also take samples for *Salmonella* analysis. When doing so, they shall give priority to whole poultry carcases with neck skin, if available, but ensuring that also poultry portions with skin and/or poultry portions without skin or with only a small amount of skin are covered, and that choice shall be risk-based.

Slaughterhouses shall include in their sampling plans poultry carcases from flocks with an unknown *Salmonella* status or with a status known to be positive for *Salmonella Enteritidis* or *Salmonella Typhimurium*.

When testing against the process hygiene criteria set out in Row 2.1.5 and Row 2.1.9 of Chapter 2 for *Salmonella* and *Campylobacter* in poultry carcases in slaughterhouses and the tests for *Salmonella* and *Campylobacter* are carried out in the same laboratory, neck skins from a minimum of 15 poultry carcases shall be sampled at random after chilling during each sampling session. Before examination, the neck skin samples from at least three poultry carcases from the same flock of origin shall be pooled into one sample of 26 g. Thus, the neck skin samples form 5 × 26 g final samples (26 g are needed to perform analyses for*Salmonella* and *Campylobacter* from one sample in parallel). The samples shall be kept after sampling and transported to the laboratory at a temperature not lower than 1 °C and not higher than 8 °C and the time between the sampling and the testing for *Campylobacter* shall be of less than 48 hours in order to ensure maintenance of sample integrity. Samples that have reached a temperature of 0 °C shall not be used to verify compliance with the *Campylobacter* criterion. The 5 × 26 g samples shall be used to verify the compliance with process hygiene criteria set out in Row 2.1.5 and Row 2.1.9 of Chapter 2 and the food safety criterion set out in Row 1.28 of Chapter 1. In order to prepare the initial suspension at the laboratory, the 26 g test portion shall be transferred to nine volumes (234 ml) buffered peptone water (BPW). The BPW shall be brought to room temperature before adding. The mixture shall be treated in a stomacher or pulsifier for approximately one minute. Foaming shall be avoided by removing the air from the stomacher bag as much as possible. 10 ml (~ 1 g) of this initial suspension shall be transferred to an empty sterile tube and 1 ml of

the 10 ml shall be used for the enumeration of *Campylobacter* on selective plates. The rest of the initial suspension (250 ml ~ 25 g) shall be used for the detection of *Salmonella*.

When testing against the process hygiene criteria set out in Row 2.1.5 and Row 2.1.9 of Chapter 2 for *Salmonella* and *Campylobacter* in poultry carcases in slaughterhouses and the tests for *Salmonella* and *Campylobacter* are carried out in two different laboratories, neck skins from a minimum of 20 poultry carcases shall be sampled at random after chilling during each sampling session. Before examination, the neck skin samples from at least four poultry carcases from the same flock of origin shall be pooled into one sample of 35 g. Thus, the neck skin samples form 5 × 35 g samples, which in turn shall be split in order to obtain 5 × 25 g final samples (to be tested for *Salmonella*) and 5 × 10 g final samples (to be tested for *Campylobacter*). The samples shall be kept after sampling and transported to the laboratory at a temperature not lower than 1 °C and not higher than 8 °C and the time between the sampling and the testing for *Campylobacter* shall be of less than 48 hours in order to ensure maintenance of sample integrity. Samples that have reached a temperature of 0 °C shall not be used to verify compliance with the *Campylobacter* criterion. The 5 × 25 g samples shall be used to verify the compliance with process hygiene criteria set out in Row 2.1.5 of Chapter 2 and the food safety criterion set out in Row 1.28 of Chapter 1. The 5 × 10 g final samples shall be used to verify the compliance with the process hygiene criterion set out in Row 2.1.9 of Chapter 2.

For the *Salmonella* analyses for fresh poultry meat other than poultry carcases, five samples of at least 25 g of the same batch shall be collected. The sample taken from poultry portions with skin shall contain skin and a thin surface muscle slice in case the amount of skin is not sufficient to form a sample unit. The sample taken from poultry portions without skin or with only a small amount of skin shall contain a thin surface muscle slice or slices added to any skin present to make a sufficient sample unit. The slices of meat shall be taken in a way that includes as much as possible of the surface of the meat.

Guidelines for sampling

More detailed guidelines on the sampling of carcases, in particular concerning the sampling sites, may be included in the guides to good practice referred to in Article 7 of Regulation (EC) No 852/2004.

Sampling frequencies for carcases, minced meat, meat preparations, mechanically separated meat and fresh poultry meat

The food business operators of slaughterhouses or establishments producing minced meat, meat preparations, mechanically separated meat or fresh poultry meat shall take samples for microbiological analysis at least once a week. The day of sampling shall be changed each week to ensure that each day of the week is covered.

