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)

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THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Regulation (EC) No 852/2004 of the European Parliament and of the Council of 29 April 2004 on the hygiene of foodstuffs[(1)], and in particular Article 4(4) thereof,

Whereas:

(1) Commission Regulation (EC) No 2073/2005 of 15 November 2005 on microbiological criteria for foodstuffs[(2)] lays down microbiological criteria for certain micro-organisms and the implementing rules to be complied with by food business operators when implementing the general and specific hygiene measures referred to in Article 4 of Regulation (EC) No 852/2004. Regulation (EC) No 2073/2005 also provides that food business operators are to ensure that foodstuffs comply with the relevant microbiological criteria set out in Annex I to that Regulation.

(2) Chapters 1 and 2 of Annex I to Regulation (EC) No 2073/2005 set out food safety criteria and process hygiene criteria regarding dried infant formulae and dried dietary foods for special medical purposes intended for infants below six months of age (dried infant formulae and dried dietary foods). Part 2.2 of Chapter 2 of that Annex provides that where dried infant formulae and dried dietary foods are tested and Enterobacteriaceae are detected in any of the sample units, the batch is to be tested for *Enterobacter sakazakii* and *Salmonella*.

(3) On 24 January 2007, the Scientific Panel on Biological Hazards (BIOHAZ Panel) of the European Food Safety Authority (EFSA) issued an opinion with regard to Enterobacteriaceae as indicators of *Salmonella* and *Enterobacter sakazakii*. It concluded that it is not possible to establish a correlation between Enterobacteriaceae and *Salmonella*, and no universal correlation between Enterobacteriaceae and *Enterobacter sakazakii* exists. At individual plant level, a correlation between Enterobacteriaceae and *Enterobacter sakazakii* may however be established.

(4) Therefore the requirement laid down in Regulation (EC) No 2073/2005 as regards the testing of dried infant formulae and dried dietary foods for *Salmonella* and *Enterobacter sakazakii* where Enterobacteriaceae are detected in any of the sample units should no

longer apply. Part 2.2 of Chapter 2 of Annex I to that Regulation should therefore be amended accordingly.

(5) In line with the opinion on the microbiological risks in infant formulae and follow-on formulae issued by the BIOHAZ Panel of EFSA on 9 September 2004, microbiological criteria on *Salmonella* and Enterobacteriaceae should be laid down for dried follow-on formulae.

(6) The BIOHAZ Panel of EFSA issued an opinion on *Bacillus cereus* and other *Bacillus* spp. in foodstuffs on 26 and 27 January 2005. It concluded that one of the major control measures is to control temperature and to establish a system based on hazard analysis and critical control point principles. Dehydrated foods, in which the presence of spores of pathogenic *Bacillus* spp. is frequent, might permit the growth of *Bacillus cereus* once rehydrated in warm water. Some dehydrated foods, including dried infant formulae and dried dietary foods, are consumed by potentially fragile consumers. In line with the EFSA opinion, the numbers of *Bacillus cereus* spores in dried infant formulae and dried dietary foods should be as low as possible during processing and a process hygiene criterion should be laid down in addition to good practices designed to reduce delay between preparation and consumption.

(7) Chapter 1 of Annex I to Regulation (EC) No 2073/2005 provides for the analytical reference method for staphylococcal enterotoxins in certain cheeses, milk powder and whey powder. That method has been revised by the Community reference laboratory for coagulase positive staphylococci. The reference to that analytical reference method should therefore be amended. Chapter 1 of Annex I to that Regulation should therefore be amended accordingly.

(8) Chapter 3 of Annex I to Regulation (EC) No 2073/2005 sets out sampling rules for carcasses of cattle, pig, sheep, goats and horses for *Salmonella* analyses. Pursuant to those rules the sampling area is to cover a minimum of 100 cm^2 per site selected. However, neither the number of sampling sites nor the minimum total area of sampling is specified. In order to improve the implementation of these rules in the Community, it is appropriate to further specify in Regulation (EC) No 2073/2005 that the areas most likely to be contaminated should be selected for sampling and that the total sampling area should be increased. Chapter 3 of Annex I to that Regulation should therefore be amended accordingly.

(9) In the interests of clarity of Community legislation, it is appropriate to replace Annex I to Regulation (EC) No 2073/2005 by the text set out in the Annex to this Regulation.

