# REGULATION ON TURKISH FOOD CODEX MICROBIOLOGICAL CRITERIA

**Law of Authorization:** 5996

**Official Gazette of Publication:** 29.12.2011-28157

## SECTION ONE
## Objective, Scope, Legal Basis and Definitions

### Objective

**ARTICLE 1 –** (1) The objective of the present Regulation is to define microbiological criteria for foodstuffs and the mandatory rules to be complied with and to be implemented by food business operators.

### Scope

**ARTICLE 2 –** (1) This Regulation covers microbiological criteria for foodstuffs and the mandatory rules to be complied with and to be implemented by food business operators.

(2) This Regulation shall be implemented without prejudice to the provisions pertaining to;-

a) Health standards for foodstuffs as specified in the Regulation on Specific Hygiene Rules for Animal Foodstuffs published on the Official Gazette dated 27/12/2011 and No. 28155 laying down other specific rules for control of microorganisms,

b) Parasites specified in the Regulation Laying down Specific Rules for Official Controls of Animal Foodstuffs published on the Official Gazette dated 17/12/2011 and No. 28145,

c) Microbiological criteria specified in the Regulation on Waters intended for Human Consumption published on the Official Gazette dated 17/2/2005 and No. 25730.

**Legal Basis**

**ARTICLE 3 –** (1) This Regulation was prepared;-

a) On the basis of Articles 21, 22, 23, 24, 29, 30, 31, 32 and 34 of the Law dated 11/6/2010 and No. 5996 on Veterinary Services, Plant Health, Food and Feed,

b) In parallel with the European Union Commission Regulation 2073/2005/EC on Microbiological Criteria for Foodstuffs.

**Definitions**

**ARTICLE 4 –** (1) In addition to the definitions listed in Article 3 of the Law No. 5996, the definitions given in the second paragraph shall also apply.

(2) For the purposes of this Regulation, the following definitions shall apply:

a) Ministry: Ministry of Food, Agriculture and Livestock,

b) Food intended for Infants: Foodstuffs prepared for the purpose of meeting the special nutritional needs of infants defined as being younger than twelve months of age,

c) Food safety criterion: A criterion defining the acceptability of a product or a batch of foodstuff applicable to products placed on the market,

d) Microorganisms and Toxins and Metabolites thereof: Bacteria, virus, yeast, mould, algae, parasitic protozoa, microscopic parasitic helminth and their toxins and metabolites,

e) Microbiological Criteria: Criteria taken as a basis for the determination of the acceptability of a foodstuff, a batch of foodstuff or procedure and defining the presence/absence or number of microorganisms and the quantities of their toxins and metabolites by mass, volume, area, batch or unit,

f) Compliance with Microbiological Criteria: Obtaining satisfactory or acceptable results set in Annex 1 and Annex 2 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 the legal arrangements pertaining to the Law No. 5996 and the instructions of the Ministry,

g) Sample: 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,

h) Food intended for Special Medical Purposes: Foodstuffs prepared for the purpose of meeting the nutritional requirements of persons affected by a disease, ailment or medical condition and suffering from nutritional disorders arising therefrom and required to be consumed under medical observation,

I) Batch: 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,

j) Shelf-Life: The expiration date defined in the Turkish Food Codex Labelling Regulation or a period of time in consistence with the recommended "use by" date,

k) Representative Sample: A sample in which the characteristics of the batch from which it is drawn are maintained and which has the same probability as that of the initial sample selected on a random basis from each item or primary sample of the batch,

l) Food Ready for Consumption: 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,

m) Process Hygiene Criterion: A criterion indicating the acceptable functioning of the production process which is not applicable to products placed on the market and sets an indicative contamination value above which corrective actions are required in order to maintain the hygiene of the process in compliance with the Law No. 5996;

# SECTION TWO
# General Provisions

**General provisions**

**ARTICLE 5 –** (1) Food business operators shall ensure that foodstuffs comply with the relevant microbiological criteria set out in Annex 1 and Annex 2. 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 hazard analysis and critical control points (HACCP) principles together with the implementation of good hygiene practices designated in the Food Hygiene Regulation published on the Official Gazette dated 17/12/2011 and No. 28145, to ensure compliance with:

(a) The process hygiene criteria specified in Annex 2 during supply, handling and processing of raw materials and foodstuffs,

(b) The food safety criteria specified in Annex 1 and applicable throughout the shelf-life of the products can be met under reasonably foreseeable conditions of distribution, storage and use.

(2) The Ministry has the right to collect more detailed samples and perform analyses for the purpose of verifying process compliance or performing risk analyses with the objective of determining microorganisms and their toxins and metabolites not included in Annex 1 for foodstuffs suspected to be unsafe. To this end, the criteria given in Annex 3 shall be taken into consideration.

(3) Food business operators are responsible to provide for sampling in line with the rules specified in Annex 4 in order to ensure compliance with the process hygiene criteria given in Annex 2.

(4) Food business operators may also utilize the guides to good hygiene practice for the purpose of implementing the provisions of the present Regulation.

**Analyses against criteria**

**ARTICLE 6 –** (1) Food business operators shall perform testing as appropriate against the microbiological criteria set out in Annex 1 and Annex 2, 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 and Annex 2. 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.

(3) 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.

(4) The number of samples (n) to be collected from foodstuffs falling under the scope of this Regulation shall be as defined in Annex 1. However, one sample shall be collected from food sales and collective consumption areas and evaluated against the “M” value.

# SECTION THREE
# Specific Provisions for Sampling and Analysis Methods

**Sampling and analysis methods**

**ARTICLE 7 –** (1) The analytical methods and the sampling plans and methods in Annex 1 and Annex 2 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. Accordingly;-

a) In that sampling the ISO standard 18593 shall be used as a reference method.

