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 [F1]... 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[(1)], the rules on parasites laid down under Regulation (EC) No 854/2004 of the European Parliament and of the Council[(2)] and the microbiological criteria laid down under Council Directive 80/777/EEC[(3)].

Textual Amendments

F1 Word in Art. 1 omitted (31.12.2020) by virtue of The General Food Hygiene (Amendment) (EU Exit) Regulations 2019 (S.I. 2019/642), regs. 1, **21**; 2020 c. 1, Sch. 5 para. 1(1)

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;

(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 **[**F2Regulation (EU) No 609/2013**]**;

(i) 'food intended for special medical purposes' means dietary food for special medical purposes, as defined in **[**F3Regulation (EU) No 609/2013**]**;

(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**[**F4;**]**

(m) **[**F5the 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 (4)**[**F6;**]]**

(n) '**[**F7a 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 (5) ;

(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 **[**F8;**]]**

(q) '**[**F9reptile meat' means reptile meat as laid down in point (16) of Article 2 of Commission Delegated Regulation (EU) 2019/625 (6) .**]**

Textual Amendments

F2 Words in Art. 2(h) substituted (31.12.2020) by The General Food Hygiene (Amendment) (EU Exit) Regulations 2019 (S.I. 2019/642), regs. 1, **22(b)**; 2020 c. 1, Sch. 5 para. 1(1)

F3 Words in Art. 2(i) substituted (31.12.2020) by The General Food Hygiene (Amendment) (EU Exit) Regulations 2019 (S.I. 2019/642), regs. 1, **22(c)**; 2020 c. 1, Sch. 5 para. 1(1)

F4 Substituted by Commission Regulation (EU) No 209/2013 of 11 March 2013 amending Regulation (EC) No 2073/2005 as regards microbiological criteria for sprouts and the sampling rules for poultry carcases and fresh poultry meat (Text with EEA relevance).

F5 Inserted by Commission Regulation (EU) No 209/2013 of 11 March 2013 amending Regulation (EC) No 2073/2005 as regards microbiological criteria for sprouts and the sampling rules for poultry carcases and fresh poultry meat (Text with EEA relevance).

F6 Substituted by Commission Regulation (EU) 2019/229 of 7 February 2019 amending Regulation (EC) No 2073/2005 on microbiological criteria for foodstuffs as regards certain methods, the food safety criterion for Listeria monocytogenes in sprouted seeds, and the process hygiene criterion and food safety criterion for unpasteurised fruit and vegetable juices (ready-to-eat) (Text with EEA relevance).

F7 Inserted by Commission Regulation (EU) 2019/229 of 7 February 2019 amending Regulation (EC) No 2073/2005 on microbiological criteria for foodstuffs as regards certain methods, the food safety criterion for Listeria monocytogenes in sprouted seeds, and the process hygiene criterion and food safety criterion for unpasteurised fruit and vegetable juices (ready-to-eat) (Text with EEA relevance).

F8 Substituted by Commission Regulation (EU) 2020/205 of 14 February 2020 amending Regulation (EC) No 2073/2005 as regards Salmonella in reptile meat (Text with EEA relevance).

F9 Inserted by Commission Regulation (EU) 2020/205 of 14 February 2020 amending Regulation (EC) No 2073/2005 as regards Salmonella in reptile meat (Text with EEA relevance).

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.

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.

[[F6]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.**]**

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.

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.

[[F6]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.**]**

Textual Amendments

F6 Substituted by Commission Regulation (EU) 2019/229 of 7 February 2019 amending Regulation (EC) No 2073/2005 on microbiological criteria for foodstuffs as regards certain methods, the food safety criterion for Listeria monocytogenes in sprouted seeds, and the process hygiene criterion and food safety criterion for unpasteurised fruit and vegetable juices (ready-to-eat) (Text with EEA relevance).

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.

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.

F10 Article 8

Transitional derogation

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Textual Amendments

F10 Art. 8 omitted (31.12.2020) by virtue of The General Food Hygiene (Amendment) (EU Exit) Regulations 2019 (S.I. 2019/642), regs. 1, **23**; 2020 c. 1, Sch. 5 para. 1(1)

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 carcases 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.

F11 …

Textual Amendments

F11 Words in Signature omitted (31.12.2020) by virtue of The General Food Hygiene (Amendment) (EU Exit) Regulations 2019 (S.I. 2019/642), regs. 1, **24**; 2020 c. 1, Sch. 5 para. 1(1)

(**1**) OJ L 139, 30.4.2004, p. 55, corrected by OJ L 226, 25.6.2004, p. 22.

(**2**) OJ L 139, 30.4.2004, p. 206, corrected by OJ L 226, 25.6.2004, p. 83.

(**3**) OJ L 229, 30.8.1980, p. 1.

(**4**) **[**[F5]See page 16 of this Official Journal.**]**

(**5**) **[**[F7]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).**]**

(**6**) **[**[F9]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).**]**

Textual Amendments

F5 Inserted by Commission Regulation (EU) No 209/2013 of 11 March 2013 amending Regulation (EC) No 2073/2005 as regards microbiological criteria for sprouts and the sampling rules for poultry carcases and fresh poultry meat (Text with EEA relevance).

F7 Inserted by Commission Regulation (EU) 2019/229 of 7 February 2019 amending Regulation (EC) No 2073/2005 on microbiological criteria for foodstuffs as regards certain methods, the food safety criterion for Listeria monocytogenes in sprouted seeds, and the process hygiene criterion and food safety criterion for unpasteurised fruit and vegetable juices (ready-to-eat) (Text with EEA relevance).

F9 Inserted by Commission Regulation (EU) 2020/205 of 14 February 2020 amending Regulation (EC) No 2073/2005 as regards Salmonella in reptile meat (Text with EEA relevance).

Changes to legislation:
There are currently no known outstanding effects for the Commission Regulation (EC) No 2073/2005.