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.	*Listeria monocytogenes*	10	0	Absence in 25 g		EN/ISO 11290-1	Products placed on the market during their shelf-life
1.2.	*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

Ready-to-eat foods intended for infants and ready-to-eat foods for special medical purposes[d]

Ready-to-eat foods able to support the growth of *L. monocytogenes*, other than those intended for infants and for special

	medical purposes					
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 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.	*Salmonella* Minced meat and meat preparations made from other species than poultry intended to be eaten cooked	5	0	Absence in 10 g	EN/ISO 6579	Products placed on the market during their shelf-life
1.7.	*Salmonella* Mechanically separated meat (MSM)[i]	5	0	Absence in 10 g	EN/ISO 6579	Products placed on the market during their shelf-life
1.8.	*Salmonella* Meat products intended to be eaten raw, excluding products where the manufacturing process or the composition of the product will eliminate the salmonella risk	5	0	Absence in 25 g	EN/ISO 6579	Products placed on the market during their shelf-life
1.9.	*Salmonella* Meat products	5	0	From 1.1.2006 Absence in 10 g From 1.1.2010	EN/ISO 6579	Products placed on the

	made from poultry meat intended to be eaten cooked			Absence in 25 g		market during their shelf-life
1.10.	Gelatine and collagen	*Salmonella*	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[j]	*Salmonella*	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[j]	*Salmonella*	5	0	Absence in 25 g	EN/ISO 6579	Products placed on the market during their shelf-life
1.13.	Ice cream[k], excluding products where the manufacturing	*Salmonella*	5	0	Absence in 25 g	EN/ISO 6579	Products placed on the market during their shelf-life

	process or the composition of the product will eliminate the salmonella risk					
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 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	*Salmonella*	5	0	Absence in 25 g or ml	EN/ISO 6579	Products placed on the market during their shelf-life

	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 25g	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* Pre-cut 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.	Staphylococcal enterotoxins Cheeses, milk powder	5	0	Not detected in 25g	European screening method of	Products placed on the market

	and whey powder, as referred to in the coagulase-positive staphylococci criteria in Chapter 2.2 of this Annex				the CRL for Milk[m]	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, as referred to in the Enterobacteriaceae criterion in Chapter 2.2 of this Annex	*Salmonella*	30	0	Absence in 25 g	EN/ISO 6579	Products placed on the market during their shelf-life

1.23.	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 Chapter 2.2 of this Annex	*Enterobacter sakazakii*	30	0	Absence in 10 g	ISO/DTS 22964	Products placed on the market during their shelf-life
1.24.	Live bivalve molluscs and live echinoderms, tunicates and gastropods	*E.coli*[n]	1[o]	0	230 MPN/100g of flesh and intra-valvular liquid	ISO TS 16649-3	Products placed on the market during their shelf-life
1.25.	Fishery products from fish species associated with a	Histamine	9[q]	2	100 mg/kg 200 mg/kg	HPLC[r]	Products placed on the market during their shelf-life

	high amount of histidine[p]						
1.26.	Histamine Fishery products which have undergone enzyme maturation treatment in brine, manufactured from fish species associated with a high amount of histidine[p]	9	2	200 mg/kg	400 mg/kg	HPLC[r]	Products placed on the market during their shelf-life

a	n = number of units comprising the sample; c = number of sample units giving values over m or between m and M.
b	For points 1.1-1.24 m=M.
c	The most recent edition of the standard shall be used.
d	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 (e.g. 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 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.
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 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.
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 are automatically considered to belong to this category. Other categories of products can also belong to this category, subject to scientific justification.
i	This criterion applies to mechanically separated meat (MSM) produced with the techniques referred to in Chapter III, paragraph 3, in section V of Annex III to Regulation (EC) No 853/2004 of the European Parliament and of the Council of 29 April 2004 laying down specific hygiene rules for food of animal origin.
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 to be carried out at the stage where the highest probability of finding *Salmonella* is expected.
m	Reference: Hennekinne et al., J. AOAC Internat. Vol. 86, No 2, 2003.
n	*E. coli* is used here as an indicator of faecal contamination.
o	A pooled sample comprising a minimum of 10 individual animals.
p	Particularly fish species of the families: *Scombridae, Clupeidae, Engraulidae, Coryfenidae, Pomatomidae, Scombresosidae.*
q	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.
r	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[(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.

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.

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