



COMMISSION OF THE EUROPEAN COMMUNITIES

Brussels, 21.10.2003  
COM(2003) 577 final

2002/0141 (COD)

Amended proposal for a

**REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL**

**laying down specific rules for the organisation of official controls on products of animal  
origin intended for human consumption**

(presented by the Commission pursuant to article 250 (2) of the EC Treaty)

## **EXPLANATORY MEMORANDUM**

### **I. PROCEDURE**

1. On 11 July 2002, the Commission adopted its proposal for a Regulation of the European Parliament and of the Council laying down specific rules for the organisation of official controls on products of animal origin intended for human consumption [Document COM (2002) 377 final]. The proposal was submitted to the Council and the European Parliament on the same day for adoption pursuant to Article 251 of the Treaty.
2. On 5 June 2003, the European Parliament in its first reading gave its opinion on the proposal.
3. The present proposal amends the original proposal so as to take into account the amendments of the European Parliament that were accepted by the Commission.
4. With regard to the original proposal, the European Parliament adopted 136 amendments. The Commission had indicated to the plenary meeting on 6 June 2003 that it could accept more than half of the amendments, wholly or in part, and subject to drafting amendments. The amendments that cannot be accepted by the Commission are: 2, 4, 6, 10, 14, 15, 21 (point 6), 25, 30, 31, 33, 36, 37, 38, 44, 46, 55, 58, 59, 60, 62, 63, 64, 65, 67, 68, 69, 70, 71, 72, 73, 75, 76, 77, 78, 80, 81, 83, 86, 87 (middle part), 88 (first part), 90, 100, 101, 102, 103, 105, 106, 107, 109, 112, 114, 117, 118, 119, 122 (first part), 123, 125, 126, 127, 128, 129, 135, 136, 137, 139, 140, 143.
5. The amendments accepted in the revised proposal are in bold and underlined. A number of amendments have been reformulated so as to ensure consistency of the terminology used throughout the proposal, or to bring the text in line with the approach of the Council. The numbering of the Articles has been adapted to take into account a number of amendments.

### **II. OBJECTIVES OF THE PROPOSAL**

6. The proposal concerns the recast and modernisation of specific Community rules on the official controls on food of animal origin. The proposal contains specific rules for official controls on meat and meat products, live bivalve molluscs, fishery products and milk and milk products. The proposal is part of the package on the recast of Community hygiene rules, proposal COM (2000) 438 final.
7. The main purpose of the proposal is to make existing rules more science- and risk-based, and to bring them in line with the hygiene requirements for operators, proposed in the other parts of the package on the recast of hygiene rules.

### **III. OVERVIEW OF THE AMENDMENTS OF THE EUROPEAN PARLIAMENT**

#### **Technical and editorial amendments**

8. A large number of the proposed amendments aim to improve the proposal from a technical and editorial point of view. These are the amendments 1, 5, 7, 8, 9, 13, 14, 16, 17, 18, 20, 22, 23, 24, 26, 39, 40, 41, 42, 43, 44, 45, 46, 50, 53, 54, 55, 56, 58, 59, 66, 67, 74, 76, 78, 79, 84, 104, 105, 106, 108, 110, 111, 112, 113, 114, 115, 117, 118, 129, 137.
9. Most of these amendments are welcomed by the Commission (in some cases subject to editorial changes). However, certain of these amendments unnecessarily tighten the requirements of the proposal. In other cases, more appropriate wording has been proposed in the framework of the work carried out in Council. These amendments should therefore be rejected. These are: 2, 14, 44, 46, 55, 58, 59, 67, 68, 69, 75, 76, 77, 78, 80, 105, 106, 112, 114, 117, 118, 119, 128, 129, 137.

#### **Transfer of requirements from Annexes to Articles (Article 4)**

10. Amendment 21 aims at ensuring that all the basic requirements as regards official controls on meat appear in the Articles. This would ensure legal security for food businesses. Amendment 21 is in principle acceptable, subject to editorial changes. However, point 6 of the Amendment cannot be accepted as it conflicts with the policy of the Commission as regards the use of company staff for certain control activities.

#### **Relation with the future Regulation on official feed and food controls**

11. The amendments 4, 25 and 70 concern subjects that are being dealt with in the Commission proposal for a Regulation on official feed and food controls [COM(2003)52 final], especially the costs, the right of appeal and, to a minor extent, the issue of penalties. These amendments cannot be accepted as the issues concerned should be dealt with under the proposed Regulation on official feed and food controls.

#### **Flexibility for small businesses (Recital 9 and Article 16)**

12. Three amendments (3, 15 and 138) aim at introducing extra flexibility as regards official controls in small meat businesses.
13. The amendments 3 and 138 are acceptable (subject to editorial amendments), as they refer to the flexibility agreed upon in the framework of the political agreement (at Council level) on other parts of the package on the recast of Community hygiene rules [proposal COM (2000) 438 final]. Amendment 15 cannot be accepted as it introduces the concept of ‘artisanal small businesses’, a concept that conflicts with the general food safety policy of the Commission.

### **Comitology ( Article 17, Article 18 and Annex 1, Chapter 3, Section IX.G)**

14. A number of amendments have been tabled that are related to the issue of comitology. Amendment 38 deletes the possibility of comitology, but this is partly reintroduced by 116, 120 and 131 (and some other amendments dealt with hereunder), and notably by amendment 130.
15. Amendment 38 cannot be accepted as it deprives the Commission of the possibility to take implementing decisions and to amend the annexes. The amendments 116, 120 and 131 can in principle be accepted as a whole or in part, subject to editorial amendments. Amendment 130 is welcomed as it reintroduces the possibility for the Commission to take implementing decisions or change certain rules under comitology.

### **Imports (Articles 8-15)**

16. The amendments 27, 28, 29, 30, 31, 32, 33, 34, 35, 36 and 37 aim at introducing in the text requirements for imports that were previously contained in 'Hygiene 2'. This is in principle in line with the approach of the Commission and of the Council. However, the detailed requirements contained in these amendments are not always consistent with the approach of the Commission and of the Council, and sometimes duplicate the Commission proposal on official feed and food controls. The amendments 30, 31, 33, 36 and 37 can therefore not be accepted. The other amendments require important redrafting.

### **Food chain information (Annex I, Chapter 1, section I.2.A)**

17. A number of amendments aim at introducing flexibility in the system of food chain information (information from the farm that has to accompany the animals to slaughter). These are the amendments 47, 48, 49, 51, 71, 72, 73, 101, 102, 103 and 107.
18. Amendments 47, 48, 49 and 51 are acceptable. However, amendments 71, 72, 73, 101, 102, 103 and 107 would dilute the system and render it ineffective. As regards the identification of animals in particular, animals whose identity cannot be ascertained should in principle not be slaughtered for human consumption. These amendments can therefore not be accepted.

### **Health marking (Annex I, Chapter 1, Section I.2.G, paragraph 3)**

19. In the framework of the political agreement at Council on 'Hygiene 2', it has been decided that health marking would be limited to red meat (thus excluding poultry and rabbits) at the level of the slaughterhouse, as it was considered that systematic official carcass-by-carcass inspection was only required at this level.