(10) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on the Food Chain and Animal Health,

HAS ADOPTED THIS REGULATION:

Article 1

Annex I to Regulation (EC) No 2073/2005 is replaced by the text in the Annex to this Regulation.

Article 2

This Regulation shall enter into force on the 20th day following its publication in the *Official Journal of the European Union*.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels, 5 December 2007.

For the Commission

Markos KYPRIANOU

Member of the Commission

ANNEX

ANNEX I

Microbiological criteria for foodstuffs

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	Absence in 25 g		EN/ISO 11290-1	Products placed on the market during their shelf-life
1.2	Ready-to-eat foods able to support the growth of *L. monocytogenes*, other than those intended for	*Listeria monocytogenes* 5	0	100 cfu/g[e]		EN/ISO 11290-2[f]	Products placed on the market during their shelf-life
		5	0	Absence in 25 g[g]		EN/ISO 11290-1	Before the food has left the immediate control of the food business operator, who has

	infants and for special medical purposes					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	Absence in 25 g	EN/ISO 6579	Products placed on the market during their shelf-life
1.5	Minced meat and meat preparations made from poultry meat intended	*Salmonella*	5	0	From 1.1.2006 Absence in 10 g From 1.1.2010 Absence in 25 g	EN/ISO 6579	Products placed on the market during their shelf-life

	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	Absence in 10 g	EN/ISO 6579	Products placed on the market during their shelf-life
1.7	Mechanically separated meat (MSM)[i]	*Salmonella*	5	0	Absence in 10 g	EN/ISO 6579	Products placed on the market during their shelf-life
1.8	Meat products intended to be eaten raw, excluding products where the manufacturing process or the composition of the product will eliminate the	*Salmonella*	5	0	Absence in 25 g	EN/ISO 6579	Products placed on the market during their shelf-life

	salmonella risk					
1.9	*Salmonella* Meat products made from poultrymeat intended to be eaten cooked	5	0	From 1.1.2006 Absence in 10 g From 1.1.2010 Absence in 25 g	EN/ISO 6579	Products placed on the market during their shelf-life
1.10	*Salmonella* Gelatine and collagen	5	0	Absence in 25 g	EN/ISO 6579	Products placed on the market during their shelf-life
1.11	*Salmonella* Cheeses, butter and cream made from raw milk or milk that has undergone a lower heat treatment than pasteurisation[j]	5	0	Absence in 25 g	EN/ISO 6579	Products placed on the market during their shelf-life
1.12	*Salmonella* Milk powder and whey powder	5	0	Absence in 25 g	EN/ISO 6579	Products placed on the market during their shelf-life
1.13	*Salmonella* Ice cream[k], excluding	5	0	Absence in 25 g	EN/ISO 6579	Products placed on the market

	products where the manufacturing process or the composition of the product will eliminate the salmonella risk					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	Absence in 25 g	EN/ISO 6579	Products placed on the market during their shelf-life
1.15	Ready-to-eat foods containing raw egg, excluding products where the manufacturing process or the	*Salmonella*	5	0	Absence in 25 g or ml	EN/ISO 6579	Products placed on the market during their shelf-life

	composition of the product will eliminate the salmonella risk					
1.16	*Salmonella* Cooked crustaceans and molluscan shellfish	5	0	Absence in 25 g	EN/ISO 6579	Products placed on the market during their shelf-life
1.17	*Salmonella* Live bivalve molluscs and live echinoderms, tunicates and gastropods	5	0	Absence in 25 g	EN/ISO 6579	Products placed on the market during their shelf-life
1.18	*Salmonella* Sprouted seeds (ready-to-eat)[1]	5	0	Absence in 25 g	EN/ISO 6579	Products placed on the market during their shelf-life
1.19	*Salmonella* Precut fruit and vegetables (ready-to-eat)	5	0	Absence in 25 g	EN/ISO 6579	Products placed on the market during their shelf-life
1.20	*Salmonella* Unpasteurised fruit and vegetable juices (ready-to-eat)	5	0	Absence in 25 g	EN/ISO 6579	Products placed on the market during 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	European screening method of the CRL for coagulase positive staphylococci[m]	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	Absence in 25 g	EN/ISO 6579	Products placed on the market during their shelf-life
1.23	Dried follow-on formulae	*Salmonella*	30	0	Absence in 25 g	EN/ISO 6579	Products placed on the market during their shelf-life
1.24	Dried infant	*Enterobacter sakazakii*	30	0	Absence in 10 g	ISO/TS 22964	Products placed on the