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

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

(3) The number of sample units of the sampling plans set out in Annex 1 and Annex 2 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 analysis is to specifically assess the acceptability of a certain batch of foodstuffs or a process, the sampling plans set out in Annex 1 and Annex 2 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 authorized body of the Ministry that these procedures provide at least equivalent guarantees. Accordingly;-

a) Those procedures may include use of alternative sampling sites and use of new analysis methods.

b) Testing against alternative micro-organisms and related microbiological limits not included in Annex 2 as well as testing of analytes other than microbiological ones shall be allowed only for process hygiene criteria.

c) The use of alternative analytical methods is acceptable when the methods are validated against the reference method in Annex 1 and Annex 2 and if a proprietary method, certified by a third party in accordance with the protocol set out in EN/ISO standard 16140 or other internationally accepted similar protocols, is used.

d) If the food business operator wishes to use analytical methods other than those validated and certified as described in sub-paragraph (c), the methods shall be validated according to internationally accepted protocols and their use authorised by the Ministry.

# SECTION FOUR
# Specific Provisions

**Unsatisfactory results**

**ARTICLE 8 –** (1) When the results of testing against the criteria set out in Annex 1 and Annex 2 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.

(2) Food business operators shall take measures to find the cause of the unsatisfactory results in order to prevent the recurrence of the unacceptable microbiological contamination including modifications to the HACCP-based procedures or other food hygiene control measures in place.

(3) When testing against food safety criteria set out in Annex I provides unsatisfactory results, the product or batch of foodstuffs shall be withdrawn or recalled in accordance with Article 22 of the Law No. 5996. However, on the condition that the relevant operations be carried out by food business operators;-

a) 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.

b) 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 Ministry.

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

**Labelling**

**ARTICLE 9 –** (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 1 and Annex 2 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.

# SECTION FIVE
# Miscellaneous and Final Provisions

**Administrative sanctions**

**ARTICLE 10 –** (1) Those acting in contradiction with this Regulation shall be made subject to administrative sanctions in accordance with the relevant articles of the Law No. 5996. .

**Burden of compliance**

**PROVISIONAL ARTICLE 1 –** (1) Food business operators that have been active before the publication date of this Regulation are obliged to ensure compliance with the provisions given in Annex 2 and Annex 4 of the present Regulation until 31/12/2013.

**Effectiveness**

**ARTICLE 11 –** (1) This Regulation shall be effective as of its date of publication.

**Execution**

**ARTICLE 12 –** (1) The provisions of the present Regulation shall be executed by the Ministry of Food, Agriculture and Livestock.

**ANNEX-1**

**FOOD SAFETY CRITERIA**

| | Food | Microorganisms/ toxins/ metabolites | Sampling plan ([1]) | | Limits ([2]) | | Reference method ([3]) |
|---|---|---|---|---|---|---|---|
| | | | n | c | m | M | |
| | **1.1. Milk, dairy products and milk-based products** | | | | | | |
| | 1.1.**1**. Pasteurized milk | *Enterobacteriaceae* | 5 | 0 | $10^1$ cfu/mL | | ISO 21528-1 |
| | 1.1.**2**. Fermented dairy products (*kefir*[1], yoghurt, fruit yoghurts, *ayran*[2], etc.) | *E. coli* ([4]) | 5 | 0 | <3 | | ISO 16649-3 |

[1] Fermented milky drink with traces of alcohol

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| | 1.1.**3**. Cream and cream products | | | | | | |
| | 1.1.3.**1**. Cream (pasteurized) | *Salmonella* | 5 | 0 | 0/25 g-mL | | EN/ISO 6579 |
| | | *L. monocytogenes* | 5 | 0 | 0/25 g-mL | | EN/ISO 11290-1 |
| | 1.1.3.**2**. Butter and spreadable dairy products and clarified butter | Coagulase positive staphylococci | 5 | 2 | $10^2$ | $10^3$ | EN/ISO 6888-1 or 2 |
| | | *Salmonella* | 5 | 0 | 0/25 g-mL | | EN/ISO 6579 |
| | 1.1.3.**3**. Clotted cream | Coagulase positive staphylococci | 5 | 2 | $10^2$ | $10^3$ | EN/ISO 6888-1 or 2 |
| | | *Salmonella* | 5 | 0 | 0/25 g-mL | | EN/ISO 6579 |
| | | *L. monocytogenes* | 5 | 0 | 0/25 g-mL | | EN/ISO 11290-1 |
| | 1.1.**4**. Milk powder or cream powder, powder mix for ice cream, whey cheese, buttermilk powder and milk-based products, casein and caseinate | *Enterobacteriaceae* | 5 | 0 | $10^1$ cfu/mL | | ISO 21528-2 |
| | | Coagulase positive staphylococci | 5 | 2 | $10^2$ | $10^3$ | EN/ISO 6888-1 or 2 |
| | | *Salmonella* | 5 | 0 | 0/25 g-mL | | EN/ISO 6579 |
| | 1.1.**5**. Cheese (all cheeses except for melted cheese) | Coagulase positive staphylococci | 5 | 2 | $10^2$ | $10^3$ | EN/ISO 6888-1 or 2 |
| | | *Salmonella* | 5 | 0 | 0/25 g-mL | | EN/ISO 6579 |
| | | *L. monocytogenes* | 5 | 0 | 0/25 g-mL | | EN/ISO 11290-1 |
| | 1.1.**6**. Melted cheeses and melted cheese | *Staphylococcal enterotoxins* | 5 | 0 | absence in 25 g | | |

[2] Traditional drink prepared with yoghurt, water and salt.

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| | products | *E. coli* ([4]) | 5 | 0 | <$10^1$ | | ISO 16649-1 and 2 |
| | | *L. monocytogenes* | 5 | 0 | 0/25 g-mL | | EN/ISO 11290-1 |
| | 1.1.**7**. Condensed milk | *E. coli* ([4]) | 5 | 0 | <3 | | ISO 16649-3 |
| | | *Salmonella* | 5 | 0 | 0/25 g-mL | | EN/ISO 6579 |
| | 1.1.**8**. İce cream and milky ice | *Enterobacteriaceae* | 5 | 2 | $10^1$ | $10^2$ | ISO 21528-2 |
| | | *Salmonella* | 5 | 0 | 0/25 g-mL | | EN/ISO 6579 |
| | | *L. monocytogenes* | 5 | 0 | 0/25 g-mL | | EN/ISO 11290-1 |
| | **1.2. Egg products (pasteurized and frozen egg, egg powder etc.)** | *Enterobacteriaceae* | 5 | 2 | $10^1$ | $10^2$ | ISO 21528-2 |
| | | *Salmonella* | 5 | 0 | 0/25 g-mL | | EN/ISO 6579 |
| | **1.3. Meat and meat products** | | | | | | |
| | 1.3.**1**. Minced meat | Aerobic colony count | 5 | 2 | $5x10^5$ | $5x10^6$ | ISO 4833 |
| | | *Salmonella* | 5 | 0 | 0/25 g-mL | | EN/ISO 6579 |
| | | *E. coli* O157 | 5 | 0 | 0/25 g-mL | | ISO 16654 |
| | 1.3.**2**. Raw red meat and red meat preparations | *Salmonella* | 5 | 0 | 0/25 g-mL | | EN/ISO 6579 |
| | | *E. coli* O157 | 5 | 0 | 0/25 g-mL | | ISO 16654 |
| | 1.3.**3**. Raw poultry meat and poultry meat preparations | *Salmonella* | 5 | 0 | 0/25 g-mL | | EN/ISO 6579 |

