



**COMMISSION REGULATION (EC) No 2073/2005****of 15 November 2005****on microbiological criteria for foodstuffs****(Text with EEA relevance)***Article 1***Subject-matter and scope**

This Regulation lays down the 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. The competent authority shall verify compliance with the rules and criteria laid down in this Regulation in accordance with Regulation (EC) No 882/2004, without prejudice to its right to undertake further sampling and analyses for the purpose of detecting and measuring other micro-organisms, their toxins or metabolites, either as a verification of processes, for food suspected of being unsafe, or in the context of a risk analysis.

This Regulation shall apply without prejudice to other specific rules for the control of micro-organisms laid down in Community legislation and in particular the health standards for foodstuffs laid down in Regulation (EC) No 853/2004 of the European Parliament and of the Council <sup>(1)</sup>, the rules on parasites laid down under Regulation (EC) No 854/2004 of the European Parliament and of the Council <sup>(2)</sup> and the microbiological criteria laid down under Council Directive 80/777/EEC <sup>(3)</sup>.

*Article 2***Definitions**

The following definitions shall apply:

- (a) ‘micro-organisms’ means bacteria, viruses, yeasts, moulds, algae, parasitic protozoa, microscopic parasitic helminths, and their toxins and metabolites;
- (b) ‘microbiological criterion’ means a criterion defining the acceptability of a product, a batch of foodstuffs or a process, based on the absence, presence or number of micro-organisms, and/or on the quantity of their toxins/metabolites, per unit(s) of mass, volume, area or batch;
- (c) ‘food safety criterion’ means a criterion defining the acceptability of a product or a batch of foodstuff applicable to products placed on the market;
- (d) ‘process hygiene criterion’ a criterion indicating the acceptable functioning of the production process. Such a criterion is not applicable to products placed on the market. It sets an indicative contamination value above which corrective actions are required in order to maintain the hygiene of the process in compliance with food law;

<sup>(1)</sup> OJ L 139, 30.4.2004, p. 55, corrected by OJ L 226, 25.6.2004, p. 22.

<sup>(2)</sup> OJ L 139, 30.4.2004, p. 206, corrected by OJ L 226, 25.6.2004, p. 83.

<sup>(3)</sup> OJ L 229, 30.8.1980, p. 1.

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- (e) ‘batch’ means a group or set of identifiable products obtained from a given process under practically identical circumstances and produced in a given place within one defined production period;
- (f) ‘shelf-life’ means either the period corresponding to the period preceding the ‘use by’ or the minimum durability date, as defined respectively in Articles 9 and 10 of Directive 2000/13/EC;
- (g) ‘ready-to-eat food’ means food intended by the producer or the manufacturer for direct human consumption without the need for cooking or other processing effective to eliminate or reduce to an acceptable level micro-organisms of concern;
- (h) ‘food intended for infants’ means food specifically intended for infants, as defined in Commission Directive 91/321/EEC <sup>(1)</sup>;
- (i) ‘food intended for special medical purposes’ means dietary food for special medical purposes, as defined in Commission Directive 1999/21/EC <sup>(2)</sup>;
- (j) ‘sample’ means a set composed of one or several units or a portion of matter selected by different means in a population or in an important quantity of matter, which is intended to provide information on a given characteristic of the studied population or matter and to provide a basis for a decision concerning the population or matter in question or concerning the process which has produced it;
- (k) ‘representative sample’ means a sample in which the characteristics of the batch from which it is drawn are maintained. This is in particular the case of a simple random sample where each of the items or increments of the batch has been given the same probability of entering the sample;
- (l) ‘compliance with microbiological criteria’ means obtaining satisfactory or acceptable results set in Annex I when testing against the values set for the criteria through the taking of samples, the conduct of analyses and the implementation of corrective action, in accordance with food law and the instructions given by the competent authority;

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- (m) the definition of ‘sprouts’ in Article 2(a) of Commission Implementing Regulation (EU) No 208/2013 of 11 March 2013 on traceability requirements for sprouts and seeds intended for the production of sprouts <sup>(3)</sup>;

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- (n) ‘a broad range of foods’, as referred to in EN ISO 16140-2, means food as defined by the first subparagraph of Article 2 of Regulation (EC) No 178/2002 of the European Parliament and of the Council <sup>(4)</sup>;

<sup>(1)</sup> OJ L 175, 4.7.1991, p. 35.

<sup>(2)</sup> OJ L 91, 7.4.1999, p. 29.

<sup>(3)</sup> See page 16 of this Official Journal.

<sup>(4)</sup> Regulation (EC) No 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 safety (OJ L 31, 1.2.2002, p. 1).

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- (o) ‘independent certification body’ means a body which is independent from the organisation that manufactures or distributes the alternative method and which provides a written assurance, in the form of a certificate, testifying that the validated alternative method meets the requirements of EN ISO 16140-2;
- (p) ‘production process assurance of the manufacturer’ means a production process whose management system guarantees that the validated alternative method remains conform to the characteristics required by EN ISO 16140-2 and ensures that mistakes and defects in the alternative method are prevented;

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- (q) ‘reptile meat’ means reptile meat as laid down in point (16) of Article 2 of Commission Delegated Regulation (EU) 2019/625 <sup>(1)</sup>.

**▼ B***Article 3***General requirements**

1. Food business operators shall ensure that foodstuffs comply with the relevant microbiological criteria set out in Annex I. To this end the food business operators at each stage of food production, processing and distribution, including retail, shall take measures, as part of their procedures based on HACCP principles together with the implementation of good hygiene practice, to ensure the following:

- (a) that the supply, handling and processing of raw materials and foodstuffs under their control are carried out in such a way that the process hygiene criteria are met,
- (b) that the food safety criteria applicable throughout the shelf-life of the products can be met under reasonably foreseeable conditions of distribution, storage and use.

2. As necessary, the food business operators responsible for the manufacture of the product shall conduct studies in accordance with Annex II in order to investigate compliance with the criteria throughout the shelf-life. In particular, this applies to ready-to-eat foods that are able to support the growth of *Listeria monocytogenes* and that may pose a *Listeria monocytogenes* risk for public health.

Food businesses may collaborate in conducting those studies.

Guidelines for conducting those studies may be included in the guides to good practice referred to in Article 7 of Regulation (EC) No 852/2004.

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<sup>(1)</sup> Commission Delegated Regulation (EU) 2019/625 of 4 March 2019 supplementing Regulation (EU) 2017/625 of the European Parliament and of the Council with regard to requirements for the entry into the Union of consignments of certain animals and goods intended for human consumption (OJ L 131, 17.5.2019, p. 18).

