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EUROPEAN COMMISSION

Brussels,
C(2009)

Draft

COMMISSION REGULATION

of

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)

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COMMISSION REGULATION (EC) No .../..

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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)

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Regulation (EC) No 852/2004 of the European Parliament and of the Council of 29 April 2004 on the hygiene of foodstuffs¹, and in particular Article 4(4) thereof,

Whereas:

- (1) Commission Regulation (EC) No 2073/2005 of 15 November on microbiological criteria for foodstuffs² 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.
- (2) According to the article 10 of Regulation (EC) No 2073/2005 microbiological criteria shall be reviewed taking into account progress in science, technology and methodology, emerging pathogenic micro-organisms in foodstuffs, and information from risk assessments.
- (3) Chapter 1 of Annex I to Regulation (EC) No 2073/2005 sets out food safety criteria for *Listeria monocytogenes* in certain ready-to-eat foods. Part 1.3 provides limits for ready-to-eat foods unable to support the growth of *L. monocytogenes*, other than those intended for infants and for special medical purposes. The compliance of the criteria needs to be proven in products placed on the market during their shelf-life.
- (4) According to the Regulation (EC) 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety³, food grade salt is a ready-to-eat food. According to scientific evidence, presence and survival of *L. monocytogenes* in salt is unlikely in normal circumstances. Therefore, food grade

¹ OJ L 139, 30.4.2004, p. 1.

² OJ L 338, 22.12.2005, p. 1

³ OJ L 31, 1.2.2002, p. 1.

salt should be added to ready-to-eat foods in which regular testing of *L. monocytogenes* is not required.

- (5) According to Regulation (EC) No 2073/2005, a process hygiene criterion applies to Enterobacteriaceae in pasteurised milk and other pasteurised liquid dairy products including an analytical reference method and limits.
- (6) The analytical reference method set out for Enterobacteriaceae in pasteurised milk and other pasteurised liquid dairy products ISO 21528-1 has been shown to be difficult to use for routine analyses in own checks since it is very laborious and time consuming. Due to the methodological development the analytical reference method of Enterobacteriaceae in pasteurised milk and other liquid dairy products should be changed to ISO 21528-2 which is quicker and easier to perform. ~~According to the Community Reference Laboratory for milk and milk products the change of the method does not affect the sensitivity of testing.~~
- (7) Analytical reference methods have an effect on test results. Therefore, the criterion limit of Enterobacteriaceae in pasteurised milk and other liquid dairy products needs to be changed accordingly. The change would still guarantee sufficient detection limit of process hygiene since likely problems in manufacturing process would cause much higher growth of Enterobacteriaceae. ~~Enterobacteriaceae are not pathogenic bacteria thus the change would have no influence on human health.~~
- ~~(8)~~ (9) Due to a change in taxonomy the name of *Enterobacter sakazakii* should be changed to *Cronobacter spp. (Enterobacter sakazakii)*.
- ~~(8)~~ (9) 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 amended in accordance with 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, x xxxxxxx 20

The President

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ANNEX

ANNEX I

In Annex I to Regulation (EC) No 2073/2005, Chapter I is replaced by the following:

'Chapter 1. Food safety criteria

Food category	Micro-organisms/ their toxins, metabolites	Sampling-plan ¹		Limits ²		Analytical reference method ³	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 ⁴	<i>Listeria monocytogenes</i>	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 <i>L. monocytogenes</i> , other than those intended for infants and for special medical purposes	<i>Listeria monocytogenes</i>	5	0	100 cfu/g ⁵		EN/ISO 11290-2 ⁶	Products placed on the market during their shelf-life
		5	0	Absence in 25 g ⁷		EN/ISO 11290-1	Before the food has left the immediate control of the food business operator, who has produced it

1.3	Ready-to-eat foods unable to support the growth of <i>L. monocytogenes</i> , other than those intended for infants and for special medical purposes ^{4,8}	<i>Listeria monocytogenes</i>	5	0	100 cfu/g	EN/ISO 11290-2 ⁶	Products placed on the market during their shelf-life
1.4	Minced meat and meat preparations intended to be eaten raw	<i>Salmonella</i>	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 to be eaten cooked	<i>Salmonella</i>	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
1.6	Minced meat and meat preparations made from other species than poultry intended to be eaten cooked	<i>Salmonella</i>	5	0	Absence in 10 g	EN/ISO 6579	Products placed on the market during their shelf-life
1.7	Mechanically separated meat (MSM) ⁹	<i>Salmonella</i>	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 risk	<i>Salmonella</i>	5	0	Absence in 25 g	EN/ISO 6579	Products placed on the market during their shelf-life
1.9	Meat products made from poultry meat intended to be eaten cooked	<i>Salmonella</i>	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	Gelatine and collagen	<i>Salmonella</i>	5	0	Absence in 25 g	EN/ISO 6579	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 ¹⁰	<i>Salmonella</i>	5	0	Absence in 25 g	EN/ISO 6579	Products placed on the market during their shelf-life
1.12	Milk powder and whey powder	<i>Salmonella</i>	5	0	Absence in 25 g	EN/ISO 6579	Products placed on the market during their shelf-life

1.13	Ice cream ¹¹ , excluding products where the manufacturing process or the composition of the product will eliminate the salmonella risk	<i>Salmonella</i>	5	0	Absence in 25 g	EN/ISO 6579	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	<i>Salmonella</i>	5	0	Absence in 25g	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 composition of the product will eliminate the salmonella risk	<i>Salmonella</i>	5	0	Absence in 25 g or ml	EN/ISO 6579	Products placed on the market during their shelf-life
1.16	Cooked crustaceans and molluscan shellfish	<i>Salmonella</i>	5	0	Absence in 25 g	EN/ISO 6579	Products placed on the market during their shelf-life
1.17	Live bivalve molluscs and live echinoderms, tunicates and gastropods	<i>Salmonella</i>	5	0	Absence in 25g	EN/ISO 6579	Products placed on the market during their shelf-life