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| | 1.3.**4**. Mechanically separated red meat and mechanically separated poultry meat (MSM) | Aerobic colony count | 5 | 2 | $5x10^5$ | $5x10^6$ | ISO 4833 |
| | | *Salmonella* | 5 | 0 | 0/25 g-mL | | EN/ISO 6579 |
| | | *E. coli* O157 | 5 | 0 | 0/25 g-mL | | ISO 16654 |
| | 1.3.**5**. Meat products | | | | | | |
| | 1.3.5.**1**. Non-heat treated meat products | | | | | | |
| | 1.3.5.1.**1**. Cured and dried (bacon, etc.) | Coagulase positive staphylococci | 5 | 2 | $10^2$ | $10^4$ | EN/ISO 6888-1 or 2 |
| | | Sulphide reducing anaerobic bacteria | 5 | 2 | $10^2$ | $10^3$ | ISO 7937 |
| | | *Salmonella* | 5 | 0 | 0/25 g-mL | | EN/ISO 6579 |
| | 1.3.5.1.**2**. Fermented (sausage etc.) | *Salmonella* | 5 | 0 | 0/25 g-mL | | EN/ISO 6579 |
| | | *L. monocytogenes* | 5 | 0 | 0/25 g-mL | | EN/ISO 11290-1 |
| | | *E. coli* O157 | 5 | 0 | 0/25 g-mL | | ISO 16654 |
| | 1.3.5.**2**. Heat treated meat products (sausage, ham, fried meat, *döner*, meatballs, jelly tripe etc.) | *Salmonella* | 5 | 0 | 0/25 g-mL | | EN/ISO 6579 |
| | | *L. monocytogenes* | 5 | 0 | 0/25 g-mL | | EN/ISO 11290-1 |
| | 1.3.**6**. Other Animal Products | | | | | | |
| | 1.3.6.**1**. Gelatine and Collagen | *Salmonella* | 5 | 0 | 0/25 g-mL | | EN/ISO 6579 |
| | **1.4. Fishery products, live bivalve molluscs, live sea urchins, live tunicates and live sea** | | | | | | |

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| | **gastropods** | | | | | | |
| | 1.4.**1**. Live bivalve molluscs, live sea urchins, live tunicates and live sea gastropods | *E. coli* ([4]) (in intravalvular fluid and meat) | 1 ([5]) | 0 | <3 | | ISO 16649-3 |
| | | *Salmonella* | 5 | 0 | 0/25 g-mL | | EN/ISO 6579 |
| | 1.4.**2**. Fishery products | | | | | | |
| | 1.4.2.**1**. Fresh chilled fish | Histamine ([6]) | 9 | 2 | 100 mg/kg | 200 mg/kg | HPLC |
| | 1.4.2.**2**. Frozen fish | Histamine ([6]) | 9 | 2 | 100 mg/kg | 200 mg/kg | HPLC |
| | 1.4.2.**3**. Processed bivalve molluscs (black mussels, bearded mussels, carpet shell clams, sand mussels, etc.), shellfish (crayfish, shrimps, lobster, crabs, etc.), gastropods (limpets, etc.), cephalopods (octopus, squid, calamari, etc.), fish | Histamine ([6]) | 9 | 2 | 200 mg/kg | 400 mg/kg | HPLC |
| | | *Salmonella* | 5 | 0 | 0/25 g-mL | | EN/ISO 6579 |
| | | *L. monocytogenes* | 5 | 0 | 0/25 g-mL | | EN/ISO 11290-1 |
| | 1.4.2.**4**. Canned fishery products | Histamine ([6]) | 9 | 2 | 200 mg/kg | 400 mg/kg | HPLC |
| | 1.4.2.**5**. Caviars and caviar-like products obtained from fish eggs | *Salmonella* | 5 | 0 | 0/25 g-mL | | EN/ISO 6579 |
| | | *L. monocytogenes* | 5 | 0 | 0/25 g-mL | | EN/ISO 11290-1 |
| | **1.5. Bouillon cubes, powders, dry soup mix, seasoning, whipped cream, other food mixtures** | *Salmonella* | 5 | 0 | 0/25 g-mL | | EN/ISO 6579 |

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| | **in powder or cube form such as sauces** | | | | | | |
| | **1.6. Cereal and bakery products** | | | | | | |
| | 1.6.**1**. Cereal flours, soy flour and other flours (including potato flours) | Coliform bacteria | 5 | 2 | $10^3$ | $10^4$ | ISO 4832 |
| | | Mould | 5 | 2 | $10^4$ | $10^5$ | ISO 7698 |
| | 1.6.**2**. Bread and bread varieties, pita bread, flat bread, bagels, thin bread, pastry, etc. | Rope spores ([4]) | 5 | 2 | $4{,}5x10^3$ | $1{,}1x10^4$ | |
| | | Yeast and Mould | 5 | 2 | $10^2$ | $10^3$ | ISO 7698 |
| | 1.6.**3**. Wafers, shredded pastry etc. | Coliform bacteria | 5 | 2 | $10^2$ | $10^3$ | ISO 4832 |
| | | Mould | 5 | 2 | $10^3$ | $10^4$ | ISO 7698 |
| | 1.6.**4**. Breakfast cereals, semolina, whole grain products, muesli, cornflakes, popcorn, puffed rice, chips etc. Grain-based products (including aromatic products), bran intended for human consumption | Coliform bacteria | 5 | 2 | $10^2$ | $10^3$ | ISO 4832 |
| | | Yeast and Mould | 5 | 2 | $10^3$ | $10^4$ | ISO 7698 |
| | 1.6.**5**. Pasta products such as pasta, noodles, etc. | Yeast and Mould | 5 | 2 | $10^2$ | $10^3$ | ISO 7698 |
| | | *Salmonella* | 5 | 0 | 0/25 g-mL | | EN/ISO 6579 |
| | 1.6.**6**. Pasta, ravioli and similar products stuffed with meat, vegetables and other fillings (raw, frozen) | Coagulase positive staphylococci | 5 | 2 | $10^3$ | $10^4$ | EN/ISO 6888-1 or 2 |
| | | Sulphide reducing anaerobic bacteria | 5 | 2 | $10^3$ | $10^4$ | ISO 7937 |
| | | *Salmonella* | 5 | 0 | 0/25 g-mL | | EN/ISO 6579 |

