

Regulation (EC) No 852/2004 of the European Parliament and
of the Council of 29 April 2004 on the hygiene of foodstuffs

CHAPTER I

GENERAL PROVISIONS

Article 1

Scope

1 This Regulation lays down general rules for food business operators on the hygiene of foodstuffs, taking particular account of the following principles:

- a primary responsibility for food safety rests with the food business operator;
- b it is necessary to ensure food safety throughout the food chain, starting with primary production;
- c it is important, for food that cannot be stored safely at ambient temperatures, particularly frozen food, to maintain the cold chain;
- d general implementation of procedures based on the HACCP principles, together with the application of good hygiene practice, should reinforce food business operators' responsibility;
- e guides to good practice are a valuable instrument to aid food business operators at all levels of the food chain with compliance with food hygiene rules and with the application of the HACCP principles;
- f it is necessary to establish microbiological criteria and temperature control requirements based on a scientific risk assessment;
- g it is necessary to ensure that imported foods are of at least the same hygiene standard as food produced in the Community, or are of an equivalent standard.

This Regulation shall apply to all stages of production, processing and distribution of food and to exports, and without prejudice to more specific requirements relating to food hygiene.

2 This Regulation shall not apply to:

- a primary production for private domestic use;
- b the domestic preparation, handling or storage of food for private domestic consumption;
- c the direct supply, by the producer, of small quantities of primary products to the final consumer or to local retail establishments directly supplying the final consumer;
- d collection centres and tanneries which fall within the definition of food business only because they handle raw material for the production of gelatine or collagen.

3 Member States shall establish, under national law, rules governing the activities referred to in paragraph 2(c). Such national rules shall ensure the achievement of the objectives of this Regulation.

Article 2

Definitions

- 1 For the purposes of this Regulation:
 - a " food hygiene ", hereinafter called " hygiene ", means the measures and conditions necessary to control hazards and to ensure fitness for human consumption of a foodstuff taking into account its intended use;
 - b " primary products " means products of primary production including products of the soil, of stock fanning, of hunting and fishing;
 - c " establishment " means any unit of a food business;
 - d " competent authority " means the central authority of a Member State competent to ensure compliance with the requirements of this Regulation or any other authority to which that central authority has delegated that competence; it shall also include, where appropriate, the corresponding authority of a third country;
 - e "equivalent" means, in respect of different systems, capable of meeting the same objectives;
 - f "contamination" means the presence or introduction of a hazard;
 - g "potable water" means water meeting the minimum requirements laid down in Council Directive 98/83/EC of 3 November 1998 on the quality of water intended for human consumption⁽¹⁾;
 - h "clean seawater" means natural, artificial or purified seawater or brackish water that does not contain micro-organisms, harmful substances or toxic marine plankton in quantities capable of directly or indirectly affecting the health quality of food;
 - i "clean water" means clean seawater and fresh water of a similar quality;
 - j "wrapping" means the placing of a foodstuff in a wrapper or container in direct contact with the foodstuff concerned, and the wrapper or container itself;
 - k "packaging" means the placing of one or more wrapped foodstuffs in a second container, and the latter container itself;
 - l "hermetically sealed container" means a container that is designed and intended to be secure against the entry of hazards;
 - m "processing" means any action that substantially alters the initial product, including heating, smoking, curing, maturing, drying, marinating, extraction, extrusion or a combination of those processes;
 - n "unprocessed products" means foodstuffs that have not undergone processing, and includes products that have been divided, parted, severed, sliced, boned, minced, skinned, ground, cut, cleaned, trimmed, husked, milled, chilled, frozen, deep-frozen or thawed;
 - o "processed products" means foodstuffs resulting from the processing of unprocessed products. These products may contain ingredients that are necessary for their manufacture or to give them specific characteristics.
- 2 The definitions laid down in Regulation (EC) No 178/2002 shall also apply.
- 3 In the Annexes to this Regulation the terms "where necessary", "where appropriate", "adequate" and "sufficient" shall mean respectively where necessary, where appropriate, adequate or sufficient to achieve the objectives of this Regulation.

CHAPTER II

FOOD BUSINESS OPERATORS' OBLIGATIONS*Article 3***General obligation**

Food business operators shall ensure that all stages of production, processing and distribution of food under their control satisfy the relevant hygiene requirements laid down in this Regulation.

*Article 4***General and specific hygiene requirements**

1 Food business operators carrying out primary production and those associated operations listed in Annex I shall comply with the general hygiene provisions laid down in Part A of Annex I and any specific requirements provided for in Regulation (EC) No.../2004⁽²⁾.