20. The amendments 60, 62, 63, 64 and 65 cannot be accepted as they are not in line with this approach. Amendment 61 can be accepted, partly and subject to editorial amendments, as it brings some aspects of health marking in line with the practical situation in slaughterhouses.

#### **Visual post-mortem inspection (Annex I, Chapter 3, Section IV.B, paragraph 2)**

21. On the basis of scientific advice (SCVPH), the possibility of visual post-mortem inspection of certain categories of fattening pigs had been introduced in the Commission text. Amendment 109 eliminates this possibility. Amendment 109 can therefore not be accepted.

#### **The use of company staff in control activities (Article 4)**

22. The Commission text provides for the possibility of the use of company staff for certain control activities. A number of amendments have been adopted that aim at bringing this company staff very much into the sphere of the competent authority. The Commission believes these two things should be kept separate. The amendments 81, 83 and 87 (partly) can therefore not be accepted.
23. The rest of Amendment 87 can however be accepted as the Commission agrees to introduce some extra requirements for the establishments using company staff in control activities. Amendment 100 cannot be accepted as it eliminates some necessary flexibility as regards the training of company staff.
24. A number of amendments have been adopted that seriously limit the use of company staff. These cannot be accepted. These are 127, 135, 136, 139 and 140.

#### **Presence of the official veterinarian (Annex I, Chapter 2, Section II, paragraph 2(a), subparagraph 1)**

25. Amendment 85 can be accepted, subject to editorial changes, as it states that the presence of the official veterinarian in small slaughterhouses should be based on an analysis of risks. This is in line with the original Commission proposal.

#### **Training (Annex I, Chapter 2, Section IV.A)**

26. The Environment Committee has adopted a large number of amendments that deal with the training requirements for official veterinarians and official auxiliaries. These are the amendments 88, 89, 90, 91, 92, 93, 94, 95, 96, 97, 98 and 99. These are nearly all very technical. Some however aim at introducing flexibility as regards the training requirements for veterinarians that already work or deal with small artisanal businesses.
27. Nearly all amendments can be accepted as they integrate technical specifications that are more or less in line with the general food safety policy. The amendments 88 (partly) and 90 cannot be accepted as they aim at introducing extra flexibility as regards the training of veterinarians, flexibility that is already sufficiently provided for in the original Commission proposal.

**Live bivalve molluscs and fishery products (Annex II, Section I, point 4(b) and (c), and Annex III, point 1)**

28. A number of amendments have been tabled that specifically concern live bivalve molluscs and fishery products. Most of these concern the issue of marine biotoxins in molluscs. These are the amendments 6, 121, 122, 123, 124, 125 and 126. The amendments 121 and 124 are welcomed as they contain useful specifications.
29. Amendments 6, 122 (partly) and 123 cannot be accepted as they aim at unnecessarily weakening the provisions for marine biotoxins. Amendment 125 cannot be accepted as it contains a specification that may be confusing. Amendment 126 cannot be accepted as it unnecessarily limits the freedom of action by the competent authority in case of risks.

**Various**

30. This covers the amendments tabled on various other subjects. Amendments 11 and 12 concern the scope of the Regulation (Article 1), 19 concerns communication of the lists of approved establishments (Article 3, paragraph 3), 52 animal welfare (Annex I, Chapter 1, Section I.2.C), 57 emergency slaughter (Annex I, Chapter 1, Section I.2.D, point 6), 82 the tasks of official auxiliaries (Annex I, Chapter 2, Section I(b)), 110 the approved veterinarian (Annex I, Chapter 3, Section VII.B, point 3), 132 and 133 'pronounced sexual odour' in pig meat (Annex I, Chapter 1, Section II.E(p)), and 134 the presence of the competent authority in cutting plants (Annex I, Chapter 2, Section II, point 5).
31. Certain technical changes have been made to the text to improve its conformity with the Interinstitutional Agreement of 22 December 1998 on common guidelines for the quality of drafting of Community legislation (OJ C 73, 17.3.1999, p. 1), drawn up pursuant to Declaration No 39 annexed to the Final Act of Amsterdam on the quality of the drafting of Community legislation. In accordance with points (b) and (g) of that Agreement, the text has been revised to take account of the common guidelines and the Joint Practical Guide drawn up under point (a) thereof.

**Conclusion**

Pursuant to Article 250(2) of the EC Treaty, the Commission is amending its proposal as indicated above.

Amended proposal for a

**REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL**

**laying down specific rules for the organisation of official controls on products of animal origin intended for human consumption**

**(EEA relevance)**

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty establishing the European Community, and in particular Article 152(4)(b) thereof,

Having regard to the proposal from the Commission<sup>1</sup>,

Having regard to the opinion of the European Economic and Social Committee<sup>2</sup>,

Having regard to the opinion of the Committee of the Regions<sup>3</sup>,

Acting in accordance with the procedure laid down in Article 251 of the Treaty<sup>4</sup>,

Whereas:

- (1) Regulation (EC) No .../... of the European Parliament and of the Council of ... on the hygiene of foodstuffs<sup>5</sup> lays down general hygiene rules applying to all foodstuffs, while specific hygiene rules for food of animal origin are contained in Regulation (EC) No .../... of the European Parliament and of the Council of ... laying down specific hygiene rules for food of animal origin<sup>6</sup>.
- (2) Regulation (EC) No .../... of the European Parliament and of the Council of ... on official feed and food controls<sup>7</sup> lays down the general rules for performing official controls of foodstuffs.
- (3) Council Directive 2002/99/EC of 16 December 2002 lays down the animal health rules governing the production, processing, distribution and introduction of products of animal origin for human consumption<sup>8</sup>.

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<sup>1</sup> OJ C [...], [...], p. [...].

<sup>2</sup> OJ C [...], [...], p. [...].

<sup>3</sup> OJ C [...], [...], p. [...].

<sup>4</sup> OJ C [...], [...], p. [...].

<sup>5</sup> OJ C [...], [...], p. [...].

<sup>6</sup> OJ C [...], [...], p. [...].

<sup>7</sup> OJ C [...], [...], p. [...].

<sup>8</sup> OJ L 18, 23.1.2003.

- (4) Regulation (EC) No 1774/2002 of the European Parliament and of the Council of 3 October 2002 lays down the health rules concerning animal by-products not intended for human consumption<sup>9</sup>.
- (5) In addition to the general rules for performing official controls of foodstuffs, specific rules should be laid down for official controls on products of animal origin in order to take account of the specific aspects associated with such products.
- (6) Official controls on products of animal origin should cover all aspects which are important for protecting public health, animal health and animal welfare ~~and for consumers to be provided with suitable and healthy food~~. They should be based on the most recent information available and should therefore be adapted as relevant new information becomes available.
- (7) Community legislation on food safety should have a sound scientific basis. To that end, the European Food Safety Authority should be consulted whenever necessary.
- (8) The nature and intensity of the official controls should be based on an assessment of the public and animal health risks, the animal welfare aspects and the product suitability aspects related to the species and category of animals, the type of process and the food business operator concerned.
- (9) **Official controls should take into account the flexibility for traditional production, remote areas, and structural requirements, provided for in Regulation (EC) No. .../... [on food hygiene], and Regulation (EC) No. .../... [laying down specific hygiene rules for food of animal origin]. Such flexible treatment should not entail lowering the overall level of hygiene.**
- (10) Official controls on the production of meat should be carried out to ensure that hygiene rules are continuously being respected and that the criteria and targets laid down in Community legislation are being met by ~~meat~~ **food** business operators. These official controls should consist of audits of the food business operators' activities, **including good hygienic practices and hazard analysis and critical control point (HACCP)-based procedures**, and of inspection activities.
- (11) Official controls on the production of live bivalve molluscs and on fishery products should be carried out to ascertain that the criteria and targets laid down in Community legislation are being met. Official controls on the production of live bivalve molluscs should among other things target relaying and production areas for bivalve molluscs, and the end-product.
- (12) Furthermore, official controls on the production of milk and milk products should be carried out to ascertain that the criteria and targets laid down in Community legislation are being met. Official controls on the production of milk and milk products should among other things target production holdings, raw milk upon collection and processed milk products.