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| | 1.6.**7**. Pasta, ravioli and similar products stuffed with meat, vegetables and other fillings (baked) | Coagulase positive staphylococci | 5 | 2 | $10^2$ | $10^3$ | EN/ISO 6888-1 or 2 |
| | | Sulphide reducing anaerobic bacteria (only for those containing meat) | 5 | 2 | $10^2$ | $10^3$ | ISO 7937 |
| | | *Salmonella* | 5 | 0 | 0/25 g-mL | | EN/ISO 6579 |
| | 1.6.**8**. Pizza, dough and dough-based products (frozen, ready-to-cook) | Mould | 5 | 2 | $10^3$ | $10^4$ | ISO 7698 |
| | | Coagulase positive staphylococci | 5 | 2 | $10^3$ | $10^4$ | EN/ISO 6888-1 or 2 |
| | | *Salmonella* | 5 | 0 | 0/25 g-mL | | EN/ISO 6579 |
| | | *L. monocytogenes* | 5 | 0 | 0/25 g-mL | | EN/ISO 11290-1 |
| | 1.6.**9**. Light bakery products | | | | | | |
| | 1.6.9.**1**. Plain cake, plain cookies, plain crackers etc., coated, stuffed and/or seasoned cookies, cakes and crackers and wafers (plain, creamy, coated, etc.) | *Coliform bacteria* | 5 | 2 | $10^1$ | $10^2$ | ISO 4832 |
| | | *Salmonella* | 5 | 0 | 0/25 g-mL | | EN/ISO 6579 |
| | 1.6.9.**2**. Pies and cakes (creamy, chocolate, stuffed, fruit etc.) | Coagulase positive staphylococci | 5 | 2 | $10^2$ | $10^3$ | EN/ISO 6888-1 or 2 |
| | | *E. coli* ([4]) | 5 | 0 | <3 | | ISO 16649-3 |
| | | *Salmonella* | 5 | 0 | 0/25 g-mL | | EN/ISO 6579 |
| | | *L. monocytogenes* | 5 | 0 | 0/25 g-mL | | EN/ISO 11290-1 |
| | 1.6.**10**. Starch | *E. coli* ([4]) | 5 | 0 | $<10^1$ | | ISO 16649-1 or 2 |

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| | **1.7. Fruits and vegetables and their processed products** | | | | | | |
| | 1.7.**1**. Washed, sliced and packaged, separate or mixed raw vegetables and frozen or dried fruits | *Salmonella* | 5 | 0 | 0/25 g-mL | | EN/ISO 6579 |
| | | *L. monocytogenes* | 5 | 0 | 0/25 g-mL | | EN/ISO 11290-1 |
| | | *E. coli* O157 | 5 | 0 | 0/25 g-mL | | ISO 16654 |
| | 1.7.**2**. Dried or frozen fruits | Yeast and Mould | 5 | 2 | $10^4$ | $10^5$ | ISO 7954 |
| | 1.7.**3**. Jam, marmalades and mashes | Mould | 5 | 2 | $10^2$ | $10^3$ | ISO 7954 |
| | **1.8. Spices** | | | | | | |
| | 1.8.**1**. Spices, herbs and/or mixtures thereof (powder, pastes, mixtures, etc.) | Coagulase positive staphylococci | 5 | 2 | $10^3$ | $10^4$ | EN/ISO 6888-1 or 2 |
| | | *B. cereus* | 5 | 2 | $10^3$ | $10^4$ | EN/ISO 7932 |
| | | *Salmonella* | 5 | 0 | 0/25 g-mL | | EN/ISO 6579 |
| | **1.9. Juices, non-alcoholic beverages and similar products** | | | | | | |
| | 1.9.**1**. Directly squeezed, non-pasteurized, ready-to-eat fruit and vegetable juices required to be maintained in cold conditions | *Salmonella* | 5 | 0 | 0/25 g-mL | | EN/ISO 6579 |
| | | *L. monocytogenes* | 5 | 0 | 0/25 g-mL | | EN/ISO 11290-1 |
| | | *E. coli* O157 | 5 | 0 | 0/25 g-mL | | ISO 16654 |
| | 1.9.**2**. Drink powders | *Coliform bacteria* | 5 | 2 | $10^1$ | $10^2$ | ISO 4832 |

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| | **1.10. Coffee and tea** | | | | | | |
| | 1.10.**1**. Tea (green, black), herb and fruit teas and their mixtures (including teabags) | Yeast and Mould | 5 | 2 | $10^4$ | $10^5$ | ISO 7954 |
| | | *Salmonella* | 5 | 0 | 0/25 g-mL | | EN/ISO 6579 |
| | 1.10.**2**. Roasted coffee beans, roasted ground coffee and ready-to-drink coffee including coffee extracts and aromatised coffee ingredients | *Coliform bacteria* | 5 | 2 | $10^1$ | $10^2$ | ISO 4832 |
| | **1.11. Cocoa and cocoa products, chocolate and chocolate products** | *Salmonella* | 5 | 0 | 0/25 g-mL | | EN/ISO 6579 |
| | **1.12. Sugary products** | | | | | | |
| | 1.12.**1**. Halva, grape molasses, Turkish delight, *baklava* and other syrup desserts, paste, *cezerye*[3], walnut and peanut butters and confection, etc. | Yeast and Mould | 5 | 2 | $10^2$ | $10^3$ | ISO 7954 |
| | | *E. coli* | 5 | 0 | <$10^1$ | | ISO 16649-1 or 2 |
| | 1.12.**2**. Ready-to-eat sweet sauces | Yeast and Mould | 5 | 2 | $10^1$ | $10^2$ | ISO 7954 |
| | **1.13. Ready-to-eat meals** | | | | | | |
| | 1.13.**1**. All types of ready-to-eat (cooked) meat and vegetable meal etc. | *Staphylococcal enterotoxins* | 5 | 0 | absence in 25 g | | |
| | | *B. cereus* | 5 | 2 | $10^2$ | $10^3$ | EN/ISO 7932 |

[3] Traditiıonal type of Turkish delight prepared with nuts and carrot paste.