**▼B***Article 4***Testing against criteria**

1. Food business operators shall perform testing as appropriate against the microbiological criteria set out in Annex I, when they are validating or verifying the correct functioning of their procedures based on HACCP principles and good hygiene practice.
2. Food business operators shall decide the appropriate sampling frequencies, except where Annex I provides for specific sampling frequencies, in which case the sampling frequency shall be at least that provided for in Annex I. Food business operators shall make this decision in the context of their procedures based on HACCP principles and good hygiene practice, taking into account the instructions for use of the foodstuff.

The frequency of sampling may be adapted to the nature and size of the food businesses, provided that the safety of foodstuffs will not be endangered.

*Article 5***Specific rules for testing and sampling**

1. The analytical methods and the sampling plans and methods in Annex I shall be applied as reference methods.
2. Samples shall be taken from processing areas and equipment used in food production, when such sampling is necessary for ensuring that the criteria are met. In that sampling the ISO standard 18593 shall be used as a reference method.

Food business operators manufacturing ready-to-eat foods, which may pose a *Listeria monocytogenes* risk for public health, shall sample the processing areas and equipment for *Listeria monocytogenes* as part of their sampling scheme.

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Food business operators manufacturing dried infant formulae or dried foods for special medical purposes intended for infants below six months, which pose a *Cronobacter* spp. risk shall monitor the processing areas and equipment for Enterobacteriaceae as part of their sampling scheme.

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3. The number of sample units of the sampling plans set out in Annex I may be reduced if the food business operator can demonstrate by historical documentation that he has effective HACCP-based procedures.
4. If the aim of the testing is to specifically assess the acceptability of a certain batch of foodstuffs or a process, the sampling plans set out in Annex I shall be respected as a minimum.
5. Food business operators may use other sampling and testing procedures, if they can demonstrate to the satisfaction of the competent authority that these procedures provide at least equivalent guarantees. Those procedures may include use of alternative sampling sites and use of trend analyses.

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Testing against alternative micro-organisms and related microbiological limits as well as testing of analytes other than microbiological ones shall be allowed only for process hygiene criteria.

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The use of alternative analytical methods is acceptable provided they are:

- validated against the specific reference method provided for in Annex I in accordance with the protocol set out in standard EN ISO 16140-2, and
- validated for the food category specified in the relevant microbiological criterion set in Annex I the compliance with which is verified by the food business operator, or validated for a broad range of food as referred to in EN ISO 16140-2.

Proprietary methods may be used as alternative analytical methods, provided they are:

- validated, in accordance with the protocol set out in standard EN ISO 16140-2, against the specific reference method provided for verifying compliance with the microbiological criteria laid down in Annex I, as provided for in the third subparagraph, and
- certified by an independent certification body.

The certification of the proprietary method referred to in the second indent of the fourth subparagraph shall:

- be subject, at least every 5 years, to reassessment through renewal procedures,
- show that the production process assurance of the manufacturer was evaluated, and
- include a summary of or a reference to the validation results of the proprietary method and a statement on the quality management of the production process of the method.

Food business operators may use other analytical methods than those validated or certified as provided for in the third, fourth and fifth subparagraphs, where such methods have been validated in accordance with internationally accepted protocols and their use has been authorised by the competent authority.

**▼B***Article 6***Labelling requirements**

1. When the requirements for *Salmonella* in minced meat, meat preparations and meat products intended to be eaten cooked of all species set down in Annex I are fulfilled, the batches of those products placed on the market must be clearly labelled by the manufacturer in order to inform the consumer of the need for thorough cooking prior to consumption.

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2. As from 1 January 2010 labelling as referred to in paragraph 1 in respect of minced meat, meat preparations and meat products made from poultrymeat will no longer be required.

*Article 7***Unsatisfactory results**

1. When the results of testing against the criteria set out in Annex I are unsatisfactory, the food business operators shall take the measures laid down in paragraphs 2 to 4 of this Article together with other corrective actions defined in their HACCP-based procedures and other actions necessary to protect the health of consumers.

In addition, they shall take measures to find the cause of the unsatisfactory results in order to prevent the recurrence of the unacceptable microbiological contamination. Those measures may include modifications to the HACCP-based procedures or other food hygiene control measures in place.

2. When testing against food safety criteria set out in Chapter 1 of Annex I provides unsatisfactory results, the product or batch of foodstuffs shall be withdrawn or recalled in accordance with Article 19 of Regulation (EC) No 178/2002. However, products placed on the market, which are not yet at retail level and which do not fulfil the food safety criteria, may be submitted to further processing by a treatment eliminating the hazard in question. This treatment may only be carried out by food business operators other than those at retail level.

The food business operator may use the batch for purposes other than those for which it was originally intended, provided that this use does not pose a risk for public or animal health and provided that this use has been decided within the procedures based on HACCP principles and good hygiene practice and authorised by the competent authority.

3. A batch of 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, with unsatisfactory results in respect of the *Salmonella* criterion, may be used in the food chain only to manufacture heat-treated meat products in establishments approved in accordance with Regulation (EC) No 853/2004.

4. In the event of unsatisfactory results as regards process hygiene criteria the actions laid down in Annex I, Chapter 2 shall be taken.

*Article 8***Transitional derogation**

1. A transitional derogation is granted until 31 December 2009 at the latest pursuant to Article 12 of Regulation (EC) No 852/2004 as regards compliance with the value set in Annex I to this Regulation for

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*Salmonella* in minced meat, meat preparations and meat products intended to be eaten cooked placed on the national market of a Member State.

2. The Member States using this possibility shall notify the Commission and other Member States thereof. The Member State shall:

- (a) guarantee that the appropriate means, including labelling and a special mark, which cannot be confused with the identification mark provided for in Annex II, Section I to Regulation (EC) No 853/2004, are in place to ensure that the derogation applies only to the products concerned when placed on the domestic market, and that products dispatched for intra-Community trade comply with the criteria laid down in Annex I;
- (b) provide that the products to which such transitional derogation applies shall be clearly labelled that they must be thoroughly cooked prior to consumption;
- (c) undertake that when testing against the *Salmonella* criterion pursuant to Article 4, and for the result to be acceptable as regards such transitional derogation, no more than one out of five sample units shall be found to be positive.

*Article 9***Analyses of trends**

Food business operators shall analyse trends in the test results. When they observe a trend towards unsatisfactory results, they shall take appropriate actions without undue delay to remedy the situation in order to prevent the occurrence of microbiological risks.

*Article 10***Review**

This Regulation shall be reviewed taking into account progress in science, technology and methodology, emerging pathogenic micro-organisms in foodstuffs, and information from risk assessments. In particular, the criteria and conditions concerning the presence of salmonella in carcasses of cattle, sheep, goats, horses, pigs and poultry shall be revised in the light of the changes observed in salmonella prevalence.