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<sup>9</sup> OJ L 273, 10.10.2002, p. 1.

- (13) In order to ensure that products of animal origin imported into the Community comply with Community legislation on food and feed and in particular Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002<sup>10</sup>, or conditions recognised by the Community to be at least equivalent thereto, it is appropriate to lay down specific rules for the organisation of official controls on imports of those products.
- (14) The measures necessary for the implementation of this Regulation should be adopted in accordance with Council Decision 1999/468/EC of 28 June 1999 laying down the procedures for the exercise of implementing powers conferred on the Commission<sup>11</sup>. ~~Since the measures necessary for the implementation of this Regulation are measures of general scope within the meaning of Article 2 of Council Decision 1999/468/EC of 28 June 1999 laying down the procedures for the exercise of implementing powers conferred on the Commission, they should be adopted by use of the regulatory procedure provided for in Article 5 of that Decision~~
- (15) In accordance with the principle of proportionality, it is necessary and appropriate for the achievement of the objectives of this Regulation to lay down rules on technical matters related to official controls. This Regulation does not go beyond what is necessary in order to achieve the objectives pursued in accordance with the third paragraph of Article 5 of the Treaty,

HAVE ADOPTED THIS REGULATION:

## **CHAPTER I**

### **Subject matter, scope and definitions**

#### *Article 1*

#### **Subject matter and scope**

This Regulation lays down the specific rules for the organisation of official controls of products of animal origin intended for human consumption in order to supplement the rules laid down in Regulation (EC) No .../.. [of the European Parliament and of the Council of... on official feed and food controls.]

**It shall apply only in respect of official controls concerning the activities of food business operators and persons to which Regulation (EC) No .../... [laying down specific hygiene rules for food of animal origin] applies.**

**This Regulation shall apply without prejudice to the animal health rules for the introduction of products of animal origin for human consumption laid down in Council Directive 2002/99/EC.**

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<sup>10</sup> OJ L 31, 1.2.2002, p. 31.

<sup>11</sup> OJ L 184, 17.7.1999, p. 23.

*Article 2*  
**Definitions**

1. For the purposes of this Regulation, the definitions set out in the following Regulations shall apply as appropriate:
  - (a) Regulation (EC) No 178/2002,
  - (b) Regulation (EC) No .../... [on official feed and food controls],
  - (c) Regulation (EC) No .../... [on the hygiene of foodstuffs],
  - (d) Regulation (EC) No .../... [laying down specific hygiene rules for food of animal origin],
  - (e) Regulation (EC) No .../... 1774/2002.
2. The following definitions shall also apply:
  - (a) ‘official veterinarian’ means a veterinarian qualified, in accordance with Article 8(1) to act in such a capacity and appointed by the competent authority.
  - (b) ‘approved veterinarian’ means a veterinarian designated by the competent authority to carry out specific official controls on its behalf.
  - (c) ‘official auxiliary’ means an officer qualified, in accordance with Article 8(1) to act in such a capacity, appointed by the competent authority and working under the authority and responsibility of an official veterinarian.
  - (d) ‘health mark’ means a mark applied by or under the responsibility of the official veterinarian indicating that the rules set out in this Regulation have been complied with.

**CHAPTER II**

**OFFICIAL CONTROLS ON COMMUNITY ESTABLISHMENTS**

*Article 3*  
**Approval of establishments**

1. Where Community or national legislation requires establishments to be approved, the competent authority shall make an on-site visit.

The competent authority shall approve establishments only if it has been demonstrated that they meet the relevant requirements **of Regulations (EC) No .../... [on food hygiene] and (EC) No. .../... [laying down specific hygiene rules for food of animal origin] and other relevant requirements** of food law.

In establishments starting up their activities, the competent authority may grant a conditional approval if it appears from an on-site visit that all of the infrastructure and equipment requirements provided for in this Regulation are complied with.

It shall grant full approval only if it appears from a new on-site visit, carried out within three months from the date of the conditional approval, that the other requirements of relevant feed and food law are complied with.

2. Approved establishments shall be given an approval number to which codes shall be added to indicate the types of products of animal origin manufactured.

For wholesale markets, the approval number may be completed with a secondary number indicating units or groups of units selling or manufacturing products of animal origin.

3. Member States shall maintain up-to-date lists of approved establishments with their approval numbers.

**Member States shall make such lists available to other Member States and the public in a manner that may be specified in accordance with the procedure referred to in Article 19(2).**

#### **Article 4** **Fresh meat**

~~In addition to more general requirements on the official control of foodstuffs laid down in Community legislation, Member States shall ensure that products of animal origin are subject to the official controls described in Annexes I to IV.~~

**Member States shall ensure that official controls of fresh meat shall be carried out in accordance with Annex I. For that purpose,**

- 1. Official veterinarians and official auxiliaries shall be qualified and undergo training in accordance with Section IV of Chapter 2 of Annex I.**
- 2. The official veterinarian shall, in accordance with Section I.I.1 of Chapter 1 of Annex I, carry out auditing tasks in slaughterhouses, game handling establishments, and in cutting plants placing fresh meat on the market, in particular as regards:**
  - (a) good hygienic practices;**
  - (b) Hazard analysis and critical control points (HACCP)-based procedures.**
- 3. The official veterinarian shall, in accordance with Section I.I.2 of Chapter 1 of Annex I, and the specific requirements of Chapter 3 of Annex I, carry out inspections in slaughterhouses, game handling establishments, and in cutting plants placing fresh meat on the market, in particular as regards:**

- (a) food chain information;
- (b) ante-mortem inspections;
- (c) animal welfare;
- (d) post-mortem inspections;
- (e) specified risk material and other animal by-products; and
- (f) laboratory testing .

4. 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.I.2 of Chapter 1 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.

5. After having carried out the controls provided for in paragraphs 2 and 3, the official veterinarian shall take the appropriate measures in accordance with Section I.2.H and Section II of Chapter 1 of Annex I, 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.

6. Official auxiliaries may assist the official veterinarian with official controls carried out in accordance with Section I of Chapter 2 of Annex I. In that case, the official auxiliaries shall work as part of an independent team.

7. Member States shall ensure that they have sufficient staff to carry out the official controls in accordance with Section I of Chapter I of Annex I and with the frequency specified in Section II of Chapter 2 of that Annex.