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| | | *Salmonella* | 5 | 0 | 0/25 g-mL | | EN/ISO 6579 |
| | 1.13.**2**. All types ready-to-eat salads, delicatessen products and cold side dishes, etc. | *E. coli* | 5 | 2 | $<10^1$ | $10^1$ | ISO 16649-1 or 2 |
| | | *Staphylococcal enterotoxins* | 5 | 0 | absence in 25 g | | |
| | | *Salmonella* | 5 | 0 | 0/25 g-mL | | EN/ISO 6579 |
| | | *L. monocytogenes* | 5 | 0 | 0/25 g-mL | | EN/ISO 11290-1 |
| | 1.13.**3**. All types of ready-to-eat (cooked) baked products (pasta, all varieties of pastry, pizza, ravioli, etc.) | *E. coli* | 5 | 0 | $<10^1$ | | ISO 16649-1 or 2 |
| | | *Staphylococcal enterotoxins* | 5 | 0 | absence in 25 g | | |
| | | *B. cereus* | 5 | 2 | $10^2$ | $10^3$ | EN/ISO 7932 |
| | | *Salmonella* | 5 | 0 | 0/25 g-mL | | EN/ISO 6579 |
| | 1.13.**4**. All types of ready-to-eat (cooked) sweet pudding, cream, Noah's pudding etc.) | *Staphylococcal enterotoxins* | 5 | 0 | absence in 25 g | | |
| | | *Salmonella* | 5 | 0 | 0/25 g-mL | | EN/ISO 6579 |
| | **1.14. Foodstuffs for special nutrition** | | | | | | |
| | 1.14.**1**. İnfant formulae and follow-up formulae (including dietary foodstuffs for special medical purposes) | *B. cereus* | 5 | 2 | $5x10^1$ | $5x10^2$ | EN/ISO 7932 |
| | | *Cronobacter sakazakii* | 10 | 0 | 0/25 g-mL | | ISO/DTS 22964 |
| | | *Salmonella* | 10 | 0 | 0/25 g-mL | | EN/ISO 6579 |
| | | *L. monocytogenes* | 10 | 0 | 0/25 g-mL | | EN/ISO 11290-1 |

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| | 1.14.**2**. Food supplements for infants and children (including dietary foodstuffs for special medical purposes) | *B. cereus* | 5 | 2 | $10^2$ | $10^3$ | EN/ISO 7932 |
| | | *Enterobacteriaceae* | 5 | 0 | <$10^1$ | | ISO 21528-2 |
| | | *Salmonella* | 5 | 0 | 0/25 g-mL | | EN/ISO 6579 |
| | | *L. monocytogenes* | 5 | 0 | 0/25 g-mL | | EN/ISO 11290-1 |
| | **1.15. Other foodstuffs** | | | | | | |
| | 1.15.**1**. Salt | *Coliform bacteria* | 5 | 2 | $10^1$ | $10^2$ | ISO 4832 |
| | 1.15.**2**. Soy milk and soy products | *E. coli* | 5 | 2 | <$10^1$ | $10^1$ | ISO 16649-1 or 2 |
| | | *Salmonella* | 5 | 0 | 0/25 g-mL | | EN/ISO 6579 |
| | 1.15.**3**. Soy milk (in powder form) | *Coliform bacteria* | 5 | 2 | $10^2$ | $10^3$ | ISO 4832 |
| | 1.15.**4**. Mayonnaise and salad dressing containing mayonnaise | Coagulase positive staphylococci | 5 | 2 | $10^2$ | $10^3$ | EN/ISO 6888-1 or 2 |
| | | *Salmonella* | 5 | 0 | 0/25 g-mL | | EN/ISO 6579 |
| | 1.15.**5**. Salad and gravy sauces, tomato-based sauces (including ketchup, soy sauce, mustard, pomegranate syrup, etc.) | Yeast and Mould | 5 | 2 | $10^2$ | $10^3$ | ISO 7954 |
| | | *Salmonella* | 5 | 0 | 0/25 g-mL | | EN/ISO 6579 |
| | 1.15.**6**. Animal oils except for butter | Aerobic colony count | 5 | 2 | $10^4$ | $10^5$ | ISO 4833 |
| | 1.15.**7**. Non-milk-based edible salts (fruit ice, sorbet and others) | *Enterobacteriaceae* | 5 | 2 | $10^2$ | $10^3$ | ISO 21528-2 |
| | | *Salmonella* | 5 | 0 | 0/25 g-mL | | EN/ISO 6579 |

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| | 1.15.**8**. Coffee whitener | *E. coli* | 5 | 0 | $<10^1$ | | ISO 16649-1 or 2 |
| | 1.15.**9**. Food supplements | *E. coli* | 5 | 0 | $<10^1$ | | ISO 16649-1 or 2 |
| | 1.15.**10**. Bread yeast (wet and dry) | Rope spores ([4]) | 5 | 3 | 95 | 210 | |
| | 1.15.**11**. Spreadable oils, margarine and rich oils | *Coliform bacteria* | 5 | 2 | $10^1$ | $10^2$ | ISO 4832 |
| | | Yeast and Mould | 5 | 2 | $10^1$ | $10^2$ | ISO 7988 |

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

(2) Limit is regarded as cfu/g-mL unless otherwise stated. cfu: colony-forming unit (in solid medium)

(3) The most recent edition of the Standards given in this Regulation shall be used.

