

Chapter IV Specific control rules for animal products

Basic text:

- **REGULATION (EC) No 854/2004** of 29 April 2004 laying down specific rules for the organisation of official controls on products of animal origin intended for human consumption

Scope

1. This Regulation lays down specific rules for the organisation of official controls on products of animal origin.
2. It shall apply only in respect of activities and persons to which Regulation (EC) No 853/2004 applies.

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- **Definitions**

(a) 'official control'

(b) 'verification'

(c) 'competent authority' - **competent to carry out veterinary checks**

(d) 'audit'

(e) 'inspection'

(f) 'official veterinarian'

(g) 'approved veterinarian'

(h) 'official auxiliary'

(i) 'health mark'

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- **Approval of establishments (Art. 3)**
- **The competent authority shall make an on-site visit**
- **Approve only:** when the food business operator has demonstrated that it meets the relevant requirements of Regulations (EC) No 852/2004 and (EC) No 853/2004 and other relevant requirements of food law.
- **Conditional approval if:** it appears from the on-site visit that the establishment meets all the **infrastructure and equipment requirements**.
- **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**.

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- 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.
- The competent authority shall keep the approval of establishments under review when carrying out official controls
- 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.
- 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

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- **Article 4**
 - **General principles for official controls in respect of all products of animal origin falling within the scope of this Regulation**
 - **food business operators offer all assistance** needed to ensure that official controls carried out by the competent authority can be performed effectively
- in particular:**
- give access to all buildings, premises, installations or other infrastructures;
 - make available any documentation and record required

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- 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.

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- **The official controls shall include:**
 - audits of good hygiene practices and hazard analysis and critical control point (HACCP)-based procedures;
- 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;
 - (i) controls on food entering and leaving the establishment and any accompanying documentation.
 - (j) comply with **microbiological criteria laid down under Community legislation (Reg. No 2073/2005; Application text)**
 - (k) comply with **Community legislation on residues, contaminants and prohibited substances (see 96/22; 96/23; Dec.99/879.....)**

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- 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**

- **The official veterinarian** shall carry out inspection tasks in:

- slaughterhouses
 - game handling establishments
 - cutting plants

placing fresh meat on the market

in accordance with the **general** requirements of:

- Section I, Chapter II (**inspection tasks**), of Annex I and
 - **specific** requirements of Section IV (**specific inspection tasks**)

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- **inspection tasks** 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;
 - (f) laboratory testing.

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- **health marking of carcasses of**
 - domestic ungulates,
 - farmed game mammals other than lagomorphs, and large wild game
 - half-carcases
 - quarters and cuts produced by cutting half-carcases into three wholesale cuts
- Carried out
 - in slaughterhouses
 - game-handling establishments
- **In accordance with Section I, Chapter III, of Annex I**
- **by, or under the responsibility of, the official veterinarian**

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- **After carrying out the controls:**
- 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;
 - (e) decisions concerning meat.
- **Official auxiliaries** may assist the official veterinarian

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- *Article 6*
- **Live bivalve molluscs**
 - official controls as described in Annex II
- *Article 7*
- **Fishery products**
 - in accordance with Annex III.
- *Article 8*
- **Raw milk and dairy products**
 - - in accordance with Annex IV.
- *Article 9*
- **Action in the case of non-compliance**

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- *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).

- **Application text: 2074/2005 and 2076/2005 concerning**

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- *Article 18 (Implementing measures may be laid down...)*

parageaph 13(a)

- limit values and analysis methods for marine biotoxins **(Art. 3)**

paragraph 14

- organoleptic criteria for the evaluation of the freshness of fishery products **(Art. 2)**

paragraph15

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;

- ***Application text: Art. 2 and 3 of 2074/2005 (Annex II)***

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- ANNEX I

- FRESH MEAT

- SECTION I: TASKS OF THE OFFICIAL VETERINARIAN

- CHAPTER I: AUDITING TASKS

1. In addition to the general requirements of Article 4(4) concerning **audits of good hygiene practices**, the official veterinarian is to verify continuous compliance with food business operators' own procedures concerning any collection, transport, storage, handling, processing and use or disposal of **animal by-products**, including **specified risk material**, for which the food business operator is responsible.
2. In addition to the general requirements of Article 4(5) concerning audits of HACCP-based principles, the official veterinarian is to check that the operators' procedures guarantee, to the extent possible, **that meat**:
 - (a) does not contain patho-physiological abnormalities or changes;
 - (b) does not bear faecal or other contamination;
 - (c) does not contain specified risk material, except as provided for under Community legislation, and has been produced in accordance with Community legislation on TSEs.

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- **CHAPTER II: INSPECTION TASKS**
- **A. Food chain information**
 - OV is to check and analyse relevant information from the records of the holding of provenance
 - take account of the documented results of this check and analysis when carrying out ante- and post-mortem inspection
 - take account of official certificates accompanying animals (official veterinarians and approved veterinarians)

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- **B. Ante-mortem inspection**

(a) the official veterinarian is to carry out an ante-mortem inspection of all animals before slaughter

(b) that inspection must take place within 24 hours of arrival at the slaughterhouse and less than 24 hours before slaughter.

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- **D. Post-mortem inspection**

1. Carcasses and accompanying offal are to be subjected without delay after slaughter to post-mortem inspection.
2. All external surfaces are to be viewed. Minimal handling of the carcass and offal or special technical facilities may be required for that purpose.
3. Particular attention is to be paid to the detection of zoonotic diseases and diseases on OIE List A and, where appropriate, OIE List B.
4. The speed of the slaughter line and the number of inspection staff present are to be such as to allow for proper inspection.