8. The competent authority shall follow a risk-based approach to assess the number of staff that need to be present on the slaughter line in any given slaughterhouse.

The number of staff involved shall be sufficient to ensure that all the requirements of this Regulation are met.

9. Member States may permit 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 poultry-meat, meat of lagomorphs, fattening pigs and fattening veal in accordance with Section III of Chapter 2 of Annex I.
10. The slaughterhouse staff carrying out the tasks referred to in paragraph 9 must:
- (a) be qualified and undergo training in accordance with Section IV.B of Chapter 2 of Annex I;
  - (b) act independently from slaughterhouse staff involved in production; and
  - (c) report any deficiency to the official veterinarian.
11. Provisions may be adopted in accordance with the procedure provided for in Article 19(2) to permit Member States to extend the provisions of paragraph 9 to meat from other types of animals.

Article 5  
Live bivalve molluscs

Official controls on the production and placing on the market of live bivalve molluscs, live echinoderms, live tunicates and live marine gastropods shall be carried out in accordance with Annex II.

Article 6  
Fishery products

Official controls on fishery products shall be carried out in accordance with Annex III.

Article 7  
Raw milk and dairy products

Official controls of raw milk and dairy products shall be carried out in accordance with Annex IV.

## CHAPTER III IMPORTS

### Article 8

#### *Lists of third countries and parts of third countries from which imports of specified products of animal origin are permitted*

1. Products of animal origin shall be imported only from a third country or a part of a third country that appears on a list drawn up and updated in accordance with the procedure referred to in Article 19(2).

Such lists may be combined with other lists drawn up for public and animal health purposes.

2. When drawing up or updating lists as provided for in paragraph 1, particular account shall be taken of the following:

(a) the legislation of the third country on:

(i) products of animal origin;

(ii) the use of veterinary medicinal products, including rules on their prohibition or authorisation, their distribution, their placing on the market and the rules covering administration and inspection;

(iii) the preparation and use of feedingstuffs, including the procedures for using additives and the preparation and use of medicated feedingstuffs, as well as the hygiene quality of the raw materials used for preparing feedingstuffs and of the final product.

(b) the organisation of the third countries' competent authorities, their powers and independence, the supervision to which they are subject and the authority that they have effectively to enforce the applicable legislation;

(c) the resources including diagnostic facilities available to the competent authorities;

(d) the training of staff in the performance of official controls;

(e) the extent and operation of official controls on imports of animals and products of animal origin;

(f) the results of official controls by the Community carried out in the third country, in particular the results of the assessment of the competent authorities, and the action that competent authorities have taken in the light of any recommendations addressed to them following such official controls;

- (g) the existence and operation of documented control procedures and control systems based on priorities;
- (h) where applicable, the situation regarding animal health and procedures for notifying the Commission and relevant international bodies of outbreaks of animal diseases;
- (i) the assurances which the third country can give regarding compliance with Community rules or rules equivalent to Community rules;
- (j) the hygiene conditions of production, manufacture, handling, storage and dispatch actually applied to products of animal origin destined for the Community;
- (k) any experience of marketing of the product from the third country and the results of any import controls carried out;
- (l) the existence, implementation and communication of an approved zoonoses control programme;
- (m) the existence, implementation and communication of an approved residue control programme.

#### Article 9

#### List of establishments in third countries from which imports of specified products of animal origin are permitted

1. Products of animal origin shall be imported only from establishments in third countries that appear on lists drawn up and updated in accordance with this Article, except as provided for in paragraph 4.
2. An establishment may be placed on a list provided for in paragraph 1 only if the competent authority of the third country of origin guarantees that:
  - (a) the establishment complies with:
    - (i) relevant Community rules, in particular those provided for in Regulation (EC) .../... [laving down specific hygiene rules for food of animal origin]; or
    - (ii) rules that were determined to be equivalent to such rules when deciding to add that third country to the relevant list in accordance with Article 8(1);
  - (b) an official inspection service in the third country of origin supervises the establishment; and

(c) it has real powers to stop the establishment from exporting to the Community in the event that the establishment fails to meet the rules referred to in point (a).

3. The competent authorities of third countries appearing on the lists provided for in Article 8(1) shall guarantee that lists of establishments from which the specified products of animal origin may be dispatched to the Community shall be drawn up, kept up-to-date and communicated to the Commission.

4. By way of derogation from paragraph 1, specified products of animal origin may be imported from establishments not appearing on a list as provided for in paragraph 1, in the following cases:

(a) where it is decided on a case-by-case basis in accordance with the procedure referred to in Article 19(2), that the guarantees provided by the third country in respect of imports of specified products of animal origin are sufficient to ensure compliance with the requirements of paragraph 2; and

(b) in the cases listed in Annex V.

#### Article 10

#### *Lists of production areas in third countries of live bivalve molluscs echinoderms, tunicates and marine gastropods from which imports are permitted*

1. Live bivalve molluscs, echinoderms, tunicates and marine gastropods shall be imported only from production areas in third countries that appear on lists drawn up and updated in accordance with Article 9.

2. The requirement of paragraph 1 shall not apply to pectinidae harvested outside classified production areas. However, official controls with respect to pectinidae shall take place in accordance with Annex II, Section III.

3. When drawing up the lists provided for in paragraph 1, particular account shall be taken of the guarantees that the competent authority of the third country can give concerning respect for the rules of this Regulation on the classification and official control of production areas.

A Community inspection visit on-the-spot must take place before such lists are drawn up unless:

(a) the risk determined does not warrant it; and

- (b) it is determined, when deciding to add a particular production area to a list as provided for in paragraph 1, that other information indicates that the competent authority provides the necessary guarantees.

#### Article 11

##### *Lists of factory or freezer vessels and document to be signed by the captain of such vessels*

1. Fishery products imported from a factory or freezer vessel flying the flag of a third country shall come from vessels that appear on a list drawn up and updated in accordance with Article 9.
2. When fishery products are imported into the Community directly from a factory or freezer vessel, a document signed by the captain may replace the document required under Article 15.
3. The procedures laid down in this Chapter do not apply to fresh fishery products landed in the Community directly from a fishing vessel flying the flag of a third country. Official controls with respect to such fishery products shall take place in accordance with Annex III.

#### Article 12

##### *Derogations from Article 11(2)*

By way of derogation from Article 9(2), a factory or freezer vessel may be included on a list referred to in Article 9,

1. On the basis of a joint communication from the competent authority of the third country the flag of which the vessel is flying and the competent authority of another third country to which the flag third country has delegated responsibility for the inspection of the vessel subject to the following conditions:
  - (a) the flag third country appears on the list of third countries, drawn up in accordance with Article 8, from which imports of fishery products are permitted;
  - (b) all fishery products from the vessel that are destined for placing on the market in the Community are landed directly in the flag third country;
  - (c) the competent authority of the flag third country has inspected the vessel and declares that it complies with Community rules; and
  - (d) the competent authority of the flag third country declares that it will regularly inspect the vessel to ensure that it continues to comply with Community rules.

