

Commission Regulation (EC) No 2073/2005 of 15 November 2005  
on microbiological criteria for foodstuffs (Text with EEA relevance)

*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 [F1Regulation (EU) No 609/2013];
- (i) ‘food intended for special medical purposes’ means dietary food for special medical purposes, as defined in [F2Regulation (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;

*Changes to legislation:* There are currently no known outstanding effects for the Commission Regulation (EC) No 2073/2005, Article 2. (See end of Document for details)

- (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<sup>[F3];</sup>
- (m) <sup>[F4]</sup>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>(1)</sup><sup>[F5];</sup>
- (n) ‘<sup>[F6]</sup>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>(2)</sup> ;
- (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 <sup>[F7];</sup>
- (q) ‘<sup>[F8]</sup>reptile meat’ means reptile meat as laid down in point (16) of Article 2 of Commission Delegated Regulation (EU) 2019/625 <sup>(3)</sup> .]

#### Textual Amendments

- F1** 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)
- F2** 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)
- F3** 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 carcasses and fresh poultry meat (Text with EEA relevance).
- F4** 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 carcasses and fresh poultry meat (Text with EEA relevance).
- F5** 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).
- F6** 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).
- F7** 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).
- F8** 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).

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- (1) [<sup>F4</sup>See page 16 of this Official Journal.]
- (2) [<sup>F6</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).]
- (3) [<sup>F8</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).]

#### Textual Amendments

- F4** 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 carcasses and fresh poultry meat](#) (Text with EEA relevance).
- F6** 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** 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).

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