	formulae and dried dietary foods for special medical purposes intended for infants below six months of age[n]						market during their shelf-life
1.25	*E. coli*[o]	Live bivalve molluscs and live echinoderms, tunicates and gastropods	1[p]	0	230 MPN/100 g of flesh and intra-valvular liquid	ISO TS 16649-3	Products placed on the market during their shelf-life
1.26	Histamine	Fishery products from fish species associated with a high amount of histidine[q]	9[r]	2	100 mg/kg	200 mg/kg	HPLC[s]	Products placed on the market during their shelf-life
1.27	Histamine	Fishery products which have undergone enzyme maturation treatment in brine, manufactured	9	2	200 mg/kg	400 mg/kg	HPLC[s]	Products placed on the market during their shelf-life

	from fish species associated with a high amount of histidine[q]						

a	n = number of units comprising the sample; c = number of sample units giving values between m and M.
b	For points 1.1-1.25 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, 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.
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	Preliminary testing of the batch of seeds before starting the sprouting process or the sampling must be carried out at the stage where the highest probability of finding Salmonella is expected.
m	*Reference:* Community reference laboratory for coagulase positive staphylococci. European screening method for the detection of staphylococcal enterotoxins in milk and milk products.
n	Parallel testing for Enterobacteriaceae and *E. sakazakii* shall be conducted, unless a correlation between these micro-organisms has been established at an individual plant level. If Enterobacteriaceae are detected in any of the product samples tested in such a plant, the batch must be tested for *E. sakazakii*. 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 *E. sakazakii*.
o	*E. coli* is used here as an indicator of faecal contamination.
p	A pooled sample comprising a minimum of 10 individual animals.
q	Particularly fish species of the families: *Scombridae, Clupeidae, Engraulidae, Coryfenidae, Pomatomidae, Scombresosidae*.
r	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 is to be deemed unsafe, shall not apply.
s	*References*: 1. Malle P., Valle M., Bouquelet S. Assay of biogenic amines involved in fish decomposition. J. AOAC Internat. 1996, 79, 43-49. 2. Duflos G., Dervin C., Malle P., Bouquelet S. Relevance of matrix effect in determination

of biogenic amines in plaice (*Pleuronectes platessa*) and whiting (*Merlangus merlangus*. J. AOAC Internat. 1999, 82, 1097-1101.

Interpretation of the test results

The limits given refer to each sample unit tested, excluding live bivalve molluscs and live echinoderms, tunicates and gastropods in relation to testing *E. coli*, where the limit refers to a pooled sample.

The test results demonstrate the microbiological quality of the batch tested[(3)].

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.

L. monocytogenes in other ready-to-eat foods and *E. coli* in live bivalve molluscs:
— 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.

Enterobacter sakazakii 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.

Histamine in fishery products from fish species associated with a high amount of histidine:
— 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 exceed 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.

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			3,5 log cfu/cm^2 daily mean log	5,0 log cfu/cm^2 daily mean log	ISO 4833	Carcases after dressing but before chilling	Improvements in slaughter hygiene and review of process controls
	Enterobacteriaceae			1,5 log cfu/cm^2 daily mean log	2,5 log cfu/cm^2 daily mean log	ISO 21528-2	Carcases after dressing but before chilling	Improvements in slaughter hygiene and review of process controls
2.1.2	Aerobic colony count			4,0 log cfu/cm^2 daily mean log	5,0 log cfu/cm^2 daily mean log	ISO 4833	Carcases after dressing but before chilling	Improvements in slaughter hygiene and review of process controls
	Enterobacteriaceae			2,0 log cfu/cm^2 daily mean log	3,0 log cfu/cm^2 daily mean log	ISO 21528-2	Carcases after dressing but before chilling	Improvements in slaughter hygiene and review of process controls
2.1.3	*Salmonella*	50[e]	2[f]	Absence in the area tested per carcase		EN/ISO 6579	Carcases after dressing but	Improvements in slaughter hygiene,

Carcases of cattle, sheep, goats and horses[d]

Carcases of pigs[d]

