

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specific rules for the organisation of official controls on products of animal origin intended for human consumption (repealed)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

[^{F1} The competent authorities shall approve establishments when, and in the manner, specified in Article 31(2) of Regulation (EC) No 882/2004.]

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

[^{F2}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.

Status: Point in time view as at 01/01/2006.

Changes to legislation: There are outstanding changes not yet made to Regulation (EC) No 854/2004 of the European Parliament and of the Council (repealed). Any changes that have already been made to the legislation appear in the content and are referenced with annotations. (See end of Document for details)

F26

Textual Amendments

- F1** Substituted by Regulation (EC) No 882/2004 of the European Parliament and of the Council of 29 April 2004 on official controls performed to ensure the verification of compliance with feed and food law, animal health and animal welfare rules.
- F2** Deleted by Regulation (EC) No 882/2004 of the European Parliament and of the Council of 29 April 2004 on official controls performed to ensure the verification of compliance with feed and food law, animal health and animal welfare rules.

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 852/2004;
 - b Regulation (EC) No 853/2004;
- 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;

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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 853/2004. 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 852/2004, 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 853/2004 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.

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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.

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- (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.

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^{F2}Article 9

[^{F2}Action in the case of non-compliance]

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Textual Amendments

- F2** Deleted by [Regulation \(EC\) No 882/2004 of the European Parliament and of the Council of 29 April 2004 on official controls performed to ensure the verification of compliance with feed and food law, animal health and animal welfare rules.](#)

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