(4) Most Possible Number (MPN) Method

(5) Analysis sample must be prepared from at least 10 different samples.

(6) In species belonging to *Engraulidae*, *Scombridae*, *Clupeidae*, *Coryfenidae*, *Pomatomidae*, *Scrombressosidae* family

**ANNEX-2**

**PROCESS HYGIENE CRITERIA**

**2.1. Meat and meat products**

| Food | Microorganisms/ toxins/ metabolites | Sampling plan ([1]) | | Limits ([2]) | | Reference method ([3]) | Stage where the criterion applies | Measures to be taken in case of unsatisfactory results |
|---|---|---|---|---|---|---|---|---|
| | | n | c | m | M | | | |
| 2.1.1. Cattle, sheep, goat and horse carcass | Aerobic colony count | | | $3,2x10^3$ cfu/$cm^2$ ([4]) | $1,0x10^5$ cfu/$cm^2$ ([4]) | ISO 4833 | ([9]) | ([12]) |
| | *Enterobacteriaceae* | | | $3,2x10^1$ cfu/$cm^2$ ([4]) | $3,2x10^2$ cfu/$cm^2$ ([4]) | ISO 21528-2 | ([9]) | ([12]) |
| 2.1.2. Swine carcass | Aerobic colony count | | | $1,0x10^4$ cfu/$cm^2$ ([4]) | $1,0x10^5$ cfu/$cm^2$ ([4]) | ISO 4833 | ([9]) | ([12]) |
| | *Enterobacteriaceae* | | | $1,0x10^2$ cfu/$cm^2$ ([4]) | $1,0x10^3$ cfu/$cm^2$ ([4]) | ISO 21528-2 | ([9]) | ([12]) |
| 2.1.3. Cattle, sheep, goat and horse carcass | *Salmonella* | 50 ([5]) | 2 ([6]) | Absence in the tested percentage of each carcass. | | EN/ISO 6579 | ([9]) | ([13]) |
| 2.1.4. Swine carcass | *Salmonella* | 50 ([5]) | 5 ([6]) | Absence in the tested percentage of each carcass. | | EN/ISO 6579 | ([9]) | ([14]) |
| 2.1.5. Broiler and turkey carcass | *Salmonella* | 50 ([5]) | 5 ([6]) | Absence in 25 g sample made up of the combination of samples collected from neck skin. | | EN/ISO 6579 | ([10]) | ([14]) |

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| 2.1.6. Minced meat | Aerobic colony count ([7]) | 5 | 2 | $5x10^5$ cfu/g | $5x10^6$ cfu/g | ISO 4833 | ([11]) | ([15]) |
| | *E. coli* ([8]) | 5 | 2 | $5x10^1$ cfu/g | $5x10^2$ cfu/g | ISO 16649-1 or 2 | ([11]) | ([15]) |
| 2.1.7. Mechanically separated meat ([9]) | Aerobic colony count | 5 | 2 | $5x10^5$ cfu/g | $5x10^6$ cfu/g | ISO 4833 | ([11]) | ([15]) |
| | *E. coli* ([8]) | 5 | 2 | $5x10^1$ cfu/g | $5x10^2$ cfu/g | ISO 16649-1 or 2 | ([11]) | ([15]) |
| 2.1.8. Meat preparations | *E. coli* ([8]) | 5 | 2 | $5x10^2$ cfu/g - $cm^2$ | $5x10^3$ cfu/g - $cm^2$ | ISO 16649-1 or 2 | ([11]) | ([15]) |

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

(2) For points 2.1.3, 2.1.4 and 2.1.5, m=M, cfu: colony-forming unit (in solid medium).

(3) The most recent edition of the Standards specified in this Regulation shall be used.

(4) The limits (m and M) apply only to samples taken by the destructive method. The daily mean log is calculated by first taking a log value of each individual test result and then calculating the mean of these log values.

(5) The 50 samples are derived from 10 consecutive sampling sessions in accordance with the sampling rules and frequencies laid down in this Regulation.

(6) 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. The food business operator may use a lower c value before this evaluation in order to reduce the presence of *salmonella.*

(7) This criterion does not apply to minced meat produced upon the request of consumers and sold without a long holding period.

(8) E. coli is used here as an indicator of faecal contamination.

(9) Carcasses after

(10) Carcases after dressing but before chilling

(11) Carcases after chilling

(12) End of the manufacturing process

(13) Improvements in slaughter hygiene and review of production controls.

(14) Improvements in slaughter hygiene, review of production controls and review of origins of animals.

(15) Improvements in slaughter hygiene, review of production controls, review of origins of animals and review of biosafety measures.

(16) Improvements in production hygiene and improvements in selection and/or origin of raw materials.

**Evaluation of analysis results**

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

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

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

— SATISFACTORY, if the daily mean log is < m,

— ACCEPTABLE, if the daily mean log is between m and M,

— UNSATISFACTORY, if the daily mean log is >M.

Salmonella in carcases:

— SATISFACTORY, if the presence of Salmonella is detected in a maximum of c samples,

— UNSATISFACTORY, if the presence of Salmonella is detected in more than c samples.

After each sampling session, the results of the last 10 sampling sessions are 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 < 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.

**2.2. Milk and dairy products**

| Food | Microorganisms/ toxins/ metabolites | Sampling plan ([1]) | | Limits ([2]) | | Reference method ([3]) | Stage where the criterion applies | Measures to be taken in case of unsatisfactory results |
|---|---|---|---|---|---|---|---|---|
| | | n | c | m | M | | | |
| 2.2.1. Pasteurized milk and other pasteurized liquid milk products | *Enterobacteriaceae* ([4]) | 5 | 0 | $10^1$ cfu/mL | | ISO 21528-1 | ([11]) | ([13]) |
| 2.2.2. Heat-treated milk or cheeses produced from whey | *E. coli* ([5]) | 5 | 2 | $10^2$ cfu/g | $10^3$ cfu/g | ISO 16649-1 or 2 | ([6]) | ([14]) |
| 2.2.3. Cheeses produced from raw milk | Coagulase positive staphylococci | 5 | 2 | $10^4$ cfu/g | $10^5$ cfu/g | EN/ISO 6888-2 | ([12]) | ([15]) |
| 2.2.4. Cheeses produced from heat-treated milk at lower temperatures than those of pasteurization ([7]) and seasoned cheeses produced from pasteurized or heat-treated milk at higher temperatures ([7]) | Coagulase positive staphylococci | 5 | 2 | $10^2$ cfu/g | $10^4$ cfu/g | EN/ISO 6888-1 or 2 | | |
| 2.2.5. Unseasoned cheeses produced from pasteurized or heat-treated milk at higher | Coagulase positive | 5 | 2 | $10^1$ cfu/g | $10^2$ cfu/g | EN/ISO 6888- | ([11]) | ([15]) |