Carcases of cattle,

	sheep, goats and horses						before chilling	review of process controls and of origin of animals
2.1.4	Carcases of pigs	*Salmonella*	50[e]	5[f]	Absence in the area tested per carcase	EN/ISO 6579	Carcases after dressing but before chilling	Improvements in slaughter hygiene and review of process controls, origin of animals and of the biosecurity measures in the farms of origin
2.1.5	Poultry carcases of broilers and turkeys	*Salmonella*	50[e]	7[f]	Absence in 25 g of a pooled sample of neck skin	EN/ISO 6579	Carcases after chilling	Improvements in slaughter hygiene and review of process controls, origin of animals and biosecurity measures in the farms of origin
2.1.6	Minced meat[g]	Aerobic colony count	5	2	5×10^5 cfu/g	5×10^6 cfu/g	ISO 4833	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	ISO 4833	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

a	n = number of units comprising the sample; c = number of sample units giving values between m and M.
b	For points 2.1.3-2.1.5 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.

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.

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**			

2.2.1	Pasteurised milk and other pasteurised liquid dairy products[d]	Enterobacteriaceae	5	2	< 1/ml	5/ml	ISO 21528-1	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	Cheeses made from milk or whey that has undergone heat treatment	*E. coli*[e]	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	Cheeses made from raw milk	Coagulase-positive staphylococci	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	Cheeses made from milk that has undergone a lower heat treatment than pasteurisation[g] and ripened cheeses made	Coagulase-positive staphylococci	5	2	100 cfu/g	1 000 cfu/g	EN/ISO 6888-1 or 2		

	from milk or whey that has undergone pasteurisation or a stronger 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	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	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	Absence in 10 g	ISO 21528-1	End of the manufacturing process	Improvements in production hygiene to minimise contamination[i]

2.2.10	Dried follow-on formulae	Enterobacteriaceae	0	Absence in 10 g		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	For points 2.2.7, 2.2.9 and 2.2.10 m = M.
c	The most recent edition of the standard shall be used.
d	The criterion shall not apply to products intended for further processing in the food industry.
e	E. coli is used here as an indicator for the level of hygiene.
f	For cheeses which are not able to support the growth of E. coli, the E. coli count is usually the highest at the beginning of the ripening period, and for cheeses which are able to support the growth of E. coli, it is normally at the end of the ripening period.
g	Excluding cheeses where the manufacturer can demonstrate, to the satisfaction of the competent authorities, that the product does not pose a risk of staphylococcal enterotoxins.
h	Only ice creams containing milk ingredients.
i	Parallel testing for Enterobacteriaceae and E. sakazakii shall be conducted, unless a correlation between these micro-organisms has been established at an individual plant level. If Enterobacteriaceae are detected in any of the product samples tested in such a plant, the batch has to be tested for E. sakazakii. It shall be the responsibility of the manufacturer to demonstrate to the satisfaction of the competent authority whether such a correlation exists between Enterobacteriaceae and E. sakazakii.
j	1 ml of inoculum is plated on a Petri dish of 140 mm diameter or on three Petri dishes of 90 mm diameter.

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	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*

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			
2.4.1	*E. coli*	5	2	1/g	10/g	ISO TS 16649-3	End of the manufacturing process	Improvements in production hygiene
	Shelled and shucked products of cooked crustaceans and molluscan shellfish							
	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.

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			

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.

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* Unpasteurised fruit and vegetable juices (ready-to-eat)	5	2	100 cfu/g	1 000 cfu/g	ISO 16649-1 or 2	Manufacturing process	Improvements in production hygiene, selection of raw materials

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

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

Interpretation of the test results

The limits given refer to each sample unit tested.

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

E. coli in 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.

3.2 *Bacteriological sampling in slaughterhouses and at premises producing minced meat and meat preparations*

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 are described 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

For the Salmonella analyses, a minimum of 15 carcases shall be sampled at random during each sampling session and after chilling. A piece of approximately 10 g from neck skin shall be obtained from each carcase. On each occasion the neck skin samples from three carcases shall be pooled before examination in order to form 5 × 25 g final samples.

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 and mechanically separated meat

The food business operators of slaughterhouses or establishments producing minced meat, meat preparations or mechanically separated 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 and carcases, 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 described 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.

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

(**1**) OJ L 139, 30.4.2004, p. 1, as corrected by OJ L 226, 25.6.2004, p. 3.

(**2**) OJ L 338, 22.12.2005, p. 1.

(**3**) 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.

Changes to legislation:
There are currently no known outstanding effects for the Commission Regulation (EC) No 1441/2007.