2 Food business operators carrying out any stage of production, processing and distribution of food after those stages to which paragraph 1 applies shall comply with the general hygiene requirements laid down in Annex II and any specific requirements provided for in Regulation (EC) No.../2004⁽²⁾.

3 Food business operators shall, as appropriate, adopt the following specific hygiene measures:

- a compliance with microbiological criteria for foodstuffs;
- b procedures necessary to meet targets set to achieve the objectives of this Regulation;
- c compliance with temperature control requirements for foodstuffs;
- d maintenance of the cold chain;
- e sampling and analysis.

4 The criteria, requirements and targets referred to in paragraph 3 shall be adopted in accordance with the procedure referred to in Article 14(2).

Associated sampling and analysis methods shall be laid down in accordance with the same procedure.

5 When this Regulation, Regulation (EC) No/2004⁽³⁾ and their implementing measures do not specify sampling or analysis methods, food business operators may use appropriate methods laid down in other Community or national legislation or, in the absence of such methods, methods that offer equivalent results to those obtained using the reference method, if they are scientifically validated in accordance with internationally recognised rules or protocols.

6 Food business operators may use the guides provided for in Articles 7, 8 and 9 as an aid to compliance with their obligations under this Regulation.

Article 5

Hazard analysis and critical control points

1 Food business operators shall put in place, implement and maintain a permanent procedure or procedures based on the HACCP principles.

2 The HACCP principles referred to in paragraph 1 consist of the following:

- a identifying any hazards that must be prevented, eliminated or reduced to acceptable levels;
- b identifying the critical control points at the step or steps at which control is essential to prevent or eliminate a hazard or to reduce it to acceptable levels;
- c establishing critical limits at critical control points which separate acceptability from unacceptability for the prevention, elimination or reduction of identified hazards;
- d establishing and implementing effective monitoring procedures at critical control points;
- e establishing corrective actions when monitoring indicates that a critical control point is not under control;
- f establishing procedures, which shall be carried out regularly, to verify that the measures outlined in subparagraphs (a) to (e) are working effectively; and
- g establishing documents and records commensurate with the nature and size of the food business to demonstrate the effective application of the measures outlined in subparagraphs (a) to (f).

When any modification is made in the product, process, or any step, food business operators shall review the procedure and make the necessary changes to it.

3 Paragraph 1 shall apply only to food business operators carrying out any stage of production, processing and distribution of food after primary production and those associated operations listed in Annex I.

4 Food business operators shall:

- a provide the competent authority with evidence of their compliance with paragraph 1 in the manner that the competent authority requires, taking account of the nature and size of the food business;
- b ensure that any documents describing the procedures developed in accordance with this Article are up-to-date at all times;
- c retain any other documents and records for an appropriate period.

5 Detailed arrangements for the implementation of this Article may be laid down in accordance with the procedure referred to in Article 14(2). Such arrangements may facilitate the implementation of this Article by certain food business operators, in particular by providing for the use of procedures set out in guides for the application of HACCP principles, in order to comply with paragraph 1. Such arrangements may also specify the period during which food business operators shall retain documents and records in accordance with paragraph 4(c).

Article 6

Official controls, registration and approval

1 Food business operators shall cooperate with the competent authorities in accordance with other applicable Community legislation or, if it does not exist, with national law.

2 In particular, every food business operator shall notify the appropriate competent authority, in the manner that the latter requires, of each establishment under its control that carries out any of the stages of production, processing and distribution of food, with a view to the registration of each such establishment.

Food business operators shall also ensure that the competent authority always has up-to-date information on establishments, including by notifying any significant change in activities and any closure of an existing establishment.

3 However, food business operators shall ensure that establishments are approved by the competent authority, following at least one on-site visit, when approval is required:

- a under the national law of the Member State in which the establishment is located;
- b under Regulation (EC) No /2004⁽⁴⁾; or
- c by a decision adopted in accordance with the procedure referred to in Article 14(2).

Any Member State requiring the approval of certain establishments located on its territory under national law, as provided for in subparagraph (a), shall inform the Commission and other Member States of the relevant national rules.

CHAPTER III

GUIDES TO GOOD PRACTICE

Article 7

Development, dissemination and use of guides

Member States shall encourage the development of national guides to good practice for hygiene and for the application of HACCP principles in accordance with Article 8. Community guides shall be developed in accordance with Article 9.

The dissemination and use of both national and Community guides shall be encouraged. Nevertheless, food business operators may use these guides on a voluntary basis.