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| temperatures (fresh cheeses) ([7]) | staphylococci | | | | | 1 or 2 | | |
| 2.2.6. Butter and cream produced from raw milk or heat-treated milk at lower temperatures than those of pasteurization | *E. coli* ([5]) | 5 | 2 | $10^1$ cfu/g | $10^2$ cfu/g | ISO 16649-1 or 2 | ([11]) | ([14]) |
| 2.2.7. Milk powder and whey powder | *Enterobacteriaceae* ([4]) | 5 | 0 | $10^1$ cfu/g | | ISO 21528-2 | ([11]) | ([16]) |
| | Coagulase positive staphylococci | 5 | 2 | $10^1$ cfu/g | $10^2$ cfu/g | EN/ISO 6888-1 or 2 | ([11]) | ([15]) |
| 2.2.8. İce cream ([8]) and frozen milky desserts | *Enterobacteriaceae* | 5 | 2 | $10^1$ cfu/g | $10^2$ cfu/g | ISO 21528-2 | ([11]) | ([14]) |
| 2.2.9. Dried infant formulae (including dietary foodstuffs for special medical purposes) | *Enterobacteriaceae* | 10 | 0 | absence in 10 g | | ISO 21528-1 | ([11]) | ([9]) |
| | *Bacillus cereus* | 5 | 1 | $5x10^1$ cfu/g | $5x10^2$ cfu/g | EN/ISO 7932 ([10]) | ([11]) | ([17]) |
| 2.2.10. Dried follow-up formulae | *Enterobacteriaceae* | 5 | 0 | absence in 10 g | | ISO 21528-1 | ([11]) | ([9]) |

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

(2) For point 2.2.1, 2.2.7, 2.2.9 and 2.2.10, m=M. cfu: colony-forming unit (in solid medium)

(3) The most recent edition of the Standards specified in this Regulation 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) The sample must be collected from the stage where the *E. coli* count is estimated to be at the highest level throughout the production process. In general, *E. coli* count is at its highest level at the beginning of the seasoning period for cheeses that do not support the development of *E. coli*. On the other hand, for cheeses that support the development of *E. coli*, this point is generally at the end of the seasoning period.

(7) If presented by the food business operator to the authorized representative of the Ministry, excluding cheeses that do not carry a risk for staphylococcal enterotoxin formation.

(8) Only ice creams containing milk ingredients.

(9) Improvements in production hygiene to minimise contamination. If the correlation between *Enterobacteriaceae* and *C. Sakazaii* has not been separately established at the factory level, the analyses of these microorganisms shall be implemented in parallel. If *Enterobacteriaceae* are detected in any of the sample units, the batch has to be analysed for E. sakazakii and Salmonella. The demonstration of the existence of a correlation between *Enterobacteriaceae* and *C. Sakazaii* to the authorized representative of the Ministry rests with the food business operator.

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

(11) End of the manufacturing process

(12) At the time during the manufacturing process when the number of staphylococci is expected to be highest

(13) Check on the efficiency of heat- treatment and prevention of recontamination as well as the quality of raw materials.

(14) Improvements in production hygiene and selection of raw materials.

(15) Improvements in production hygiene and selection of raw materials. If values >105 cfu/g are detected, the cheese batch has to be tested for staphylococcal *enterotoxins*.

(16) Check on the efficiency of heat treatment and prevention of recontamination.

(17) Improvements in production hygiene and selection of raw materials to minimise contamination.

**Evaluation of analysis 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 sample units

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.

*B. cereus* for dried infant formulae (including dietary foodstuffs for special medical purposes);

— SATISFACTORY, if all the values observed are ≤ m,

— ACCEPTABLE, if a maximum of c 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 values are between m and M.

**2.3. Egg products**

| Food | Microorganisms/ toxins/ metabolites | Sampling plan ([1]) | | Limits ([2]) | | Reference method ([3]) | Stage where the criterion applies | Measures to be taken in case of unsatisfactory results |
|---|---|---|---|---|---|---|---|---|
| | | n | c | m | M | | | |
| 2.3.1. Egg products | *Enterobacteriaceae* | 5 | 2 | $10^1$ cfu/g - mL | $10^2$ cfu/g - mL | ISO 21528-2 | ([4]) | ([5]) |

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

(2) cfu: colony-forming unit (in solid medium)

(3) The most recent edition of the Standards specified in this Regulation shall be used.

(4) End of the manufacturing process

(5) Checks on the efficiency of the heat treatment and prevention of recontamination

**Evaluation of analysis 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 < 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.

**2.4. Water products**

| Food | Microorganisms/ toxins/ metabolites | Sampling plan ([1]) | | Limits ([2]) | | Reference method ([3]) | Stage where the criterion applies | Measures to be taken in case of unsatisfactory results |
|---|---|---|---|---|---|---|---|---|
| | | n | c | m | M | | | |
| 2.4.1. Shelled and shucked products of cooked crustaceans and molluscan | *E. coli* | 5 | 2 | 1/g | $10^1$/g | ISO TS 16649-3 | ([4]) | ([5]) |
| | Coagulase positive staphylococci | 5 | 2 | $10^2$ cfu/g | $10^3$ cfu/g | EN/ISO 6888-1 or 2 | ([4]) | ([5]) |

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

(2) cfu: colony-forming unit (in solid medium)

(3) The most recent edition of the Standards specified in this Regulation shall be used.

(4) End of the manufacturing process

(5) Improvements in production hygiene.

**Evaluation of analysis 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 < 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.

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

— 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.