*Article 11***Repeal**

Decision 93/51/EEC is repealed.

*Article 12*

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

It shall apply from 1 January 2006.

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

**▼ M1***ANNEX I***Microbiological criteria for foodstuffs**

|            |  |
|------------|--|
| Chapter 1. | Food safety criteria .....   |
| Chapter 2. | Process hygiene criteria .....   |
| 2.1        | Meat and products thereof .....  |
| 2.2        | Milk and dairy products .....  |
| 2.3        | Egg products .....   |
| 2.4        | Fishery products .....   |
| 2.5        | Vegetables, fruits and products thereof .....  |
| Chapter 3. | Rules for sampling and preparation of test samples .....   |
| 3.1        | General rules for sampling and preparation of test samples .....   |
| 3.2        | Bacteriological sampling in slaughterhouses and at premises producing minced meat, meat preparations, mechanically separated meat and fresh meat ..... |
| 3.3        | Sampling rules for sprouts .....   |

▼ M1

## 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 | ► <u>M9</u> Not detected ◀ 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 | ► <u>M9</u> Not detected ◀ 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 | ► <u>M9</u> Not detected ◀ in 25 g     |   | ► <u>M9</u> EN ISO 6579-1 ◀     | Products placed on the market during their shelf-life   |
| ▼ <u>M2</u>   |   |                   |   |  |   |                                 |   |
| 1.5 Minced meat and meat preparations made from poultry meat intended to be eaten cooked  | <i>Salmonella</i>                         | 5                 | 0 | ► <u>M9</u> Not detected ◀ in 25 g     |   | ► <u>M9</u> EN ISO 6579-1 ◀     | Products placed on the market during their shelf-life   |
| ▼ <u>M1</u>   |   |                   |   |  |   |                                 |   |
| 1.6 Minced meat and meat preparations made from other species than poultry intended to be eaten cooked  | <i>Salmonella</i>                         | 5                 | 0 | ► <u>M9</u> Not detected ◀ in 10 g     |   | ► <u>M9</u> EN ISO 6579-1 ◀     | Products placed on the market during their shelf-life   |
| 1.7 Mechanically separated meat (MSM) (9)   | <i>Salmonella</i>                         | 5                 | 0 | ► <u>M9</u> Not detected ◀ in 10 g     |   | ► <u>M9</u> EN ISO 6579-1 ◀     | Products placed on the market during their shelf-life   |

▼ **M1**

| Food category   | Micro-organisms/their toxins, metabolites | Sampling plan <sup>(1)</sup> |   | Limits <sup>(2)</sup>                    |   | Analytical reference method <sup>(3)</sup> | Stage where the criterion applies                     |
|---|---|------------------------------|---|--|---|--|---|
|   |   | n                            | c | m  | M |  |   |
| 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 | ► <b>M9</b> Not detected ◀ in 25 g       |   | ► <b>M9</b> EN ISO 6579-1 ◀                | Products placed on the market during their shelf-life |
| ▼ <b>M2</b>   |   |                              |   |  |   |  |   |
| 1.9 Meat products made from poultry meat intended to be eaten cooked  | <i>Salmonella</i>                         | 5                            | 0 | ► <b>M9</b> Not detected ◀ in 25 g       |   | ► <b>M9</b> EN ISO 6579-1 ◀                | Products placed on the market during their shelf-life |
| ▼ <b>M1</b>   |   |                              |   |  |   |  |   |
| 1.10 Gelatine and collagen  | <i>Salmonella</i>                         | 5                            | 0 | ► <b>M9</b> Not detected ◀ in 25 g       |   | ► <b>M9</b> EN ISO 6579-1 ◀                | 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 <sup>(10)</sup>                             | <i>Salmonella</i>                         | 5                            | 0 | ► <b>M9</b> Not detected ◀ in 25 g       |   | ► <b>M9</b> EN ISO 6579-1 ◀                | Products placed on the market during their shelf-life |
| 1.12 Milk powder and whey powder  | <i>Salmonella</i>                         | 5                            | 0 | ► <b>M9</b> Not detected ◀ in 25 g       |   | ► <b>M9</b> EN ISO 6579-1 ◀                | Products placed on the market during their shelf-life |
| 1.13 Ice cream <sup>(11)</sup> , excluding products where the manufacturing process or the composition of the product will eliminate the salmonella risk            | <i>Salmonella</i>                         | 5                            | 0 | ► <b>M9</b> Not detected ◀ in 25 g       |   | ► <b>M9</b> EN ISO 6579-1 ◀                | 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 | ► <b>M9</b> Not detected ◀ in 25 g       |   | ► <b>M9</b> EN ISO 6579-1 ◀                | 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 | ► <b>M9</b> Not detected ◀ in 25 g or ml |   | ► <b>M9</b> EN ISO 6579-1 ◀                | Products placed on the market during their shelf-life |
| 1.16 Cooked crustaceans and molluscan shellfish   | <i>Salmonella</i>                         | 5                            | 0 | ► <b>M9</b> Not detected ◀ in 25 g       |   | ► <b>M9</b> EN ISO 6579-1 ◀                | Products placed on the market during their shelf-life |

▼ **M1**

| 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   |                                 |   |
| 1.17 Live bivalve molluscs and live echinoderms, tunicates and gastropods   | <i>Salmonella</i>                              | 5                 | 0 | ► <b>M9</b> Not detected ◀ in 25 g              |   | ► <b>M9</b> EN ISO 6579-1 ◀     | Products placed on the market during their shelf-life |
| 1.18 Sprouted seeds (ready-to-eat) ► <b>M4</b> (23) ◀   | <i>Salmonella</i>                              | 5                 | 0 | ► <b>M9</b> Not detected ◀ in 25 g              |   | ► <b>M9</b> EN ISO 6579-1 ◀     | Products placed on the market during their shelf-life |
| 1.19 Precut fruit and vegetables (ready-to-eat)   | <i>Salmonella</i>                              | 5                 | 0 | ► <b>M9</b> Not detected ◀ in 25 g              |   | ► <b>M9</b> EN ISO 6579-1 ◀     | Products placed on the market during their shelf-life |
| 1.20 ► <b>M9</b> Unpasteurised (24) fruit and vegetable juices (ready- to-eat) ◀  | <i>Salmonella</i>                              | 5                 | 0 | ► <b>M9</b> Not detected ◀ in 25 g              |   | ► <b>M9</b> EN ISO 6579-1 ◀     | 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                            |   | ► <b>M9</b> EN ISO 19020 ◀      | 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            | <i>Salmonella</i>                              | 30                | 0 | ► <b>M9</b> Not detected ◀ in 25 g              |   | ► <b>M9</b> EN ISO 6579-1 ◀     | Products placed on the market during their shelf-life |
| 1.23 Dried follow-on formulae   | <i>Salmonella</i>                              | 30                | 0 | ► <b>M9</b> Not detected ◀ in 25 g              |   | ► <b>M9</b> EN ISO 6579-1 ◀     | Products placed on the market during their shelf-life |
| ▼ <b>M2</b>   |  |                   |   |   |   |                                 |   |
| 1.24 Dried infant formulae and dried dietary foods for special medical purposes intended for infants below 6 months of age (14)         | <i>Cronobacter</i> spp.<br>► <b>M9</b> ————— ◀ | 30                | 0 | ► <b>M9</b> Not detected ◀ in 10 g              |   | ► <b>M9</b> EN ISO 22964 ◀      | Products placed on the market during their shelf-life |
| ▼ <b>M7</b>   |  |                   |   |   |   |                                 |   |
| 1.25 Live bivalve molluscs and live echinoderms, tunicates and marine gastropods  | <i>E. coli</i> (15)                            | 5 (16)            | 1 | 230 MPN/100 g of flesh and intravalvular liquid | 700 MPN/100 g of flesh and intravalvular liquid | EN/ISO 16649-3                  | Products placed on the market during their shelf-life |
| ▼ <b>M1</b>   |  |                   |   |   |   |                                 |   |
| 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                                       | ► <b>M9</b> EN ISO 19343 ◀      | Products placed on the market during their shelf-life |