As regards the sampling of minced meat and meat preparations for *E. coli* and aerobic colony count analyses and the sampling of carcases for *Enterobacteriaceae* and aerobic colony count analyses, the frequency may be reduced to fortnightly testing if satisfactory results are obtained for six consecutive weeks.

In the case of sampling for *Salmonella* analyses of minced meat, meat preparations, carcases and fresh poultry meat, the frequency may be reduced to fortnightly if satisfactory results have been obtained for 30 consecutive weeks. The *Salmonella* sampling frequency may also be reduced if there is a national or regional *Salmonella* control programme in place and if this programme includes testing that replaces the sampling laid down in this paragraph. The sampling frequency may be further reduced if the national or regional *Salmonella* control programme demonstrates that the *Salmonella* prevalence is low in animals purchased by the slaughterhouse.

In the case of sampling for *Campylobacter* analysis of poultry carcases, the frequency may be reduced to fortnightly if satisfactory results have been obtained for 52 consecutive weeks.

The *Campylobacter* sampling frequency may be reduced, after authorisation by the competent authority, if there is an official or officially recognised national or regional *Campylobacter* control programme in place and if this programme includes sampling and testing equivalent to the sampling and testing required for verifying compliance with the process hygiene criterion set out in Row 2.1.9 of Chapter 2. If low contamination level of flocks is set for *Campylobacter* in the control programme, the sampling frequency may be further reduced if this low contamination level of *Campylobacter* is reached over a 52-week period in the farms of origin of the broilers purchased by the slaughterhouse. In case the control programme shows satisfactory results during a specific period of the year, frequency of analysis of *Campylobacter* may also be adjusted to seasonal variations after authorisation by the competent authority.

However, when justified on the basis of a risk analysis and consequently authorised by the competent authority, small slaughterhouses and establishments producing minced meat, meat preparations and fresh poultry meat in small quantities may be exempted from these sampling frequencies.**]**

[[F10]3.3 *Sampling rules for sprouts*

For the purposes of this Section, the definition of batch in Article 2(b) of Implementing Regulation (EU) No 208/2013 will apply.

A. *General rules for sampling and testing*

1. Preliminary testing of the batch of seeds

Food business operators producing sprouts shall carry out a preliminary testing of a representative sample of all batches of seeds. A representative sample shall include at least 0,5 % of the weight of the batch of seeds in sub samples of 50 g or be selected based on a structured statistically equivalent sampling strategy verified by the competent authority.

For the purposes of performing the preliminary testing, the food business operator must sprout the seeds in the representative sample under the same conditions as the rest of the batch of seeds to be sprouted.

2. Sampling and testing of the sprouts and the spent irrigation water

Food business operators producing sprouts shall take samples for microbiological testing at the stage where the probability of finding Shiga toxin producing *E. coli* (STEC) and *Salmonella* spp. is the highest, in any case not before 48 hours after the start of the sprouting process.

Samples of sprouts shall be analysed according to the requirements in rows 1.18 and 1.29 of Chapter 1.

However, if a food business operator producing sprouts has a sampling plan, including sampling procedures and sampling points of the spent irrigation water, they may replace the sampling requirement under the sampling plans set out in rows 1.18 and 1.29 of Chapter 1 with the analysis of 5 samples of 200 ml of the water that was used for the irrigation of the sprouts.

In that case requirements set out in rows 1.18 and 1.29 of Chapter 1 shall apply to the analysis of the water that was used for the irrigation of the sprouts, with the limit of absence in 200 ml.

When testing a batch of seeds for the first time, food business operators may only place sprouts on the market if the results of the microbiological analysis comply with rows 1.18 and 1.29 of Chapter 1, or the limit of absence in 200 ml if they analyse spent irrigation water.

3. Sampling frequency

Food business operators producing sprouts shall take samples for microbiological analysis at least once a month at the stage where the probability of finding Shiga toxin producing *E. coli* (STEC) and *Salmonella* spp. is the highest, in any case not before 48 hours after the start of the sprouting process.

B. *Derogation from the preliminary testing of all batches of seeds set out in point A.1 of this Section*

When justified on the basis of the following conditions and authorised by the competent authority, food business operators producing sprouts may be exempted from the sampling set out in point A.1 of this Section:

(a) the competent authority is satisfied that the food business operator implements a food safety management system in that establishment, which may include steps in the production process, which reduces the microbiological risk; and,

(b) historical data confirms that during at least 6 consecutive months prior to granting the authorisation, all batches of the different types of sprouts produced in the establishment comply with the food safety criteria set out in rows 1.18 and 1.29 of Chapter 1.**]]]**

(1) **[**[F1]The test results may be used also for demonstrating the effectiveness of the hazard analysis and critical control point principles or good hygiene procedure of the process.**]**

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).

Status:
Point in time view as at 28/02/2019.

Changes to legislation:
There are currently no known outstanding effects for the Commission Regulation (EC) No 2073/2005, ANNEX I.