[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] n	c	Limits[b] m	M	Analytical reference method[c]	Stage where the criterion applies
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
[F4 1.5	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.**]]**

(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, Chapter 1..