NEW MICROBIOLOGICAL CRITERIA

In order to standardise the regulation, to prevent differing interpretations and to contribute to the public health protection, harmonised microbiological criteria have been defined in the European level. Indeed, since the 1st January 2006, the Commission regulation (EC) n° 2073/2005 of 15th November 2005 concerning the microbiological criteria for foodstuffs is effective.

In fact, some national or community decrees relating to milk and dairy products are in process of repeal. Then, safety criteria for foodstuffs and process hygiene criteria have been elaborated in order to define their acceptability.

You will find, in the following tables, a summary of the criteria concerning milk and dairy products.

Food safety criteria

Food category	Micro-organisms/ their toxins, metabolites	Sampling plan [1]		Limits [2]		Analytical reference method [3]	Stage where the criterion applied
		n	c	m	M		
Ready-to-eat foods intended for infants and ready-to-eat foods for special medical purposes [4]	*Listeria monocytogenes*	10	0	Absence in 25 g		EN/ISO 11290-1	Products placed on the market during their shelf-life
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 ufc/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
Ready-to-eat foods unable to support the growth of *L. monocytogenes*, other than those intended for infants and for special medical purposes	*Listeria monocytogenes*	5	0	100 ufc/g		EN/ISO 11290-2 [6]	Products placed on the market during their shelf-life
Cheeses, butter and cream made from raw milk or milk that has undergone a lower heat treatment than pasteurisation [10]	*Salmonella*	5	0	Absence in 25 g		EN/ISO 6579	Products placed on the market during their shelf-life
Milk powder and whey powder [10]	*Salmonella*	5	0	Absence in 25 g		EN/ISO 6579	Products placed on the market during their shelf-life
Ice cream [11], 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
Cheeses, milk powder and whey powder, as referred to in the coagulase-positive staphylococci criteria in the table below	Staphylococcal enterotoxins	5	0	Not detected in 25 g		European screening method of the CRL for milk [13]	Products placed on the market during their shelf-life
Dried infant formulae and dried dietary foods for special medical purposes intended for infants below six months of age, as referred to in the Enterobacteriaceae criterion in the table below	*Salmonella*	30	0	Absence in 25 g		EN/ISO 6579	Products placed on the market during their shelf-life

Food category	Micro-organisms/ their toxins, metabolites	Sampling plan [1]		Limits [2]		Analytical reference method [3]	Stage where the criterion applied
		n	c	m	M		
Dried infant formulae and dried dietary foods for special medical purposes intended for infants below six months of age, as referred in the Enterobacteriaceae criterion in the table below	*Enterobacter sakazakii*	30	0	Absence in 10 g		ISO/DTS 22964	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) 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 whose have received heat treatment or other processing effective to eliminate *L. monocytogenes*, when recontamination is not possible after this treatment (e.g. products heat treated in their final package)

(5) This criterion applies 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 should be low enough to guarantee that the limit of 100 cfu/g is not exceeded at the end of the 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 applies 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 pH ≤ 4,4 or a_w ≤ 0,92, products with pH ≤ 5,0 and a_w ≤ 0,94, products with a shelf-life of less than five days are automatically considered to belong to this category. Other categories of products can also belong to this category, subject to scientific justification.

(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.

(13) Reference : Hennekinne et al., J. AOAC Internat. Vol 86, N° 2, 2003.

Interpretation of the test results

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 samples 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:

- 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.

(1) The test results can be used also for demonstrating the effectiveness of the HACCP or good hygiene procedure of the process

Process hygiene criteria – 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			
Pasteurised milk and other pasteurised liquid dairy products [4]	*Entero-bacteriaceae*	5	2	< 1 ufc/ml	5 ufc/ml	ISO 21528-1	End of the manufacturing process	Check on the efficiency of heat-treament and prevention of recontamination as well as the quality of raw materials
Cheeses made from milk or whey that has undergone heat treatment	*E. coli* [5]	5	2	100 ufc/g	1000 ufc/g	ISO 16649-1 ou 2	At the time during the manufacturing process when the *E. coli* count is expected to be highest [6]	Improvements in production hygiene and selection of raw materials
Cheeses made from raw milk	Coagulase-positive staphylococci	5	2	10^4 ufc/g	10^5 ufc/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
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 ufc/g	1000 ufc/g	EN/ISO 6888-1 ou 2		
Unripened soft cheeses (fresh cheeses) made from milk or whey that has undergone pasteurisation or a stronger heat treatment	Coagulase-positive staphylococci	5	2	10 ufc/g	100 ufc/g	EN/ISO 6888-1 ou 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
Butter and cream made from raw milk or milk that has undergone a lower heat treatment than pasteurisation	*E. coli* [5]	5	2	10 ufc/g	100 ufc/g	ISO 16649-1 ou 2	End of the manufacturing process	Improvements in production hygiene and selection of raw materials

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			
Milk powder and whey powder [4]	*Entero-bacteriaceae*	5	0	10 ufc/g		ISO 21528-1	End of the manufacturing process	Check on the efficiency of heat treatment and prevention of recontamination
	Coagulase-positive staphylococci	5	2	10 ufc/g	100 ufc/g	EN/ISO 6888-1 ou 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
Ice cream [8] and frozen dairy desserts	*Entero-bacteriaceae*	5	2	10 ufc/g	100 ufc/g	ISO 21528-2	End of the manufacturing process	Improvements in production hygiene
Dried infant formulae and dried dietary foods for special medical purposes intended for infants below six months of age	*Entero-bacteriaceae*	10	0	Absence in 10 g		ISO 21528-1	End of the manufacturing process	Improvements in production hygiene to minimise contamination. If *Enterobacteriaceae* are detected in any of the sample units, the batch has to be tested for *E. sakazakii* and *Salmonella*

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

(2) For *Enterobacteriaceae* in milk powder and whey powder, m = M

(3) The most recent edition of the standard shall be used

(4) The criterion does 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 able to support the growth of *E. coli*, it is normally at the end of the ripening period

(7) 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

(8) Only ice creams containing milk ingredients

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 and dried dietary foods for special medical purposes intended for infants below six 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 samples unit.

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.