2. On the basis of a joint communication from the competent authority of the third country the flag of which the vessel is flying and the competent authority of a Member State to which the flag third country has delegated responsibility for the inspection of the vessel subject to the following conditions:
- (a) all fishery products from the vessel that are destined for placing on the market in the Community are landed directly in that Member State;
  - (b) the competent authority of that Member State has inspected the vessel and declares that it complies with Community rules; and
  - (c) the competent authority of that Member State shall regularly inspect the vessel to ensure that it continually complies with Community rules.
3. Detailed rules for the implementation of this Articles may be laid down in accordance with the procedure referred to in Article 19(2).

### Article 13

#### *Notification of lists of establishments, production areas, and factory and freezer vessels from which specified imports are permitted*

1. The Commission shall provide the contact points designated by the Member States for the purpose of this Regulation with regular notifications concerning new or updated lists, as provided for in Article 9(1), Article 10(1) and Article 11(1), that it has received from the competent authorities of third countries in accordance with Article 9(3).

If no Member State objects to those new or updated lists within five working days from the date of the Commission's notification, imports shall be authorised from establishments or vessels appearing on such lists ten working days from the date the Commission makes such lists publicly available.

2. Where following the notification provided for in paragraph 1 at least one Member State makes written comments, or where the Commission considers that the amendment of a list is necessary in the light of relevant information such as Community inspection reports or a notification under the rapid alert system, it shall in inform all Member States and include the point on the agenda of the next meeting of the relevant section of the Standing Committee on the Food Chain and Animal Health for decision, where appropriate, in accordance with the procedure referred to in Article 19(2).

Article 14  
Up-to-date lists concerning imports

The Commission shall arrange for up-to-date versions of all lists provided for in Article 8(1), Article 9(1), Article 10(1) and Article 11(1) to be publicly available.

Article 15  
Documents

1. A document meeting the requirements set out in Annex VI shall accompany consignments of products of animal origin when they are imported into the Community.
2. The document shall certify that the products satisfy:
  - (a) the requirements laid down for such products under Regulation (EC) No .../... [on the hygiene of foodstuffs] and Regulation No .../... [laying down specific hygiene rules for food of animal origin] or provisions that are equivalent to those requirements; and
  - (b) any specific import conditions established in accordance with Article 19.
3. Documents may include details required in accordance with other Community legislation on public and animal health matters.
4. Exemptions from paragraph 1 may be established in accordance with the procedure referred to in Article 19(2) when it is possible to obtain the guarantees referred to in paragraph 2 in another way.

CHAPTER IV  
EMPOWERING PROVISIONS

Article 16  
Flexibility

1. Member States may adopt national rules adapting the rules laid down in Annex I provided that such national rules do not compromise the objectives of this Regulation and :
  - (a) enable the continued use of traditional methods at any of the stages of production, processing or distribution of food; or

- (b) accommodate the needs of food businesses:
    - (i) with a small production rate; or
    - (ii) situated in regions suffering from special geographic constraints.
- 2. The national rules provided for in paragraph 1 shall concern in particular the following matters in Annex I:
  - (a) food chain information as set out in Section I.2.A of Annex I and in Section II.B of Annex I; and
  - (b) the presence of the competent authority depending on the risk analysis as set out in Section II.2 of Chapter II of Annex I.
- 3. Any Member State wishing to adopt national rules as provided for in paragraph 2 shall notify the Commission and the other Member States. The notification shall:
  - (a) provide a detailed description of the rules that that Member State considers need to be adapted and the nature of the proposed adaptation;
  - (b) describe the establishments concerned;
  - (c) explain the reasons for the adaptation, including, where relevant a summary of:
    - (i) the hazard analysis carried out; and
    - (ii) any measures to be taken to ensure that the adaptation does not compromise the objectives of this Regulation;
  - (d) provide any other relevant information.
- 4. The other Member States shall have three months from the date of receipt of the notification provided for in paragraph 1 to send written comments to the Commission.

The Commission may, and if it receives written comments from one or more Member States shall, consult the 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 that general measures having the objectives set out in paragraph 1 and concerning the matters set out in paragraph 2 be adopted in accordance with with the procedure referred to in Article 19(2).

**5. A Member State may adopt national rules adapting the requirements of Annex I only:**

- (a) in compliance with a decision adopted in accordance with paragraph 4, or**
- (b) if, one month after the expiry of the period of three months referred to in paragraph 4, if the Commission has not informed the Member State that:**
  - (i) it has received written comments from other Member States; or**
  - (ii) it intends to propose the adoption of a decision as referred to in subparagraph (a).**

#### **Article 17**

##### **Amendment of the Annexes, implementing rules and transitional measures**

In accordance with the procedure referred to in Article **19(2)** and where necessary after having obtained the opinion of the European Food Safety Authority:

1. Annexes I to IV ~~shall~~ **may** be amended or supplemented in order to take account of scientific and technical progress;
2. Implementing rules needed to ensure uniform implementation of this Regulation ~~shall~~ **may** be adopted;
3. **Transitional measures may be laid down** ~~microbiological criteria for the control of hygiene in production facilities may be laid down.~~

#### **Article 18**

##### **Specific decisions**

**The implementing measures referred to in Article 17(2) may specify in particular:**

- 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, depending on the holding, region or country of origin and based on 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 IX;
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 co-operation 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. Detailed rules for the implementation of Articles 11 and 12
15. Organoleptic criteria for the evaluation of the freshness of fishery products;
16. 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;

- 17. The method by which the Commission will make lists of third countries and establishments in third countries available to the public pursuant to Articles 8, 9, 10 and 11;**
- 18. Models for documents and criteria for the use of electronic documents;**
- 19. Criteria for determining the risk that particular products of animal origin imported into the Community present;**
- 20. 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**
- 21. 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*  
**Regulatory 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, ~~the regulatory procedure laid down in Articles 5 and 7 of Decision 1999/468/EC shall apply, in compliance with Article 7 and~~ **having regard to the provisions of** Article 8 thereof.
3. The period provided for in Article 5(6) of Decision 1999/468/EC shall be three months.

## **CHAPTER V**

### **FINAL PROVISIONS**

#### *Article 20*

##### *Entry into force and applicability*

This Regulation shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union*.

It shall apply [insert dd/mm/yyyy]<sup>12</sup>.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels,

*For the European Parliament*  
*The President*

*For the Council*  
*The President*

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<sup>12</sup> This Regulation shall have the same date of application as the other legal texts that are part of the so-called recast of hygiene legislation.

## ANNEX I

### FRESH MEAT

This Annex applies to slaughterhouses, game handling establishments and cutting plants.

## **Chapter 1**

### **Type of controls and decisions following controls**

#### **I. TASKS OF THE OFFICIAL VETERINARIAN**

##### **I.1 Audits of the official veterinarian**

The official veterinarian shall carry out audits in meat establishments with a view to checking whether the **food business** operator complies with the requirements of Regulation (EC) No .../... [on the hygiene of foodstuffs], Regulation (EC) No .../... [laying down specific hygiene rules for food of animal origin] and Regulation (EC) No .../... [laying down health rules concerning animal by-products not intended for human consumption], and consequently has taken all appropriate measures to ensure good hygienic practices and safe meat. These audits include:

##### **A. Audits of the good hygienic practices.**

Such audits shall be carried out to verify the continuous compliance with the food business operator's own procedures concerning at least:

- (a) design and maintenance of plant structure and equipment;
- (b) plant hygiene, covering pre-operational, operational and post-operational hygiene;
- (c) personal hygiene;
- (d) training in hygiene and in work procedures;
- (e) control of pests;
- (f) control of the water quality;
- (g) control of the temperature;
- (h) control of incoming and outgoing meat;
- (i) ~~handling~~, collection, **transport**, and storage, **handling, processing and use or disposal** of animal by-products ~~not intended for human consumption~~, including Specified Risk Materials, **for which the food business operator is responsible**.