**2.5. Fruits, vegetables and their products**

| Food | Microorganisms/ toxins/ metabolites | Sampling plan ([1]) | | Limits ([2]) | | Reference method ([3]) | Stage where the criterion applies | Measures to be taken in case of unsatisfactory results |
|---|---|---|---|---|---|---|---|---|
| | | n | c | M | M | | | |
| 2.5.1. Pre-cut and ready-to-eat fruits and vegetables | *E. coli* | 5 | 2 | $10^2$ cfu/g | $10^3$ cfu/g | ISO 16649-1 or 2 | ([4]) | ([5]) |
| 2.5.2. Non-pasteurized, ready-to-eat pasteurized fruit and vegetable juices | *E. coli* | 5 | 2 | $10^2$ cfu/g | $10^3$ cfu/g | ISO 16649-1 or 2 | ([4]) | ([5]) |

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

(2) cfu: colony-forming unit (in solid medium)

(3) The most recent edition of the Standards specified in this Regulation shall be used.

(4) End of the manufacturing process

(5) Improvements in production hygiene.

**Evaluation of analysis results**

The limits given refer to each sample unit tested.

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

E. coli in pre-cut fruit and vegetables (ready-to-eat) and in unpasteurised fruit and vegetable juices (ready-to-eat):

— 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.

**ANNEX-3**

**Limits of Pathogen Microorganisms**

| Microorganisms | Food | Sampling plan ([1]) | | Limits ([2]) | | Reference Method ([3]) |
|---|---|---|---|---|---|---|
| | | N | c | m | M | |
| *Salmonella* | Ready-to-eat | 5 | 0 | 0/25 g-mL | | EN/ISO 6579 |
| *L. monocytogenes* | Ready-to-eat | 5 | 0 | 0/25 g-mL | | EN/ISO 11290-1 |
| Thermo-tolerant *Campylobacter* spp. | Ready-to-eat | 5 | 0 | 0/25 g-mL | | |
| *E. coli* O157 | Ready-to-eat | 5 | 0 | 0/25 g-mL | | ISO 16654 |
| *V. cholera* ([4]) | Ready-to-eat | 5 | 0 | 0/25 g-mL | | |
| *V. parahaemolyticus* ([4]) | Ready-to-eat | 5 | 0 | 0/25 g-mL | | |
| Coagulase positive staphylococci | Not ready-to-eat | 5 | 2 | $10^3$ | $10^4$ | EN/ISO 6888-1 or 2 |
| | Ready-to-eat | 5 | 2 | $10^2$ | $10^3$ | |
| *B. cereus* | Not ready-to-eat | 5 | 2 | $10^3$ | $10^4$ | EN/ISO 7932 |
| | Ready-to-eat | 5 | 2 | $10^2$ | $10^3$ | |
| Sulphide-reducing anaerobe | Not ready-to-eat | 5 | 2 | $10^3$ | $10^4$ | ISO 7937 |
| | Ready-to-eat | 5 | 2 | $10^2$ | $10^3$ | |

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

(2) cfu: colony-forming unit (in solid medium)

(3) The most recent edition of the Standards specified in this Regulation shall be used.

(4) Only sought in fishery products raised/hunted in salty waters.

**ANNEX-4**

**Sampling rules and preparation of analysis samples**

**4.1. Sampling rules and preparation of analysis samples**

In the absence of specific rules on sampling and preparation of test samples, the relevant standards of the ISO and the guidelines of the Codex Alimentarius shall be used as reference methods.

**4.2. Rules for microbiological sampling from slaughterhouses and establishments producing minced meat, meat preparations, mechanically separated meat and raw meat**

**4.2.1. Sampling rules for cattle, swine, sheep, goat and horse carcasses**

The destructive and non-destructive sampling methods, the selection of the sampling sites and the rules for storage and transport of samples are described in standard ISO 17604.

Five carcases shall be sampled at random during each sampling session. Sample sites should 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 carcase shall be sampled. Four tissue samples representing a total of 20 cm² 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 cm² or 50 cm² for small ruminant carcases per sampling site.

When sampling for Salmonella analyses, an abrasive sponge sampling method shall be used. The sampling area shall cover a minimum of 400 cm² per site selected.

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

**4.2.2. Sampling rules for poultry carcasses and raw poultry meat**

When sampling for Salmonella analysis in slaughterhouses, samples shall be taken from the neck skin of poultry carcasses. In other establishments, samples for Salmonella analysis in raw poultry meat shall be collected from the neck skin of poultry carcasses if possible; if this is not possible, the sample shall be collected from skinned and/or skinless poultry meat and this decision shall be made on a risk basis.

Slaughterhouses must have sampling plans for poultry carcasses on the basis of Salmonella serotypes potentially existing in the heard.

For the Salmonella analyses, a minimum of 15 carcases shall be sampled at random during each sampling session and after chilling for the analysis of the process hygiene criteria given in Article 2.1.5 of Annex 2 to the present Regulation. A piece of approximately 10 g from neck skin shall be obtained from each carcase. On each occasion the neck skin samples from three carcases from herds of the same origin shall be pooled before examination in order to form 5 x 25 g final samples. These samples shall also be used to verify the compliance with the food safety criteria given in Article 1.3.2 of Annex 1 to this Regulation.

For the Salmonella analyses in raw poultry meat except for poultry carcasses, 5 samples of at least 25 g each shall be collected from the same batch. During sampling from skinned poultry meat, if the amount of skin is not sufficient to form the sample unit, the sample shall include skin and, at a lesser extent, poultry meat. For sampling from skinless meat or poultry meat containing a small amount of skin, the sample shall be collected from the skinned part to the extent possible with a small or sufficient sample amount obtained from the meat itself.

**4.2.3. Guidelines for sampling**

More detailed guidelines pertaining to sampling from carcasses, especially those concerning the locations of sampling points may be included in the good practice guidelines specified in the Food Hygiene Regulation.

#### 4.2.4. Sampling frequencies for carcases, minced meat, meat preparations and mechanically separated meat

In the case of sampling for Salmonella analyses of minced meat, meat preparations and carcases, the frequency can be reduced to once in 15 days 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 described sampling. 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.

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

As regards the sampling of minced meat and meat preparations for E. coli and aerobic colony count analyses and the sampling of carcases for *Enterobacteriaceae* and aerobic colony count analyses, the frequency may be reduced to once in 15 days testing if satisfactory results are obtained for six consecutive weeks.

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