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

Changes to legislation: *There are currently no known outstanding effects for the Commission Regulation (EC) No 1441/2007. (See end of Document for details)*

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

Changes to legislation: *There are currently no known outstanding effects for the Commission Regulation (EC) No 1441/2007. (See end of Document for details)*

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 infants and for special medical purposes	*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 produced it
1.3 Ready-to-eat	*Listeria monocytogenes*	5	0	100 cfu/g		EN/ISO 11290-2[f]	Products placed on the

foods unable to support the growth of *L. monocytogenes*, other than those intended for infants and for special medical purposes[dh]						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 to be eaten cooked	*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
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