

Regulation (EC) No 854/2004 of the European Parliament and of the Council of 29 April 2004 laying down specific rules for the organisation of official controls on products of animal origin intended for human consumption (repealed)

CHAPTER IV

FINAL PROVISIONS

Article 16

Implementing measures and transitional measures

Implementing measures and transitional arrangements may be laid down in accordance with the procedure referred to in Article 19(2).

Article 17

Amendment and adaptation of the Annexes

1 Annexes I, II, III, IV, V and VI may be amended or supplemented to take account of scientific and technical progress in accordance with the procedure referred to in Article 19(2).

2 Exemptions from Annexes I, II, III, IV, V and VI may be granted in accordance with the procedure referred to in Article 19(2), provided that they 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, national measures adapting the requirements laid down in Annex I.

4 The national measures referred to in paragraph 3 shall:

- a have the aim of:
 - (i) enabling the continued use of traditional methods at any of the stages of production, processing or distribution of food;
 - (ii) accommodating the needs of food businesses with a low throughput or that are situated in regions that are subject to special geographic constraints; or
 - (iii) permitting pilot projects to take place in order to try out new approaches to hygiene controls on meat;
- b concern in particular the following elements of Annex I:
 - (i) food chain information;
 - (ii) the presence of the competent authority in establishments.

5 Any Member State wishing to adopt national measures as referred to in paragraph 3 shall notify the Commission and other Member States. Each 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 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. 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 19(1). The Commission may decide, in accordance with the procedure referred to in Article 19(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 paragraphs 1 or 2 of this Article.

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

- a in compliance with a decision adopted in accordance with paragraph 6;
- 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.

8 When a Member State adopts national measures implementing a pilot project to try out new approaches to hygiene controls on meat in accordance with paragraphs 3 to 7, the Member State shall communicate the results to the Commission as soon as they are available. The Commission shall then consider proposing general measures in accordance with paragraph 1.

Article 18

Specific decisions

Without prejudice to the generality of Article 16 and Article 17(1), implementing measures may be laid down, or amendments to Annexes I, II, III, IV, V or VI adopted, in accordance with the procedure referred to in Article 19(2), to specify:

- 1) tests to assess the performance of food business operators and their staff;
- 2) the method of communicating inspection results;
- 3) criteria to determine when, on the basis of a risk analysis, the official veterinarian need not be present in slaughterhouses and game handling establishments throughout ante-mortem and post-mortem inspection;
- 4) rules concerning the content of tests for official veterinarians and official auxiliaries;
- 5) microbiological criteria for process control in relation to hygiene in establishments;
- 6) alternative procedures, serological or other laboratory tests that provide guarantees at least equivalent to specific post-mortem inspection procedures described in Annex I, Section IV, and may therefore replace them, if the competent authority so decides;
- 7) circumstances in which certain of the specific post-mortem inspection procedures described in Annex I, Section IV, are not necessary, having regard to the holding, region or country of origin and to the principles of risk analysis,
- 8) rules for laboratory testing;

- 9) the cold treatment to be applied to meat in relation to cysticercosis and trichinosis;
- 10) conditions under which holdings and regions can be certified as officially free of cysticercus or trichinae;
- 11) methods to be applied when examining for the conditions referred to in Annex I, Section IV, Chapter DC;
- 12) for fattening pigs, criteria for controlled housing conditions and integrated production systems;
- 13) criteria for the classification of production and relaying areas for live bivalve molluscs in cooperation with the relevant Community Reference Laboratory, including:
 - (a) limit values and analysis methods for marine biotoxins,
 - (b) virus testing procedures and virological standards, and
 - (c) sampling plans and the methods and analytical tolerances to be applied to check compliance with the criteria;
- 14) organoleptic criteria for the evaluation of the freshness of fishery products;
- 15) analytical limits, methods of analysis and sampling plans for the official controls on fishery products required under Annex III, including with regard to parasites and environmental contaminants;
- 16) the method by which the Commission will make lists of third countries and establishments in third countries available to the public pursuant to Articles 11, 12, 13 and 15;
- 17) models for documents and criteria for the use of electronic documents;
- 18) criteria for determining the risk that particular products of animal origin imported into the Community present;
- 19) special import conditions for particular products of animal origin, taking account of the associated risks, information that relevant third countries have provided and, where necessary, the results of Community controls carried out in such third countries. These special import conditions may be established for a single product of animal origin or for group of products. They may apply to a single third country, to regions of a third country, or to a group of third countries; and
- 20) the conditions governing imports of products of animal origin from a third country or a region of a third country pursuant to the implementation of an equivalence agreement, or to a satisfactory audit, recognising that measures applied in that third country or region offer guarantees equivalent to those applied in the Community, if the third country supplies objective proof in this respect.

Article 19

Committee procedure

1 The Commission shall be assisted by the Standing Committee on the Food Chain and Animal Health instituted by Article 58 of Regulation (EC) No 178/2002.

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 20

Consultation of the European Food Safety Authority

The Commission shall consult the European Food Safety Authority on matters falling within the scope of this Regulation whenever necessary and, in particular:

- 1) before proposing to modify the specific requirements concerning post-mortem inspection procedures laid down in Section IV of Annex I;
- 2) before proposing to modify the rules of Annex I, Section IV, Chapter IX, on meat from animals in which post-mortem inspection has revealed lesions indicating infection with brucellosis or tuberculosis; and
- 3) before proposing implementing measures on the matters referred to in Article 18, points (5) to (15).

Article 21

Report to the European Parliament and to the Council

1 The Commission shall, not later than ...,⁽¹⁾ submit a report to the European Parliament and the Council reviewing the experience gained from the application of this Regulation.

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

Article 22

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⁽²⁾;
- (b) Regulation (EC) No .../2004⁽³⁾ and
- (c) Directive 2004/.../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⁽⁴⁾.

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

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

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