

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

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 853/2004.

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 853/2004.

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.

[<sup>F14</sup> The criteria, requirements and targets referred to in paragraph 3, and associated sampling and analysis methods shall be laid down by the Commission. Those measures, designed to amend non-essential elements of this Regulation by supplementing it, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 14(3).]

5 When this Regulation, Regulation (EC) No 853/2004 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.

*Status: Point in time view as at 20/04/2009.*

*Changes to legislation: There are currently no known outstanding effects for the Regulation (EC) No 852/2004 of the European Parliament and of the Council, CHAPTER II. (See end of Document for details)*

### Textual Amendments

- F1** Substituted by Regulation (EC) No 219/2009 of the European Parliament and of the Council of 11 March 2009 adapting a number of instruments subject to the procedure referred to in Article 251 of the Treaty to Council Decision 1999/468/EC with regard to the regulatory procedure with scrutiny Adaptation to the regulatory procedure with scrutiny — Part Two.

## 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 853/2004;

or

[<sup>F1</sup>c by a decision adopted by the Commission. That measure, designed to amend non-essential elements of this Regulation, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 14(3).]

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.

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