B. Audits of the procedures based on the principles of hazard analysis and critical control points (HACCP).

Such audits shall be carried out to verify whether all HACCP-principles are continuously and properly applied and whether the HACCP-based procedures guarantee:

1. that the animals entering the slaughter process:
  - (a) are properly identified;
  - (b) are accompanied by the relevant information from the holding of provenance of the animals;
  - (c) have hide, skin or fleece conditions that are such that the risk of contamination of the meat during slaughter is kept to a minimum;
  - (d) are visually healthy;
  - (e) have been transported and handled in a manner which complies with Community animal welfare rules.
2. to the extent possible, that the meat at the end of the slaughter process:
  - (a) is in conformity with the microbiological criteria laid down in Community legislation, including hygiene parameters and the relevant criteria for pathogens;
  - (b) does not contain chemical residues in excess of the levels laid down in Community legislation;
  - (c) does not contain residues of substances forbidden in Community legislation;
  - (d) does not contain contaminants in excess of the levels laid down in Community legislation;
  - (e) does not display physical hazards, such as foreign bodies;
  - (f) does not contain patho-physiological abnormalities or changes, by bringing to the attention of the official veterinarian carcasses or meat containing such abnormalities or changes;
  - (g) does not bear faecal or other contamination;

- (h) does not contain Specified Risk Material, except as provided for under Community legislation, and has been produced in accordance with the relevant Community legislation on transmissible spongiform encephalopathies;
- (i) is in conformity with the relevant Community rules concerning traceability of meat.

C. Audits of the use of guides.

Where the food business operator uses Community or national guides on good practices in order to comply with Community or national rules, the correct use of such guides shall be audited.

D. Performance of audits.

Special care shall be taken in carrying out the audits provided for in this Chapter in regard to:

- (a) keeping an oversight of the activities carried out by the staff of the establishment on an on-going basis, and at all stages of the slaughtering and cutting process; the official veterinarian may carry out performance tests in order to ascertain that the performance of the staff of the establishment meets specific criteria set by the competent authority; detailed rules concerning the performance tests shall be adopted if necessary, in accordance with the procedure referred to in **Article 19(2)**;
- (b) verification of all the relevant records of the food business operator;
- (c) taking samples for laboratory analysis whenever deemed necessary;
- (d) documenting the elements taken into account and the findings of the audit.

**I.2 Inspections to be carried out by the official veterinarian**

The results of the audits carried out under Section I.1 shall be taken into account by the official veterinarian in carrying out his inspections and shall affect, where appropriate, the way those inspections are carried out.

Those inspections shall include:

A. Food chain information

1. The relevant information contained in the records of the holding of provenance of the animals, which shall be made available by the operator of the holding in accordance with Regulation (EC) No .../... [on the hygiene of foodstuffs], shall be checked and analysed by the official veterinarian before slaughter of the animals. This information shall cover at least:
  - (a) the status of the holding of provenance or the regional animal health status;
  - (b) the animals' health status;
  - (c) the details of veterinary medicinal products or other treatments administered to the animals during the rearing period (with a maximum period of the previous six months before the date of the inspection), date(s) of administration and the withdrawal period(s). **Details shall only be given for veterinary medicinal products with a withdrawal period of more than zero or for veterinary medicinal products that may have an effect on the detection of animal diseases;**
  - (d) ~~the occurrence of~~ diseases **which have occurred and** which may affect the safety of the meat;
  - (e) the results, **if they are relevant to the protection of public health,** of any analysis carried out on samples taken from the animals or other samples **taken to diagnose diseases that may affect the safety of the meat** ~~for diagnostic purposes,~~ including samples taken in the framework of the monitoring and control of zoonoses and residues;
  - (f) the relevant reports from slaughterhouses about previous ante- and post-mortem findings in animals from the same holding of provenance;
  - (g) the relevant production data;
  - (h) the name and address of the private veterinarian normally attending the operator of the holding of provenance; and
  - (i) the name of the responsible official veterinarian/veterinary office.

2. ~~Detailed rules concerning the way this information shall be established, and the way this information shall be presented, shall be laid down in accordance with the procedure of Article 6.~~ **The following shall be laid down in accordance with the procedure referred to in Article 19(2):**

**(a) rules concerning the way food chain information shall be established and proposed;**

**(b) the form of a standard declaration on food chain information, to be signed by primary producers.**

3. In carrying out ante- and post-mortem inspection, the official veterinarian shall take into account the documented results of the check and analysis of food chain information.
4. In carrying out his inspections, the official veterinarian shall take into account official certificates accompanying the animals, and possible declarations of veterinarians carrying out controls at the level of primary production, including official veterinarians and approved veterinarians taking part in a surveillance network system, as provided for by Article 14 of Directive 64/432/EEC<sup>1</sup>.
5. When the food business operators in the food chain take additional measures to guarantee food safety by implementing integrated systems, private control systems, independent third party certification or by other means, and when such measures are documented and the animals covered by those schemes clearly identifiable, the official veterinarian may take them into account in carrying out his inspections and in reviewing the HACCP-based procedures.

B. Ante-mortem inspection (the following rules do not apply to hunted wild game).

1. Before slaughter, all animals must undergo an ante-mortem inspection by the official veterinarian. The animals must undergo ante-mortem inspection within 24 hours of arrival at the slaughterhouse and less than 24 hours before slaughter. In addition, the official veterinarian may require inspection at any other time.

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<sup>1</sup> OJ P 121, 29.7.1964, p. 1977.

2. The inspection must determine, in particular, whether:
  - (a) animal identification rules have been complied with;
  - (b) the welfare of the animals is not compromised;
  - (c) hide, skin or fleece conditions are such that the risk of contamination of the meat during slaughter is kept to a minimum;
  - (d) signs of any condition which might adversely affect human or animal health are present, with particular attention for the detection of zoonotic diseases, diseases listed on List A of the Office International des Epizooties (OIE) and other notifiable diseases.
3. The official veterinarian shall, at the slaughterhouse, also carry out a clinical inspection of all animals that the food business operator or official auxiliaries may have put aside as being unfit for slaughter.
4. Where provided for in this Regulation, part of the ante-mortem inspection may be carried out at the holding of provenance of the animals.
5. In case of emergency slaughter outside the slaughterhouse, the official veterinarian in the slaughterhouse shall examine the certificate, issued by the veterinarian, in accordance with Regulation (EC) No .../... [laying down specific hygiene rules for food of animal origin].

C. Animal welfare

The official veterinarian shall verify compliance with the relevant Community **and national** rules on the welfare of animals, including the rules concerning the protection of animals at the time of slaughter and the rules concerning the protection of animals during transport.