▼ **M1**

| Food category   | Micro-organisms/their toxins, metabolites   | Sampling plan <sup>(1)</sup> |   | Limits <sup>(2)</sup>                  |           | Analytical reference method <sup>(3)</sup>   | Stage where the criterion applies                     |
|---|---|------------------------------|---|--|-----------|--|---|
|   |   | n                            | c | m                                      | M         |  |   |
| ▼ <b>M5</b><br>1.27 Fishery products, except those in food category 1.27a, which have undergone enzyme maturation treatment in brine, manufactured from fish species associated with a high amount of histidine <sup>(17)</sup> | Histamine   | 9 <sup>(18)</sup>            | 2 | 200 mg/kg                              | 400 mg/kg | ► <b>M9</b> EN ISO 19343 ◀   | Products placed on the market during their shelf-life |
| ▼ <b>C5</b><br>1.27a Fish sauce produced by fermentation of fishery products  | Histamine   | 1                            | 0 | 400 mg/kg                              |           | ► <b>M9</b> EN ISO 19343 ◀   | Products placed on the market during their shelf-life |
| ▼ <b>M3</b><br>1.28 Fresh poultry meat <sup>(20)</sup>  | ► <b>M9</b> <i>Salmonella</i> Typhimurium <sup>(21)</sup> <i>Salmonella</i> Enteritidis ◀ | 5                            | 0 | ► <b>M9</b> Not detected ◀ in 25 g     |           | ► <b>M9</b> EN ISO 6579-1 (for detection) White-Kauffmann-Le Minor scheme (for serotyping) ◀ | Products placed on the market during their shelf-life |
| ▼ <b>M4</b><br>1.29 Sprouts <sup>(23)</sup>   | Shiga toxin producing <i>E. coli</i> (STEC) O157, O26, O111, O103, O145 and O104:H4       | 5                            | 0 | ► <b>M9</b> Not detected ◀ in 25 grams |           | CEN/ISO TS 13136 <sup>(22)</sup>   | Products placed on the market during their shelf-life |
| ▼ <b>M10</b><br>1.30 Reptile meat   | Salmonella  | 5                            | 0 | Not detected in 25 g                   |           | EN ISO 6579-1  | Products placed on the market during their shelf-life |

▼ **M1**

<sup>(1)</sup> n = number of units comprising the sample; c = number of sample units giving values between m and M.

► **M10** <sup>(2)</sup> For points 1.1-1.24, 1.27a, 1.28-1.30 m = M. ◀

<sup>(3)</sup> The most recent edition of the standard shall be used.

<sup>(4)</sup> 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 ► **M9** ————— ◀
- 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,
- **M2** — food grade salt. ◀

▼ **M1**

- (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.
- **M4** ————— ◀
- **M9** ————— ◀
- (14) Parallel testing for Enterobacteriaceae and ► **M9** *Cronobacter* spp. ◀ 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 ► **M9** *Cronobacter* spp. ◀ 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 ► **M9** *Cronobacter* spp. ◀
- (15) *E. coli* is used here as an indicator of faecal contamination.
- **M7** (16) Each sample unit comprises a minimum number of individual animals according to EN/ISO 6887-3. ◀
- (17) Particularly fish species of the families: *Scombridae*, *Clupeidae*, *Engraulidae*, *Coryfenidae*, *Pomatomidae*, *Scombresosidae*.
- **M5** (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 should be deemed unsafe, shall not apply, unless the result is above M. ◀
- **M9** ————— ◀
- **M3** (20) This criterion shall apply to fresh meat from breeding flocks of *Gallus gallus*, laying hens, broilers and breeding and fattening flocks of turkeys.
- (21) As regards monophasic *Salmonella typhimurium* only ► **C3** 1,4,[5],12:i:- ◀ is included. ◀
- **M4** (22) Taking into account the most recent adaptation by the European Union reference laboratory for *Escherichia coli*, including Verotoxigenic *E. coli* (VTEC), for the detection of STEC O104:H4.
- (23) Excluding sprouts that have received a treatment effective to eliminate *Salmonella* spp. and STEC. ◀
- **M9** (24) The term unpasteurised means that the juice has not been subjected to pasteurisation obtained by time-temperature combinations or to other processes validated to achieve an equivalent bactericidal effect to pasteurisation as regards its effect on *Salmonella*. ◀

▼ M1**Interpretation of the test results**▼ M7

The limits given refer to each sample unit tested.

▼ M1

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.

▼ M7

*L. monocytogenes* in other ready-to-eat foods:

- satisfactory, if all the values observed are  $\leq$  the limit,
- unsatisfactory, if any of the values are  $>$  the limit.

*E. coli* in live bivalve molluscs and live echinoderms, tunicates and marine gastropods:

- satisfactory, if all the five values observed are  $\leq$  230 MPN/100 g of flesh and intravalvular liquid or if one of the five values observed is  $>$  230 MPN/100 g of flesh and intravalvular liquid but  $\leq$  700 MPN/100 g of flesh and intravalvular liquid,
- unsatisfactory, if any of the five values observed are  $>$  700 MPN/100 g of flesh and intravalvular liquid or if at least two of the five values observed are  $>$  230 MPN/100 g of flesh and intravalvular liquid.

▼ M1

- 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,

(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.