1.18	Sprouted seeds (ready-to-eat) ¹²	<i>Salmonella</i>	5	0	Absence in 25 g	EN/ISO 6579	Products placed on the market during their shelf-life
1.19	Precut fruit and vegetables (ready-to-eat)	<i>Salmonella</i>	5	0	Absence in 25 g	EN/ISO 6579	Products placed on the market during their shelf-life
1.20	Unpasteurised fruit and vegetable juices (ready-to-eat)	<i>Salmonella</i>	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 25g	European screening method of the CRL for coagulase positive staphylococci ¹³	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 6 months of age	<i>Salmonella</i>	30	0	Absence in 25 g	EN/ISO 6579	Products placed on the market during their shelf-life
1.23	Dried follow-on formulae	<i>Salmonella</i>	30	0	Absence in 25 g	EN/ISO 6579	Products placed on the market during their shelf-life

1.24	Dried infant formulae and dried dietary foods for special medical purposes intended for infants below 6 months of age ¹⁴	<i>Cronobacter spp.</i> (<i>Enterobacter sakazakii</i>)	30	0	Absence in 10 g		ISO/TS 22964	Products placed on the market during their shelf-life
1.25	Live bivalve molluscs and live echinoderms, tunicates and gastropods	<i>E. coli</i> ¹⁵	1 (16)	0	230 MPN / 100g of flesh and intra-valvular liquid		ISO TS 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 ¹⁷	Histamine	9 (18)	2	100 mg/kg	200 mg/kg	HPLC ¹⁹	Products placed on the market during their shelf-life
1.27	Fishery products which have undergone enzyme maturation treatment in brine, manufactured from fish species associated with a high amount of histidine ¹⁷	Histamine	9	2	200 mg/kg	400 mg/kg	HPLC ¹⁹	Products placed on the market during their shelf-life

¹ n = number of units comprising the sample; c = number of sample units giving values over m or between m and M.

² For points 1.1-1.25 m=M

³ The most recent edition of the standard shall be used.

4 Regular testing against the criterion is not useful 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
- [food grade salt](#)

5 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.

6 1 ml of inoculum is plated on a Petri dish of 140 mm diameter or on three Petri dishes of 90 mm diameter.

7 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.

8 Products with $\text{pH} \leq 4.4$ or $a_w \leq 0.92$, products with $\text{pH} \leq 5.0$ 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.

9 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.

10 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.

11 Only ice creams containing milk ingredients.

12 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.

13 *Reference:* Community reference laboratory for coagulase positive staphylococci. European screening method for the detection of staphylococcal enterotoxins in milk and milk products.

14 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*.

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

16 A pooled sample comprising a minimum of 10 individual animals.

17 Particularly fish species of the families: *Scombridae*, *Clupeidae*, *Engraulidae*, *Coryfenidae*, *Pomatomidae*, *Scombrosidae*.

18 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.

19 *References:* 1. Malle P., Valle M., Bouquelet S. Assay of biogenic amines involved in fish decomposition. J. AOAC Internat. 1996, 79, 43-49.

2. Dufflos 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.

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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 tested¹.

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 \leq 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 \leq 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 $>M$.

¹ 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.

In Annex I to Regulation (EC) No 2073/2005, Chapter II, Part 2.2 is replaced by the following:

'Chapter 2. Process hygiene criteria

2.2 Milk and dairy products

Food category	Micro-organisms	Sampling plan ¹		Limits ²		Analytical reference method ³	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 ⁴	Enterobacteriaceae	5	2 ₀	<u>10 cfu/ml</u>		ISO 21528- 1 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 Cheeses made from milk or whey that has undergone heat treatment	<i>E. coli</i> ⁵	5	2	100 cfu/g	1 000 cfu/g	ISO 16649-1 or 2	At the time during the manufacturing process when the <i>E. coli</i> count is expected to be highest ⁶	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 ⁷ and ripened cheeses made from milk or whey that has undergone pasteurisation or a stronger heat treatment ⁷	Coagulase-positive staphylococci	5	2	100 cfu/g	1 000 cfu/g	EN/ISO 6888-1 or 2		
2.2.5	Unripened soft cheeses (fresh cheeses) made from milk or whey that has undergone pasteurisation or a stronger heat treatment ⁷	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	<i>E. coli</i> ⁵	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 ⁴	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 ⁸ 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. ⁹
2.2.10	Dried follow-on formulae	Enterobacteriaceae	5	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 <i>Bacillus cereus</i>	5	1	50 cfu/g	500 cfu/g	EN/ISO 7932 ¹⁰	End of the manufacturing process	Improvements in production hygiene. Prevention of recontamination. Selection of raw material.

¹ n = number of units comprising the sample; c = number of sample units giving values between m and M.

² For points 2.2.1, 2.2.7, 2.2.9 and 2.2.10 m=M

³ The most recent edition of the standard shall be used.

⁴ The criterion shall not apply to products intended for further processing in the food industry.

⁵ *E. coli* is used here as an indicator for the level of hygiene.

- 6 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
7 able to support the growth of *E. coli*, it is normally at the end of the ripening period.
8 Excluding cheeses where the manufacturer can demonstrate, to the satisfaction of the competent authorities, that the product does not pose a risk of staphylococcal
9 enterotoxins.
10 Only ice creams containing milk ingredients.
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*.
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 follow-on formulae:

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

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

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

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

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