- **E. Specified risk material and other animal by-products**

- **F. Laboratory testing**

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- **CHAPTER III: HEALTH MARKING**
- The official veterinarian is to supervise health marking and the marks used.
- The health mark is applied only to animals (domestic ungulates, farmed game mammals other than lagomorphs, and large wild game) having undergone ante-mortem and post-mortem inspection in accordance with this Regulation and when there are no grounds for declaring the meat unfit for human consumption.
- the health mark may be applied **before the results** of any examination for **trichinosis** is available, if the official veterinarian is satisfied that meat from the animal concerned **will be placed on the market only if the results are satisfactory**;

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- **SECTION II: ACTION FOLLOWING CONTROLS**
- **CHAPTER I: COMMUNICATION OF INSPECTION RESULTS**
 - The official veterinarian is to record and to evaluate the results of inspection activities.
 - The results of inspections and tests are to be included in relevant databases.
- **CHAPTER II: DECISIONS CONCERNING FOOD CHAIN INFORMATION**
 - The official veterinarian is to verify that animals are not slaughtered unless the slaughterhouse operator has been provided with and checked relevant food chain information.

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- **CHAPTER III: DECISIONS CONCERNING LIVE ANIMALS**
 - The official veterinarian is to verify compliance with the food business operator's duty pursuant to Regulation (EC) No 853/2004 to ensure that animals accepted for slaughter for human consumption are **properly identified**.
 - The official veterinarian is to ensure that animals whose **identity is not reasonably** ascertainable are killed separately and declared unfit for human consumption.
 - Whenever the official veterinarian considers it necessary, official controls are to be carried out on the holding of provenance.

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- **CHAPTER IV: DECISIONS CONCERNING ANIMAL WELFARE**
- When the rules concerning the protection of animals at the time of slaughter or killing are not respected, the official veterinarian is to verify that the food business operator immediately takes necessary corrective measures and prevents recurrence.
- The official veterinarian is to take a proportionate and progressive approach to enforcement action, ranging from issuing directions to slowing down and stopping production, depending on the nature and gravity of the problem.

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- **CHAPTER V: DECISIONS CONCERNING MEAT**

Meat is to be declared unfit for human consumption if it: **(List)**

- **SECTION III: RESPONSIBILITIES AND FREQUENCY OF CONTROLS**

CHAPTER I: OFFICIAL AUXILIARIES

Official auxiliaries may assist the official veterinarian with all tasks, subject to the following restrictions and to any specific rules **laid down in Section IV:**

- **CHAPTER II: FREQUENCY OF CONTROLS**

The competent authority is to ensure that at least one official veterinarian is present:

- in slaughterhouses, throughout both ante-mortem and post-mortem inspection;
- in game handling establishments, throughout post-mortem inspection.

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- CHAPTER III: INVOLVEMENT OF SLAUGHTERHOUSE STAFF

(Application text: see Chapter III, Art. 14 and 15 of Reg. 2076/2005)

- SPECIFIC TASKS CONCERNING THE PRODUCTION OF MEAT FROM POULTRY AND LAGOMORPHS
- B. SPECIFIC SAMPLING AND TESTING TASKS

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- CHAPTER IV: PROFESSIONAL QUALIFICATIONS
- A. OFFICIAL VETERINARIANS
- B. OFFICIAL AUXILIARIES

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- **SECTION IV: SPECIFIC REQUIREMENTS**
 - A. BOVINE ANIMALS UNDER SIX WEEKS OLD
 - B. BOVINE ANIMALS OVER SIX WEEKS OLD
 - CHAPTER II: DOMESTIC SHEEP AND GOATS
 - CHAPTER III: DOMESTIC SOLIPEDS
 - CHAPTER IV: DOMESTIC SWINE
 - CHAPTER V: POULTRY
 - CHAPTER VI: FARMED LAGOMORPHS
 - CHAPTER VII: FARMED GAME
 - CHAPTER VIII: WILD GAME

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- CHAPTER IX: **SPECIFIC HAZARDS**
- A. Transmissible spongiform encephalopathies
- B. Cysticercosis
- C. Trichinosis (**Application text:
Reg. 2075/2005**)
- D. Glanders
- E. Tuberculosis
- F. Brucellosis

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- ANNEX II
- LIVE BIVALVE MOLLUSCS
- CHAPTER I: SCOPE
- This Annex applies to live bivalve molluscs and, by analogy, to live echinoderms, live tunicates and live marine gastropods.
- CHAPTER II: OFFICIAL CONTROLS CONCERNING LIVE BIVALVE MOLLUSCS FROM CLASSIFIED PRODUCTION AREAS

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- ANNEX III
- **FISHERY PRODUCTS**
- CHAPTER I: OFFICIAL CONTROLS OF PRODUCTION AND PLACING ON THE MARKET
 1. Official controls on the production and placing on the market of fishery products are to include, in particular:
 - a regular check on the hygiene conditions of landing and first sale;

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- ANNEX IV
- RAW MILK AND DAIRY PRODUCTS
- CHAPTER I: CONTROL OF MILK PRODUCTION HOLDINGS
- CHAPTER II: CONTROL OF RAW MILK UPON COLLECTION