

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

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.

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- 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 ...<sup>(1)</sup>, 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<sup>(2)</sup>;
- (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<sup>(3)</sup>; 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

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*Status: This is the original version (as it was originally adopted).*

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and placing on the market of certain products of animal origin intended for human consumption<sup>(4)</sup>.

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

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**Status:** This is the original version (as it was originally adopted).

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- (1) Five years after the entry into force of this Regulation.
- (2) Note to Official Journal: insert number of Regulation laying down specific hygiene rules for food of animal origin.
- (3) Seep, of this Official Journal.
- (4) See p. of this Official Journal.