D. Post-mortem inspection

1. The carcase and **accompanying** offal shall be subjected without delay to visual post-mortem inspection. All external surfaces shall be viewed; minimal handling of the carcase and/or offal, and/or special technical facilities may be required for that purpose. Particular attention shall be paid to the detection of zoonotic diseases, diseases listed on List A of the OIE and other notifiable diseases. The speed of the slaughterline and inspection staffing level shall be such as to allow for proper inspection. Depending on the animal species, the type of holding or the country or region of origin, and based on the principles of risk analysis, additional palpation, incisions or laboratory tests are required as referred to in Chapter 3.

2. Whenever considered necessary to reach a definitive diagnosis, or to detect the presence of an animal disease or an excess of chemical residues or non-compliance with microbiological criteria, additional examination shall take place, such as palpation and incision of parts of the carcass and offal, and laboratory tests.
3. Carcasses of domestic solipeds, bovine animals over six months old, and domestic swine over four weeks old shall be submitted for post-mortem inspection split lengthways into half carcasses down the spinal column. If the inspection so necessitates, the official veterinarian may require any head or any carcass to be split lengthways. However, to take account of technological developments or specific sanitary situations, the competent authority may authorise the submission for inspection of carcasses of domestic solipeds, bovine animals over six months old, and domestic swine over four weeks old not split in half.
4. During the inspection precautions must be taken to ensure that contamination of the meat by actions such as palpation, cutting or incision is kept to a minimum.
5. Alternative procedures, serological or other laboratory tests may, after consultation of the European Food Safety Authority and following the procedure referred to in **Article 19(2)**, replace specific post-mortem inspection procedures referred to in Chapter 3 when they provide at least equivalent guarantees. **The competent authority shall be in agreement with the use of those procedures.**
6. **In the case of emergency slaughter, the carcass shall be subjected as soon as possible to a post-mortem inspection, in accordance with points 1 to 5, before being declared fit for human consumption.**

E. Specified Risk Materials (SRMs)

In accordance with the specific Community rules on SRMs the removal, separation, staining and, where appropriate, marking of SRMs shall be checked by the official veterinarian. He shall ensure that the food business operator takes all the necessary measures to avoid contamination of the meat with SRM during slaughter (including stunning) and removal of SRM.

F. Laboratory testing and base-line studies on pathogens

1. In the framework of:

- (a) official monitoring for zoonoses, including *Salmonella* spp., *Campylobacter* spp., verotoxin producing *Escherichia coli* and multi-resistant bacterial strains;
- (b) laboratory testing for the diagnosis of transmissible spongiform encephalopathies as provided for in Article 20(1) of Regulation (EC) No 999/2001<sup>2</sup>;
- (c) the detection of unauthorised substances or products, the control on regulated substances and in particular in the framework of the monitoring plans for the detection of residues or substances as provided for in Chapter II of Directive 96/23/EC<sup>3</sup>;
- (d) the detection of zoonotic diseases, diseases listed on List A of the OIE and other notifiable diseases;
- (e) laboratory testing of animals considered suspect by the official veterinarian, or laboratory testing for the official veterinarian to reach a definitive diagnosis;

the official veterinarian shall carry out the sampling and ensure the samples are identified, handled and sent to the appropriate laboratory in accordance with the relevant specifications and taking into consideration other Community rules laid down in the fields of zoonoses, transmissible spongiform encephalopathies and residues.

2. Where necessary, detailed rules for laboratory testing shall be laid down in accordance with the procedure referred to in **Article 19(2)**, including specific rules for base-line studies on *Salmonella* spp., *Campylobacter* spp., verotoxin producing *Escherichia coli* and multi-resistant bacterial strains.

G. Health and identification marking

1. Meat of domestic ungulates, farmed game mammals other than lagomorphs and large wild game shall be health marked under the responsibility of the official veterinarian. After completion of the post-mortem inspection, carcasses, half carcasses, quarters and carcasses cut into three pieces must be health-marked by stamping the mark in ink or hot-branding the mark on the external surface so as to ensure that the number of the establishment is easily identifiable.

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<sup>2</sup> OJ L 147, 31.5.2001, p. 1.

<sup>3</sup> OJ L 125, 23.5.1996, p. 10.

2. For the purposes of health and identification marking, the official veterinarian shall supervise:
  - (a) the health marking;
  - (b) the marks and wrapping material when marked as provided for in this section.
3. Except for hunted wild game, the health mark may only be applied when the animal (from which the meat has been obtained) has been inspected ante-mortem by the official veterinarian and when all the other requirements of this Regulation have been met. **However, 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 is to be placed on the market only if the results are satisfactory.**
4. The health mark must be:
  - (a) either an oval mark at least 6,5 cm wide by 4,5 cm high bearing the following information in perfectly legible characters:
    - (i) on the upper part, the initials of the consigning country in capitals: B - DK - D - EL - E - F - IRL - I - L - NL - A - P - FIN - S - UK, followed by the veterinary approval number of the establishment;
    - (ii) on the lower part, one of the following sets of initials: CE, EC, EF, EG, EK, or EY;
  - (b) or an oval mark at least 6,5 cm wide by 4,5 cm high, bearing the following information in perfectly legible characters:
    - (i) on the upper part, the name of the consigning country in capitals;
    - (ii) in the centre, the veterinary approval number of the establishment;
    - (iii) on the lower part, one of the following sets of initials: CE, EC, EF, EG, EK, EY.

The letters must be at least 0,8 cm high and the figures at least 1 cm high. The health mark may, in addition, include an indication of the official veterinarian who carried out the health inspection of the meat. The dimensions and characters of the mark may be reduced for health marking of lamb, kids and piglets.

5. Carcases must be stamped in ink or hot-branded in accordance with point 4:
  - (a) those weighing more than 65 kilograms must be marked on each half-carcase, in the following places at least: external surface of the thighs, loins, back, breast and shoulder;
  - (b) lamb, kid and piglet carcases must bear at least two stamps, one on each side of the carcase, on the shoulder or on the external surface of the thighs;
  - (c) other carcases must be marked in at least four places, on the shoulder and on the external surface of the thighs. However, in the case of lamb, kid and piglet carcases, health marking may take the form of a label or tag which may be used only once.
6. The livers of bovine animals, swine and solipeds must be hot-branded in accordance with point 4.
7. All other sub-products of slaughtering fit for human consumption must be marked immediately in accordance with point 4, either directly on the product or on the wrapping or packaging. The mark in accordance with point 4 must be applied to a label fixed to the wrapping or packaging or printed on the packaging.
8. Packaging must always be marked in accordance with point 9.
9. Packaged cut meat and packaged offal referred to in point 6 and point 7 must bear a health mark in accordance with point 4. The mark must be applied to a label fixed to the packaging, or printed on the packaging, in such a way that it is destroyed when the packaging is opened. Non-destruction of the mark must be tolerated only when the packaging is destroyed by being opened. However, when wrapping fulfils all the protective conditions of packaging, the label may be affixed to the wrapping.
10. Where fresh meat is wrapped in commercial portions intended for direct sale to the consumer, points 7 and 9 shall apply. The dimension requirements of point 4 need not apply to the mark required under this point. If meat is re-packaged in a plant other than that in which it was first wrapped, the wrapping must bear the health mark of the cutting plant where it was first wrapped, and the packaging must bear the health mark of the packaging centre.
11. Meat from solipeds and its packaging must bear a special mark, to be determined in accordance with the procedure laid down in **Article 19(2)**.