▼ M1

— unsatisfactory, if the enterotoxins are detected in any of the sample units.

► M9 *Cronobacter* spp. ◀ 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.

▼ M5

Histamine in fishery products:

Histamine in fishery products from fish species associated with a high amount of histidine except fish sauce produced by fermentation of fishery products:

— 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  $> M$ .

Histamine in fish sauce produced by fermentation of fishery products:

— satisfactory, if the value observed is  $\leq$  the limit,

— unsatisfactory, if the value observed is  $>$  the limit.

## Chapter 2. Process hygiene criteria

## 2.1 Meat and products thereof

| Food category   | Micro-organisms      | Sampling plan <sup>(1)</sup> |                  | Limits <sup>(2)</sup>                             |  | Analytical reference method <sup>(3)</sup> | Stage where the criterion applies            | Action in case of unsatisfactory results   |
|---|----------------------|------------------------------|------------------|---|--|--|--|--|
|   |                      | n                            | c                | m   | M  |  |  |  |
| 2.1.1 Carcasses of cattle, sheep, goats and horses <sup>(4)</sup> | Aerobic colony count |                              |                  | 3,5 log cfu/cm <sup>2</sup> daily mean log        | 5,0 log cfu/cm <sup>2</sup> daily mean log | ►M9 EN ISO 4833-1 ◀                        | Carcasses after dressing but before chilling | Improvements in slaughter hygiene and review of process controls                       |
|   | Enterobacteriaceae   |                              |                  | 1,5 log cfu/cm <sup>2</sup> daily mean log        | 2,5 log cfu/cm <sup>2</sup> daily mean log | ►M9 EN ISO 21528-2 ◀                       | Carcasses after dressing but before chilling | Improvements in slaughter hygiene and review of process controls                       |
| 2.1.2 Carcasses of pigs <sup>(4)</sup>                            | Aerobic colony count |                              |                  | 4,0 log cfu/cm <sup>2</sup> daily mean log        | 5,0 log cfu/cm <sup>2</sup> daily mean log | ►M9 EN ISO 4833-1 ◀                        | Carcasses after dressing but before chilling | Improvements in slaughter hygiene and review of process controls                       |
|   | Enterobacteriaceae   |                              |                  | 2,0 log cfu/cm <sup>2</sup> daily mean log        | 3,0 log cfu/cm <sup>2</sup> daily mean log | ►M9 EN ISO 21528-2 ◀                       | Carcasses after dressing but before chilling | Improvements in slaughter hygiene and review of process controls                       |
| 2.1.3 Carcasses of cattle, sheep, goats and horses                | <i>Salmonella</i>    | 50 <sup>(5)</sup>            | 2 <sup>(6)</sup> | ►M9 Not detected ◀ in the area tested per carcass |  | ►M9 EN ISO 6579-1 ◀                        | Carcasses after dressing but before chilling | Improvements in slaughter hygiene, review of process controls and of origin of animals |

▼ **M1**

| Food category  | Micro-organisms                        | Sampling plan <sup>(1)</sup> |   | Limits <sup>(2)</sup>  |                           | Analytical reference method <sup>(3)</sup> | Stage where the criterion applies            | Action in case of unsatisfactory results   |
|--|--|------------------------------|---|--|---------------------------|--|--|--|
|  |  | n                            | c   | m  | M                         |  |  |  |
| ▼ <b>M6</b><br>2.1.4 Carcasses of pigs                         | <i>Salmonella</i>                      | 50 <sup>(5)</sup>            | 3 <sup>(6)</sup>  | ▶ <b>M9</b> Not detected ◀ in the area tested per carcass          |                           | ▶ <b>M9</b> EN ISO 6579-1 ◀                | Carcasses 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 |
| ▼ <b>M3</b><br>2.1.5 Poultry carcasses of broilers and turkeys | <i>Salmonella</i> spp. <sup>(10)</sup> | 50 <sup>(5)</sup>            | 7 <sup>(6)</sup><br>From 1.1.2012<br>c = 5 for broilers<br>From 1.1.2013<br>c = 5 for turkeys | ▶ <b>M9</b> Not detected ◀ in 25 g of a pooled sample of neck skin |                           | ▶ <b>M9</b> EN ISO 6579-1 ◀                | Carcasses after chilling                     | Improvement in slaughter hygiene and review of process controls, origin of animals and biosecurity measures in the farms of origin         |
| ▼ <b>M1</b><br>2.1.6 Minced meat                               | Aerobic colony count <sup>(7)</sup>    | 5                            | 2   | 5 × 10 <sup>5</sup> cfu/g  | 5 × 10 <sup>6</sup> cfu/g | ▶ <b>M9</b> EN ISO 4833-1 ◀                | End of the manufacturing process             | Improvements in production hygiene and improvements in selection and/or origin of raw materials  |
|  | <i>E. coli</i> <sup>(8)</sup>          | 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) <sup>(9)</sup>         | Aerobic colony count                   | 5                            | 2   | 5 × 10 <sup>5</sup> cfu/g  | 5 × 10 <sup>6</sup> cfu/g | ▶ <b>M9</b> EN ISO 4833-1 ◀                | End of the manufacturing process             | Improvements in production hygiene and improvements in selection and/or origin of raw materials  |
|  | <i>E. coli</i> <sup>(8)</sup>          | 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  |

▼ **M1**

| Food category               | Micro-organisms               | Sampling plan <sup>(1)</sup> |   | Limits <sup>(2)</sup>           |                                   | Analytical reference method <sup>(3)</sup> | Stage where the criterion applies | Action in case of unsatisfactory results   |
|-----------------------------|-------------------------------|------------------------------|---|---------------------------------|-----------------------------------|--|-----------------------------------|--|
|                             |                               | n                            | c   | m                               | M                                 |  |                                   |  |
| 2.1.8 Meat preparations     | <i>E. coli</i> <sup>(8)</sup> | 5                            | 2   | 500 cfu/g<br>or cm <sup>2</sup> | 5 000 cfu/g<br>or cm <sup>2</sup> | ISO 16649-1<br>or 2                        | End of the manufacturing process  | Improvements in production hygiene and improvements in selection and/or origin of raw materials  |
| 2.1.9 Carcasses of broilers | <i>Campylobacter</i> spp.     | 50 <sup>(5)</sup>            | c = 20<br>From 1.1.2020<br>c = 15;<br>From 1.1.2025<br>c = 10 | 1 000 cfu/g                     |                                   | EN ISO 10272-2                             | Carcasses after chilling          | Improvements in slaughter hygiene, review of process controls, of animals' origin and of the biosecurity measures in the farms of origin |

▼ **M1**

<sup>(1)</sup> n = number of units comprising the sample; c = number of sample units giving values between m and M.