Article 8

National guides

1 When national guides to good practice are developed, they shall be developed and disseminated by food business sectors:

- a in consultation with representatives of parties whose interests may be substantially affected, such as competent authorities and consumer groups;
- b having regard to relevant codes of practice of the Codex Alimentarius; and

- c when they concern primary production and those associated operations listed in Annex I, having regard to the recommendations set out in Part B of Annex I.
- 2 National guides may be developed under the aegis of a national standards institute referred to in Annex II to Directive 98/34/EC⁽⁵⁾.
- 3 Member States shall assess national guides in order to ensure that:
- a they have been developed in accordance with paragraph 1;
 - b their contents are practicable for the sectors to which they refer; and
 - c they are suitable as guides to compliance with Articles 3,4 and 5 in the sectors and for the foodstuffs covered.
- 4 Member States shall forward to the Commission national guides complying with the requirements of paragraph 3. The Commission shall set up and run a registration system for such guides and make it available to Member States.
- 5 Guides to good practice drawn up under Directive 93/43/EEC shall continue to apply after the entry into force of this Regulation, provided that they are compatible with its objectives.

Article 9

Community guides

- 1 Before Community guides to good practice for hygiene or for the application of the HACCP principles are developed, the Commission shall consult the Committee referred to in Article 14. The objective of this consultation shall be to consider the case for such guides, their scope and subject matter.
- 2 When Community guides are prepared, the Commission shall ensure that they are developed and disseminated:
- a by or in consultation with appropriate representatives of European food business sectors, including SMEs, and other interested parties, such as consumer groups;
 - b in collaboration with parties whose interests may be substantially affected, including competent authorities;
 - c having regard to relevant codes of practice of the Codex Alimentarius; and
 - d when they concern primary production and those associated operations listed in Annex I, having regard to the recommendations set out in Part B of Annex I.
- 3 The Committee referred to in Article 14 shall assess draft Community guides in order to ensure that:
- a they have been developed in accordance with paragraph 2;
 - b their contents are practicable for the sectors to which they refer throughout the Community; and
 - c they are suitable as guides to compliance with Articles 3,4 and 5 in the sectors and for the foodstuffs covered.
- 4 The Commission shall invite the Committee referred to in Article 14 periodically to review any Community guides prepared in accordance with this Article, in cooperation with the bodies mentioned in paragraph 2.

The aim of this review shall be to ensure that the guides remain practicable and to take account of technological and scientific developments.

5 The titles and references of Community guides prepared in accordance with this Article shall be published in the C series of the Official Journal of the European Union.

CHAPTER IV

IMPORTS AND EXPORTS

Article 10

Imports

As regards the hygiene of imported food, the relevant requirements of food law referred to in Article 11 of Regulation (EC) No 178/2002 shall include the requirements laid down in Articles 3 to 6 of this Regulation.

Article 11

Exports

As regards the hygiene of exported or re-exported food, the relevant requirements of food law referred to in Article 12 of Regulation (EC) No 178/2002 shall include the requirements laid down in Articles 3 to 6 of this Regulation.

CHAPTER V

FINAL PROVISIONS

Article 12

Implementing measures and transitional arrangements

Implementing measures and transitional arrangements may be laid down in accordance with the procedure referred to in Article 14(2).

Article 13

Amendment and adaptation of Annexes I and II

1 Annexes I and II may be adapted or updated in accordance with the procedure referred to in Article 14(2), taking into account:

- a the need to revise the recommendations set out in Annex I, Part B, paragraph 2;
- b the experience gained from the implementation of HACCP-based systems pursuant to Article 5;
- c technological developments and their practical consequences and consumer expectations with regard to food composition;
- d scientific advice, particularly new risk assessments;
- e microbiological and temperature criteria for foodstuffs.

2 Derogations from Annexes I and II may be granted, in particular in order to facilitate the implementation of Article 5 for small businesses, in accordance with the procedure referred to in Article 14(2), taking into account the relevant risk factors, provided that such derogations do not affect the achievement of the objectives of this Regulation.

3 Member States may, without compromising achievement of the objectives of this Regulation, adopt, in accordance with paragraphs 4 to 7 of this Article, national measures adapting the requirements laid down in Annex II.

4

- a The national measures referred to in paragraph 3 shall have the aim of:
 - (i) enabling the continued use of traditional methods, at any of the stages of production, processing or distribution of food; or
 - (ii) accommodating the needs of food businesses situated in regions that are subject to special geographical constraints.
- b In other cases, they shall apply only to the construction, layout and equipment of establishments.

5 Any Member State wishing to adopt national measures as referred to in paragraph 3 shall notify the Commission and other Member States. The notification shall:

- a provide a detailed description of the requirements that that Member State considers need to be adapted and the nature of the adaptation sought;
- b describe the foodstuffs and establishments concerned;
- c explain the reasons for the adaptation, including, where relevant, by providing a summary of the hazard analysis carried out and any measures to be taken to ensure that the adaptation will not compromise the objectives of this Regulation; and
- d give any other relevant information.

