

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specific rules for the organisation of official controls on products of animal origin intended for human consumption (repealed)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 II

OFFICIAL CONTROLS IN RELATION TO COMMUNITY ESTABLISHMENTS

Article 3

Approval of establishments

1

- a When Community legislation requires the approval of establishments, the competent authority shall make an on-site visit. It shall approve an establishment for the activities concerned only if the food business operator has demonstrated that it meets the relevant requirements of Regulations (EC) No .../2004⁽¹⁾ and No .../2004⁽²⁾ and other relevant requirements of food law.
- b The competent authority may grant conditional approval if it appears from the on-site visit that the establishment meets all the infrastructure and equipment requirements. It shall grant full approval only if it appears from a new on-site visit carried out within three months of the granting of conditional approval that the establishment meets the other requirements referred to in (a). If clear progress has been made but the establishment still does not meet all of these requirements, the competent authority may prolong conditional approval. However, conditional approval shall not exceed a total of six months.

2 In the case of factory and freezer vessels flying the flag of Member States, the maximum periods of three and six months applying to the conditional approval of other establishments may be extended, if necessary. However, conditional approval shall not exceed a total of 12 months. Inspections of such vessels shall take place as specified in Annex III.

3 The competent authority shall give each approved establishment, including those with conditional approval, an approval number, to which codes may be added to indicate the types of products of animal origin manufactured. For wholesale markets, secondary numbers indicating units or groups of units selling or manufacturing products of animal origin may be added to the approval number.

4

- a The competent authority shall keep the approval of establishments under review when carrying out official controls in accordance with Articles 4 to 8.
- b If the competent authority identifies serious deficiencies or has to stop production at an establishment repeatedly and the food business operator is not able to provide adequate guarantees regarding future production, the competent authority shall initiate procedures to withdraw the establishment's approval. However, the competent authority may suspend an establishment's approval if the food business operator can guarantee that it will resolve deficiencies within a reasonable time.
- c In the case of wholesale markets, the competent authority may withdraw or suspend approval in respect of certain units or groups of units.

- 5 Paragraphs 1, 2 and 3 shall apply both:
- a to establishments that begin placing products of animal origin on the market on or after the date of application of this Regulation; and
 - b to establishments already placing products of animal origin on the market but in respect of which there was previously no requirement for approval. In the latter case, the competent authority's on-site visit required under paragraph 1 shall take place as soon as possible.

Paragraph 4 shall also apply to approved establishments that placed products of animal origin on the market in accordance with Community legislation immediately prior to the application of this Regulation.

- 6 Member States shall maintain up-to-date lists of approved establishments, with their respective approval numbers and other relevant information, and make them available to other Member States and to the public in a manner that may be specified in accordance with the procedure referred to in Article 19(2).

Article 4

General principles for official controls in respect of all products of animal origin falling within the scope of this Regulation

- 1 Member States shall ensure that food business operators offer all assistance needed to ensure that official controls carried out by the competent authority can be performed effectively

They shall in particular:

- give access to all buildings, premises, installations or other infrastructures;
- make available any documentation and record required under the present regulation or considered necessary by the competent authority for judging the situation.

- 2 The competent authority shall carry out official controls to verify food business operators' compliance with the requirements of:

- a Regulation (EC) No .../2004⁽³⁾;
- b Regulation (EC) No .../2004⁽⁴⁾; and
- c Regulation (EC) No 1774/2002.

- 3 The official controls referred to in paragraph 1 shall include:

- a audits of good hygiene practices and hazard analysis and critical control point (HACCP)-based procedures;
- b the official controls specified in Articles 5 to 8; and
- c any particular auditing tasks specified in the Annexes.

- 4 Audits of good hygiene practices shall verify that food business operators apply procedures continuously and properly concerning at least:

- a checks on food-chain information;
- b the design and maintenance of premises and equipment;
- c pre-operational, operational and post-operational hygiene;
- d personal hygiene;
- e training in hygiene and in work procedures;
- f pest control;
- g water quality;

- h temperature control; and
- i controls on food entering and leaving the establishment and any accompanying documentation.

5 Audits of HACCP-based procedures shall verify that food business operators apply such procedures continuously and properly, having particular regard to ensuring that the procedures provide the guarantees specified in Section II of Annex II to Regulation (EC) No .../2004⁽⁶⁾. They shall, in particular, determine whether the procedures guarantee, to the extent possible, that products of animal origin:

- a comply with microbiological criteria laid down under Community legislation;
- b comply with Community legislation on residues, contaminants and prohibited substances; and
- c do not contain physical hazards, such as foreign bodies.

When, in accordance with Article 5 of Regulation (EC) No .../2004⁽⁶⁾, a food business operator uses procedures set out in guides to the application of HACCP principles rather than establishing its own specific procedures, the audit shall cover the correct use of these guides.

6 Verification of compliance with the requirements of Regulation (EC) No .../2004⁽⁷⁾ concerning the application of identification marks shall take place in all establishments approved in accordance with that Regulation, in addition to verification of compliance with other traceability requirements.

7 In the case of slaughterhouses, game handling establishments and cutting plants placing fresh meat on the market, an official veterinarian shall carry out the auditing tasks referred to in paragraphs 3 and 4.

8 When carrying out auditing tasks, the competent authority shall take special care:

- a to determine whether staff and staff activities in the establishment at all stages of the production process comply with the relevant requirements of the Regulations referred to in paragraph 1(a) and (b). To support the audit, the competent authority may carry out performance tests, in order to ascertain that staff performance meets specified parameters;
- b to verify the food business operator's relevant records;
- c to take samples for laboratory analysis whenever necessary; and
- d to document elements taken into account and the findings of the audit.