► **M8** <sup>(2)</sup> For points 2.1.3-2.1.5 and 2.1.9 m = M. ◀

<sup>(3)</sup> The most recent edition of the standard shall be used.

<sup>(4)</sup> 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.

<sup>(5)</sup> The 50 samples shall be derived from 10 consecutive sampling sessions in accordance with the sampling rules and frequencies laid down in this Regulation.

<sup>(6)</sup> 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.

<sup>(7)</sup> This criterion shall not apply to minced meat produced at retail level when the shelf-life of the product is less than 24 hours.

<sup>(8)</sup> *E. coli* is used here as an indicator of faecal contamination.

<sup>(9)</sup> 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.

► **M3** <sup>(10)</sup> ► **M9** Where *Salmonella* spp. is found, the isolates shall be further serotyped for *Salmonella* Typhimurium and *Salmonella* Enteritidis in order to verify compliance with the microbiological criterion set out in Row 1.28 of Chapter 1. ◀ ◀

## ▼ M1

### Interpretation of the test results

The limits given refer to each sample unit tested, excluding testing of carcasses where the limits refer to pooled samples.

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

Enterobacteriaceae and aerobic colony count in carcasses of cattle, sheep, goats, horses and pigs:

- satisfactory, if the daily mean log is  $\leq m$ ,
- acceptable, if the daily mean log is between  $m$  and  $M$ ,
- unsatisfactory, if the daily mean log is  $> M$ .

*Salmonella* in carcasses:

- 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  $\leq m$ ,
- 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  $M$ .

## ▼ M8

*Campylobacter* spp. in poultry carcasses of broilers:

- satisfactory, if a maximum of  $c/n$  values are  $> m$ ,
- unsatisfactory, if more than  $c/n$  values are  $> m$ .

▼ M1

2.2 Milk and dairy products

| Food category  | Micro-organisms                  | Sampling plan <sup>(1)</sup> |   | Limits <sup>(2)</sup> |                       | Analytical reference method <sup>(3)</sup> | Stage where the criterion applies   | Action in case of unsatisfactory results  |
|--|----------------------------------|------------------------------|---|-----------------------|-----------------------|--|---|---|
|  |                                  | n                            | c | m                     | M                     |  |   |   |
| ▼ <u>M2</u><br>2.2.1 Pasteurised milk and other pasteurised liquid dairy products <sup>(4)</sup>   | Enterobacteriaceae               | 5                            | 0 | 10 cfu/ml             |                       | ► <u>M9</u> EN ISO 21528-2 ◀               | End of the manufacturing process  | Check on the efficiency of heat-treatment and prevention of recontamination as well as the quality of raw materials   |
| ▼ <u>M1</u><br>2.2.2 Cheeses made from milk or whey that has undergone heat treatment  | <i>E. coli</i> <sup>(5)</sup>    | 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 <sup>(6)</sup> | Improvements in production hygiene and selection of raw materials   |
| 2.2.3 Cheeses made from raw milk   | Coagulase-positive staphylococci | 5                            | 2 | 10 <sup>4</sup> cfu/g | 10 <sup>5</sup> 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 <sup>5</sup> 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 <sup>(7)</sup> and ripened cheeses made from milk or whey that has undergone pasteurisation or a stronger heat treatment <sup>(7)</sup> | 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 <sup>(7)</sup>  | 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 <sup>5</sup> cfu/g are detected, the cheese batch has to be tested for staphylococcal enterotoxins.                                |

▼ **M1**

| Food category   | Micro-organisms                  | Sampling plan <sup>(1)</sup> |   | Limits <sup>(2)</sup>              |           | Analytical reference method <sup>(3)</sup> | Stage where the criterion applies | Action in case of unsatisfactory results  |
|---|----------------------------------|------------------------------|---|------------------------------------|-----------|--|-----------------------------------|---|
|   |                                  | n                            | c | m                                  | M         |  |                                   |   |
| 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> <sup>(5)</sup>    | 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 <sup>(4)</sup>  | Enterobacteriaceae               | 5                            | 0 | 10 cfu/g                           |           | ► <b>M9</b> EN 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 <sup>5</sup> cfu/g are detected, the batch has to be tested for staphylococcal enterotoxins. |
| 2.2.8 Ice cream <sup>(8)</sup> and frozen dairy desserts  | Enterobacteriaceae               | 5                            | 2 | 10 cfu/g                           | 100 cfu/g | ► <b>M9</b> EN 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 | ► <b>M9</b> Not detected ◀ in 10 g |           | ► <b>M9</b> EN ISO 21528-1 ◀               | End of the manufacturing process  | Improvements in production hygiene to minimise contamination <sup>(9)</sup>   |
| 2.2.10 Dried follow-on formulae   | Enterobacteriaceae               | 5                            | 0 | ► <b>M9</b> Not detected ◀ in 10 g |           | ► <b>M9</b> EN ISO 21528-1 ◀               | End of the manufacturing process  | Improvements in production hygiene to minimise contamination  |

▼ **M1**

| Food category  | Micro-organisms                    | Sampling plan <sup>(1)</sup> |   | Limits <sup>(2)</sup> |           | Analytical reference method <sup>(3)</sup> | Stage where the criterion applies | Action in case of unsatisfactory results  |
|--|------------------------------------|------------------------------|---|-----------------------|-----------|--|-----------------------------------|---|
|  |                                    | n                            | c | m                     | M         |  |                                   |   |
| 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 <sup>(10)</sup>                | End of the manufacturing process  | Improvements in production hygiene. Prevention of recontamination. Selection of raw material. |

<sup>(1)</sup> n = number of units comprising the sample; c = number of sample units giving values between m and M.

► **M2** <sup>(2)</sup> For points 2.2.1, 2.2.7, 2.2.9 and 2.2.10 m=M. ◀

<sup>(3)</sup> The most recent edition of the standard shall be used.

<sup>(4)</sup> The criterion shall not apply to products intended for further processing in the food industry.

<sup>(5)</sup> E. coli is used here as an indicator for the level of hygiene.

<sup>(6)</sup> 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.

<sup>(7)</sup> 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.

<sup>(8)</sup> Only ice creams containing milk ingredients.

<sup>(9)</sup> Parallel testing for Enterobacteriaceae and ► **M9** *Cronobacter* spp. ◀ 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 ► **M9** *Cronobacter* spp. ◀ 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 ► **M9** *Cronobacter* spp. ◀

<sup>(10)</sup> 1 ml of inoculum is plated on a Petri dish of 140 mm diameter or on three Petri dishes of 90 mm diameter.

▼ M1

**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  $\leq m$ ,
- 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  $M$ .