6 The other Member States shall have three months from the receipt of a notification referred to in paragraph 5 to send written comments to the Commission. In the case of the adaptations arising from paragraph 4(b), this period shall, at the request of any Member State, be extended to four months. The Commission may, and when it receives written comments from one or more Member States shall, consult Member States within the committee referred to in Article 14(1). The Commission may decide, in accordance with the procedure referred to in Article 14(2), whether the envisaged measures may be implemented, subject, if necessary, to appropriate amendments. Where appropriate, the Commission may propose general measures in accordance with paragraph 1 or 2.

7 A Member State may adopt national measures adapting the requirements of Annex II only:

- a in compliance with a decision adopted in accordance with paragraph 6; or
- b if, one month after the expiry of the period referred to in paragraph 6, the Commission has not informed Member States that it has received written comments or that it intends to propose the adoption of a decision in accordance with paragraph 6.

Article 14

Committee procedure

1 The Commission shall be assisted by the Standing Committee on the Food Chain and Animal Health.

2 Where reference is made to this paragraph, Articles 5 and 7 of Decision 1999/468/EC shall apply, having regard to the provisions of Article 8 thereof.

The period laid down in Article 5(6) of Decision 1999/468/EC shall be set at three months.

3 The Committee shall adopt its rules of procedure.

Article 15

Consultation of the European Food Safety Authority

The Commission shall consult the European Food Safety Authority on any matter falling within the scope of this Regulation that could have a significant impact on public health and, in particular, before proposing criteria, requirements or targets in accordance with Article 4(4).

Article 16

Report to the European Parliament and the Council

1 The Commission shall, not later than ...⁽⁶⁾, submit a report to the European Parliament and the Council.

2 The report shall, in particular, review the experience gained from the application of this Regulation and consider whether it would be desirable and practicable to provide for the extension of the requirements of Article 5 to food business operators carrying out primary production and those associated operations listed in Annex I.

3 The Commission shall, if appropriate, accompany the report with relevant proposals.

Article 17

Repeal

1 Directive 93/43/EEC shall be repealed with effect from the date of application of this Regulation.

2 References to the repealed Directive shall be construed as being made to this Regulation.

3 However, decisions adopted pursuant to Articles 3(3) and 10 of Directive 93/43/EEC shall remain in force pending their replacement by decisions adopted in accordance with this Regulation or Regulation (EC) No 178/2002. Pending the setting of the criteria or requirements referred to in Article 4(3), points (a) to (e) of this Regulation, Member States may maintain any national rules establishing such criteria or requirements that they had adopted in accordance with Directive 93/43/EEC.

4 Pending the application of new Community legislation laying down rules for official controls on food, Member States shall take all appropriate measures to ensure the fulfilment of the obligations laid down in or under this Regulation.

*Article 18***Entry into force**

This Regulation shall enter into force twenty days after the date of its publication in the Official Journal of the European Union.

It shall apply 18 months after the date on which all of the following acts have entered into force:

- (a) Regulation (EC) No.../2004⁽⁷⁾;
- (b) Regulation (EC) No.../2004 of the European Parliament and of the Council of laying down specific rules for the organisation of official controls on products of animal origin intended for human consumption⁽⁸⁾; and
- (c) Directive 2004/41/EC of the European Parliament and of the Council of repealing certain Directives concerning food hygiene and health conditions for the production and placing on the market of certain products of animal origin intended for human consumption⁽⁹⁾.

However, it shall apply no earlier than 1 January 2006.

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

Done at Strasbourg, 29 April 2004.

For the European Parliament

The President

P. COX

For the Council

The President

M. MCDOWELL

- (1) [OJ L 330, 5.12.1998, p. 32](#). Directive as modified by Regulation (EC) No 1882/2003.
- (2) Note to Official Journal: insert No of Regulation laying down specific hygiene rules for food of animal origin.
- (3) Note to Official Journal: insert number of Regulation laying down specific hygiene rules for food of animal origin.
- (4) Note to Official Journal: insert number of Regulation laying down specific hygiene rules for food of animal origin.
- (5) Directive 98/34/EC of the European Parliament and of the Council of 22 June 1998 laying down a procedure for the provision of information in the field of technical standards and regulations ([OJ L 204, 21.7.1998, p. 37](#)). Directive as amended by Directive 98/48/EC ([OJ L 217, 5.8.1998, p. 18](#)).
- (6) Five years after the entry into force of this Regulation.
- (7) Note to Official Journal: insert number of Regulation laying down specific hygiene rules for food of animal origin.
- (8) See, of this Official Journal.
- (9) See p. of this Official Journal.