9 The nature and intensity of auditing tasks in respect of individual establishments shall depend upon the assessed risk. To this end, the competent authority shall regularly assess:

- a public and, where appropriate, animal health risks;
- b in the case of slaughterhouses, animal welfare aspects;
- c the type and throughput of the processes carried out; and
- d the food business operator's past record as regards compliance with food law.

Article 5

Fresh meat

Member States shall ensure that official controls with respect to fresh meat take place in accordance with Annex I.

- (1) The official veterinarian shall carry out inspection tasks in slaughterhouses, game handling establishments and cutting plants placing fresh meat on the market in accordance with the general requirements of Section I, Chapter II, of Annex I, and with the specific requirements of Section IV, in particular as regards:
 - (a) food chain information;
 - (b) ante-mortem inspection;
 - (c) animal welfare;
 - (d) post-mortem inspection;
 - (e) specified risk material and other animal by-products; and
 - (f) laboratory testing.
- (2) The health marking of carcasses of domestic ungulates, farmed game mammals other than lagomorphs, and large wild game, as well as half-carcasses, quarters and cuts produced by cutting half-carcasses into three wholesale cuts, shall be carried out in slaughterhouses and game-handling establishments in accordance with Section I, Chapter III, of Annex I. Health marks shall be applied by, or under the responsibility of, the official veterinarian when official controls have not identified any deficiencies that would make the meat unfit for human consumption.
- (3) After carrying out the controls mentioned in points 1 and 2, the official veterinarian shall take appropriate measures as set out in Annex I, Section II, in particular as regards:
 - (a) the communication of inspection results;
 - (b) decisions concerning food chain information;
 - (c) decisions concerning live animals;
 - (d) decisions concerning animal welfare; and
 - (e) decisions concerning meat.
- (4) Official auxiliaries may assist the official veterinarian with official controls carried out in accordance with Sections I and II of Annex I as specified in Section III, Chapter I.

In that case, they shall work as part of an independent team.
- (5)
 - (a) Member States shall ensure that they have sufficient official staff to carry out the official controls required under Annex I with the frequency specified in Section III, Chapter II.
 - (b) A risk-based approach shall be followed to assess the number of official staff that need to be present on the slaughter line in any given slaughterhouse. The number of official staff involved shall be decided by the competent authority and shall be such that all the requirements of this Regulation can be met.
- (6)
 - (a) Member States may allow slaughterhouse staff to assist with official controls by carrying out certain specific tasks, under the supervision of the official veterinarian, in relation to the production of meat from poultry and lagomorphs in accordance with Annex I, Section III, Chapter III, Part A. If they do so, they shall ensure that staff carrying out such tasks:

- (i) are qualified and undergo training in accordance with those provisions;
 - (ii) act independently from production staff; and
 - (iii) report any deficiency to the official veterinarian.
 - (b) Member States may also allow slaughterhouse staff to carry out specific sampling and testing tasks in accordance with Annex I, Section III, Chapter III, Part B.
- (7) Member States shall ensure that official veterinarians and official auxiliaries are qualified and undergo training in accordance with Annex I, Section III, Chapter IV.

Article 6

Live bivalve molluscs

Member States shall ensure that the production and placing on the market of live bivalve molluscs, live echinoderms, live tunicates and live marine gastropods undergo official controls as described in Annex II.

Article 7

Fishery products

Member States shall ensure that official controls with respect to fishery products take place in accordance with Annex III.

Article 8

Raw milk and dairy products

Member States shall ensure that official controls with respect to raw milk and dairy products take place in accordance with Annex IV.

Article 9

Action in the case of non-compliance

1 When the competent authority identifies non-compliance with the Regulations referred to in Article 4(2)(a) and (b), it shall take action to ensure that the food business operator remedies the situation. When deciding which action to take, the competent authority shall take account of the nature of the non-compliance and the food business operator's past record with regard to non-compliance.

- 2 Such action shall include, where appropriate, the following measures:
- a the imposition of sanitation procedures or any other corrective action deemed necessary to ensure the safety of products of animal origin or compliance with the relevant legal requirements;

- b the restriction or prohibition of the placing on the market, import or export of products of animal origin;
 - c monitoring or, if necessary, ordering the recall, withdrawal and/or destruction of products of animal origin;
 - d authorisation to use products of animal origin for purposes other than those for which they were originally intended;
 - e the suspension of operations or closure of all or part of the food business concerned for an appropriate period of time;
 - f the suspension or withdrawal of the establishment's approval;
 - g in the case of consignments from third countries, seizure followed by destruction or re-dispatch;
 - h any other measure that the competent authority deems appropriate.
- 3 The competent authority shall provide the food business operator concerned, or a representative, with:
- a written notification of its decision concerning the action to be taken in accordance with paragraph 1, together with the reasons for the decision; and
 - b information on rights of appeal against such decisions and of the applicable procedure and time limits.

Where appropriate, the competent authority shall also notify the competent authority of the Member State of dispatch of its decision.

- (1) Note for the Official Journal: insert number of Regulation on the hygiene of foodstuffs (see recital 1, 1st Regulation).
- (2) Note for the Official Journal: insert number of Regulation laying down specific hygiene rules for food of animal origin (see recital 1, 2nd Regulation).
- (3) Note for the Official Journal: insert number of Regulation on the hygiene of foodstuffs (see recital 1, 1st Regulation).
- (4) Note for the Official Journal: insert number of Regulation laying down specific hygiene rules for food of animal origin (see recital 1, 2nd Regulation).
- (5) Note for the Official Journal: insert number of Regulation laying down specific hygiene rules for food of animal origin (see recital 1, 2nd Regulation).
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- (7) Note for the Official Journal: insert number of the Regulation laying down specific hygiene rules for food of animal origin (see recital 1, 2nd Regulation).