▼ **M1**

2.3 *Egg products*

| Food category      | Micro-organisms    | Sampling plan <sup>(1)</sup> |   | Limits         |                 | Analytical reference method <sup>(2)</sup> | Stage where the criterion applies | Action in case of unsatisfactory results   |
|--------------------|--------------------|------------------------------|---|----------------|-----------------|--|-----------------------------------|--|
|                    |                    | n                            | c | m              | M               |  |                                   |  |
| 2.3.1 Egg products | Enterobacteriaceae | 5                            | 2 | 10 cfu/g or ml | 100 cfu/g or ml | ► <b>M9</b> EN ISO 21528-2 ◀               | End of the manufacturing process  | Checks on the efficiency of the heat treatment and prevention of recontamination |

<sup>(1)</sup> n = number of units comprising the sample; c = number of sample units giving values between m and M.

<sup>(2)</sup> 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  $\leq m$ ,
- 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.

▼ M1

2.4 Fishery products

▼ C4

| Food category   | Micro-organisms                  | Sampling plan <sup>(1)</sup> |   | Limits    |             | Analytical reference method <sup>(2)</sup> | Stage where the criterion applies | Action in case of unsatisfactory results |
|---|----------------------------------|------------------------------|---|-----------|-------------|--|-----------------------------------|--|
|   |                                  | n                            | c | m         | M           |  |                                   |  |
| 2.4.1. Shelled and shucked products of cooked crustaceans and molluscan shellfish | <i>E. coli</i>                   | 5                            | 2 | 1 MPN/g   | 10 MPN/g    | ISO TS 16649-3                             | End of the manufacturing process  | Improvements in production hygiene       |
|   | 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       |

<sup>(1)</sup> n = number of units comprising the sample; c = number of sample units giving values between m and M.

<sup>(2)</sup> The most recent edition of the standard shall be used.

▼ M1

**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  $\leq m$ ,
- 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.

Coagulase-positive staphylococci in shelled and cooked crustaceans and molluscan shellfish:

- 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.

▼ **M1**

2.5 Vegetables, fruits and products thereof

| Food category  | Micro-organisms | Sampling plan <sup>(1)</sup> |   | Limits    |             | Analytical reference method <sup>(2)</sup> | Stage where the criterion applies | Action in case of unsatisfactory results                       |
|--|-----------------|------------------------------|---|-----------|-------------|--|-----------------------------------|--|
|  |                 | n                            | c | m         | M           |  |                                   |  |
| 2.5.1 Precut fruit and vegetables (ready-to-eat)   | <i>E. coli</i>  | 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 ► <b>M9</b> Unpasteurised <sup>(3)</sup> fruit and vegetable juices (ready-to-eat) ◀ | <i>E. coli</i>  | 5                            | 2 | 100 cfu/g | 1 000 cfu/g | ISO 16649-1 or 2                           | Manufacturing process             | Improvements in production hygiene, selection of raw materials |

<sup>(1)</sup> n = number of units comprising the sample; c = number of sample units giving values between m and M.

<sup>(2)</sup> The most recent edition of the standard shall be used.

► **M9** <sup>(3)</sup> The term unpasteurised means that the juice has not been subjected to pasteurisation obtained by time-temperature combinations or to other processes validated to achieve an equivalent bactericidal effect to pasteurisation as regards its effect on *E.coli*. ◀

**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  $\leq m$ ,
- 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.

▼ **M1****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.

▼ **M8**3.2 *Bacteriological sampling in slaughterhouses and at premises producing minced meat, meat preparations, mechanically separated meat and fresh meat***Sampling rules for carcasses 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 to be used are set out in standard ISO 17604.

Five carcasses 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 carcass shall be sampled. Four tissue samples representing a total of 20 cm<sup>2</sup> 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<sup>2</sup> (50 cm<sup>2</sup> for small ruminant carcasses) 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<sup>2</sup>.

When samples are taken from the different sampling sites on the carcass, they shall be pooled before examination.

**Sampling rules for poultry carcasses and fresh poultry meat**

Slaughterhouses shall sample whole poultry carcasses with neck skin for *Salmonella* and *Campylobacter* analyses. Cutting and processing establishments other than those adjacent to a slaughterhouse cutting and processing meat received only from this slaughterhouse, shall also take samples for *Salmonella* analysis. When doing so, they shall give priority to whole poultry carcasses with neck skin, if available, but ensuring that also poultry portions with skin and/or poultry portions without skin or with only a small amount of skin are covered, and that choice shall be risk-based.

Slaughterhouses shall include in their sampling plans poultry carcasses from flocks with an unknown *Salmonella* status or with a status known to be positive for *Salmonella Enteritidis* or *Salmonella Typhimurium*.

When testing against the process hygiene criteria set out in Row 2.1.5 and Row 2.1.9 of Chapter 2 for *Salmonella* and *Campylobacter* in poultry carcasses in slaughterhouses and the tests for *Salmonella* and *Campylobacter* are carried out in the same laboratory, neck skins from a minimum of 15 poultry carcasses shall be sampled at random after chilling during each sampling session. Before examination, the neck skin samples from at least three poultry carcasses from the same flock of origin shall be pooled into one sample of 26 g. Thus, the neck skin samples form 5 × 26 g final samples (26 g are needed to perform analyses for

▼ **M8**

*Salmonella* and *Campylobacter* from one sample in parallel). The samples shall be kept after sampling and transported to the laboratory at a temperature not lower than 1 °C and not higher than 8 °C and the time between the sampling and the testing for *Campylobacter* shall be of less than 48 hours in order to ensure maintenance of sample integrity. Samples that have reached a temperature of 0 °C shall not be used to verify compliance with the *Campylobacter* criterion. The 5 × 26 g samples shall be used to verify the compliance with process hygiene criteria set out in Row 2.1.5 and Row 2.1.9 of Chapter 2 and the food safety criterion set out in Row 1.28 of Chapter 1. In order to prepare the initial suspension at the laboratory, the 26 g test portion shall be transferred to nine volumes (234 ml) buffered peptone water (BPW). The BPW shall be brought to room temperature before adding. The mixture shall be treated in a stomacher or pulsifier for approximately one minute. Foaming shall be avoided by removing the air from the stomacher bag as much as possible. 10 ml (~ 1 g) of this initial suspension shall be transferred to an empty sterile tube and 1 ml of the 10 ml shall be used for the enumeration of *Campylobacter* on selective plates. The rest of the initial suspension (250 ml ~ 25 g) shall be used for the detection of *Salmonella*.

When testing against the process hygiene criteria set out in Row 2.1.5 and Row 2.1.9 of Chapter 2 for *Salmonella* and *Campylobacter* in poultry carcasses in slaughterhouses and the tests for *Salmonella* and *Campylobacter* are carried out in two different laboratories, neck skins from a minimum of 20 poultry carcasses shall be sampled at random after chilling during each sampling session. Before examination, the neck skin samples from at least four poultry carcasses from the same flock of origin shall be pooled into one sample of 35 g. Thus, the neck skin samples form 5 × 35 g samples, which in turn shall be split in order to obtain 5 × 25 g final samples (to be tested for *Salmonella*) and 5 × 10 g final samples (to be tested for *Campylobacter*). The samples shall be kept after sampling and transported to the laboratory at a temperature not lower than 1 °C and not higher than 8 °C and the time between the sampling and the testing for *Campylobacter* shall be of less than 48 hours in order to ensure maintenance of sample integrity. Samples that have reached a temperature of 0 °C shall not be used to verify compliance with the *Campylobacter* criterion. The 5 × 25 g samples shall be used to verify the compliance with process hygiene criteria set out in Row 2.1.5 of Chapter 2 and the food safety criterion set out in Row 1.28 of Chapter 1. The 5 × 10 g final samples shall be used to verify the compliance with the process hygiene criterion set out in Row 2.1.9 of Chapter 2.

For the *Salmonella* analyses for fresh poultry meat other than poultry carcasses, five samples of at least 25 g of the same batch shall be collected. The sample taken from poultry portions with skin shall contain skin and a thin surface muscle slice in case the amount of skin is not sufficient to form a sample unit. The sample taken from poultry portions without skin or with only a small amount of skin shall contain a thin surface muscle slice or slices added to any skin present to make a sufficient sample unit. The slices of meat shall be taken in a way that includes as much as possible of the surface of the meat.

#### Guidelines for sampling

More detailed guidelines on the sampling of carcasses, 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 carcasses, minced meat, meat preparations, mechanically separated meat and fresh poultry meat

The food business operators of slaughterhouses or establishments producing minced meat, meat preparations, mechanically separated meat or fresh poultry 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.

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As regards the sampling of minced meat and meat preparations for *E. coli* and aerobic colony count analyses and the sampling of carcasses 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, carcasses and fresh poultry meat, 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 laid down 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.

In the case of sampling for *Campylobacter* analysis of poultry carcasses, the frequency may be reduced to fortnightly if satisfactory results have been obtained for 52 consecutive weeks. The *Campylobacter* sampling frequency may be reduced, after authorisation by the competent authority, if there is an official or officially recognised national or regional *Campylobacter* control programme in place and if this programme includes sampling and testing equivalent to the sampling and testing required for verifying compliance with the process hygiene criterion set out in Row 2.1.9 of Chapter 2. If low contamination level of flocks is set for *Campylobacter* in the control programme, the sampling frequency may be further reduced if this low contamination level of *Campylobacter* is reached over a 52-week period in the farms of origin of the broilers purchased by the slaughterhouse. In case the control programme shows satisfactory results during a specific period of the year, frequency of analysis of *Campylobacter* may also be adjusted to seasonal variations after authorisation by the competent authority.

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

**▼ M4****3.3 Sampling rules for sprouts**

For the purposes of this Section, the definition of batch in Article 2(b) of Implementing Regulation (EU) No 208/2013 will apply.

**A. General rules for sampling and testing****1. Preliminary testing of the batch of seeds**

Food business operators producing sprouts shall carry out a preliminary testing of a representative sample of all batches of seeds. A representative sample shall include at least 0,5 % of the weight of the batch of seeds in sub samples of 50 g or be selected based on a structured statistically equivalent sampling strategy verified by the competent authority.

For the purposes of performing the preliminary testing, the food business operator must sprout the seeds in the representative sample under the same conditions as the rest of the batch of seeds to be sprouted.

**2. Sampling and testing of the sprouts and the spent irrigation water**

Food business operators producing sprouts shall take samples for microbiological testing at the stage where the probability of finding Shiga toxin producing *E. coli* (STEC) and *Salmonella* spp. is the highest, in any case not before 48 hours after the start of the sprouting process.

**▼ M4**

Samples of sprouts shall be analysed according to the requirements in rows 1.18 and 1.29 of Chapter 1.

However, if a food business operator producing sprouts has a sampling plan, including sampling procedures and sampling points of the spent irrigation water, they may replace the sampling requirement under the sampling plans set out in rows 1.18 and 1.29 of Chapter 1 with the analysis of 5 samples of 200 ml of the water that was used for the irrigation of the sprouts.

In that case requirements set out in rows 1.18 and 1.29 of Chapter 1 shall apply to the analysis of the water that was used for the irrigation of the sprouts, with the limit of absence in 200 ml.

When testing a batch of seeds for the first time, food business operators may only place sprouts on the market if the results of the microbiological analysis comply with rows 1.18 and 1.29 of Chapter 1, or the limit of absence in 200 ml if they analyse spent irrigation water.

### 3. Sampling frequency

Food business operators producing sprouts shall take samples for microbiological analysis at least once a month at the stage where the probability of finding Shiga toxin producing *E. coli* (STEC) and *Salmonella* spp. is the highest, in any case not before 48 hours after the start of the sprouting process.

#### B. Derogation from the preliminary testing of all batches of seeds set out in point A.1 of this Section

When justified on the basis of the following conditions and authorised by the competent authority, food business operators producing sprouts may be exempted from the sampling set out in point A.1 of this Section:

- (a) the competent authority is satisfied that the food business operator implements a food safety management system in that establishment, which may include steps in the production process, which reduces the microbiological risk; and,
- (b) historical data confirms that during at least 6 consecutive months prior to granting the authorisation, all batches of the different types of sprouts produced in the establishment comply with the food safety criteria set out in rows 1.18 and 1.29 of Chapter 1.

**▼B***ANNEX II*

The studies referred to in Article 3(2) shall include:

- specifications for physico-chemical characteristics of the product, such as pH,  $a_w$ , salt content, concentration of preservatives and the type of packaging system, taking into account the storage and processing conditions, the possibilities for contamination and the foreseen shelf-life, and
- consultation of available scientific literature and research data regarding the growth and survival characteristics of the micro-organisms of concern.

When necessary on the basis of the abovementioned studies, the food business operator shall conduct additional studies, which may include:

- predictive mathematical modelling established for the food in question, using critical growth or survival factors for the micro-organisms of concern in the product,
- tests to investigate the ability of the appropriately inoculated micro-organism of concern to grow or survive in the product under different reasonably foreseeable storage conditions,
- studies to evaluate the growth or survival of the micro-organisms of concern that may be present in the product during the shelf-life under reasonably foreseeable conditions of distribution, storage and use.

The above mentioned studies shall take into account the inherent variability linked to the product, the micro-organisms in question and the processing and storage conditions.