12. The colours used for health marking must be those listed in the relevant Community legislation on colours for use in foodstuffs.
13. Health marks may not be removed unless the meat is further worked upon in another separate approved establishment where the original mark must be replaced by a mark with that establishment's own number.

#### H. Communication of inspection results

1. The official veterinarian shall record and evaluate the results of his inspections. If his inspection has revealed the presence of any disease or condition which might affect public or animal health, or compromised animal welfare, this information shall be communicated to:
  - (a) the food business operator of the meat establishment;
  - (b) ~~When the problem arises during primary production, this information shall also~~ the competent authority responsible for supervising the holding of provenance of the animals or the hunting area;
  - (c) the ~~private~~ veterinarian attending the holding of provenance; and
  - (d) the person responsible for the holding of provenance.

However, where it is necessary to find evidence of non-respect of good veterinary practice or for illegal use of pharmaceutical substances, the official findings shall not be communicated to the private veterinarian and the person responsible for the holding.

**The official veterinarian may decide not to communicate certain information if it is not relevant to a particular person.** Following such communication, action must be taken by the **persons** responsible **in their sphere of competence** ~~for the holding of provenance~~; to remedy the situation where appropriate.

2. The results of inspections and tests shall be communicated to the relevant databases.
3. Where the animals concerned were raised in another Member State or in a third country, the finding of a disease or condition which might affect public or animal health, or compromised animal welfare, shall be communicated to the food business operator of the meat establishment and to the central competent authority of the Member State where the meat establishment is located. The meat establishment shall inform the Commission in cases where the animals concerned were raised in a third country.

4. When the official veterinarian, while carrying out ante- or post-mortem inspection or any other inspection activity, suspects the presence of an infectious agent listed in List A of the OIE, he shall immediately notify the central competent authority. He shall take all necessary measures and precautions to prevent the possible spread of the infectious agent including the shut-down of the establishment, with no further movements either on or off the premises, until either the absence of the agent has been confirmed or all the necessary restrictions and measures have been put in place.
5. Detailed rules concerning the communication of inspection results shall be adopted if necessary, in accordance with the procedure referred to in **Article 19(2)**.

## **II. DECISIONS FOLLOWING OFFICIAL CONTROLS**

Where, following official controls, deficiencies, non-compliance or irregularities are found, appropriate measures shall be taken including:

- A. Decisions following audits of the good hygienic practices and the HACCP-based procedures
  1. When an audit of the good hygienic practices or the HACCP-based procedures reveals non-compliance, the official veterinarian shall ensure that the food business operator immediately reviews the process controls, discovers the cause if possible, rectifies the non-compliance and prevents recurrence. Depending on the nature of the problem, measures such as slowing down the process, may be taken by the official veterinarian.
  2. Whenever the audit of the good hygienic practices or the HACCP-based procedures or other investigations reveal that meat may be placed on the market that is unfit for human consumption under the provisions of Section II.E, and the food business operator fails to adapt immediately the procedures, the slaughtering or cutting process shall be stopped. The process shall only resume when the official veterinarian is satisfied that the situation is under control. A similar procedure shall, whenever considered necessary by the official veterinarian, also apply when non-compliance occurs repeatedly.
  3. Where appropriate, the official veterinarian shall order a recall, further examination and, when necessary, withdrawal and/or destruction of meat.
  4. When the process has to be stopped repeatedly, and the food business operator is not able to prevent a recurrence, the competent authority shall start the procedure for withdrawal of the approval of the establishment.

B. Decisions concerning the food chain information

1. Animals without the relevant food safety information contained in the records of the holding of provenance of the animals shall not be accepted for slaughter. When those animals are already present at the slaughterhouse, they shall, without prejudice to the specific legislation governing veterinary checks in intra-Community trade, be killed separately and declared unfit for human consumption.
2. When there are overriding animal welfare considerations the animal may be slaughtered even if the food chain information has not been supplied; however, all food chain information needed by the official veterinarian for an appropriate post-mortem inspection shall be supplied before the carcass may be approved for human consumption. Pending a final judgement, such a carcass and the related offal shall be stored separately from the other meat. This provision shall also apply in case of emergency slaughter outside the slaughterhouse.
3. When the accompanying records, documentation and other information show that:
  - (a) the animals come from a holding or an area subject to a movement prohibition or other restriction for reasons of animal or public health;
  - (b) rules on the use of veterinary medicinal products have not been complied with;
  - (c) any other condition which might adversely affect human or animal health is present;

the animals shall not be accepted for slaughter unless procedures are followed that have been introduced under Community rules to eliminate human or animal health risks. If those animals are already present at the slaughterhouse, they shall be killed separately and declared unfit for human consumption, and precautions taken to safeguard animal and public health where appropriate. Whenever considered necessary by the official veterinarian, official controls shall be carried out on the holding of provenance.

4. When the competent authority discovers that the accompanying records, documentation and other information do not correspond with the true situation on the holding of provenance or the true condition of the animals or aimed at deliberately misleading the official veterinarian, the competent authority shall take action against the food business operator responsible for the holding of provenance of the animals, or any other person involved. This may consist in particular of extra controls. The costs of such extra controls shall be borne by the food business operator of the holding of provenance or the other persons involved.

C. Decisions concerning live animals

1. Animals not properly identified shall not be accepted for slaughter. Those animals shall be killed separately and declared unfit for human consumption. Whenever considered necessary by the official veterinarian, official controls shall be carried out on the holding of provenance.
2. When there are overriding animal welfare considerations, horses may be slaughtered even if the legally required information concerning the identity has not been supplied; however, such information shall be supplied before the carcass may be approved for human consumption. This provision shall also apply in the case of emergency slaughter of horses outside the slaughterhouse.
3. Animals that have such hide, skin or fleece conditions that there is an increased risk of contamination of the meat during slaughter shall not be slaughtered for human consumption.
4. Animals with a disease or condition which may be transmitted to animals or humans through handling or eating the meat, and, in general, animals showing clinical signs of systemic disease or emaciation, shall not be slaughtered for human consumption. Such animals shall be killed separately, under conditions such that other animals or carcasses cannot be contaminated, and declared unfit for human consumption.
5. The slaughter of animals suspected of having a disease or condition which may adversely affect human or animal health, shall be deferred. Those animals shall undergo detailed examination in order to make a diagnosis. Where post-mortem inspection is necessary in order to make a diagnosis the official veterinarian may decide that the animals must undergo a post-mortem inspection supplemented, if necessary, by sampling and laboratory examinations. The animals shall be slaughtered separately or at the end of the normal slaughtering, taking all necessary precautions to avoid possible contamination of other meat.
6. In the case of animals which might have residues of veterinary medicinal products in excess of the levels laid down in Community legislation, or residues of substances prohibited under Community legislation, the measures provided for in Chapter V of Directive 96/23/EC shall be taken.
7. The ~~slaughter~~ **treatment** of animals under a specific scheme for the eradication or control of a specific disease including brucellosis or tuberculosis or other zoonotic agents shall be carried out under the conditions imposed by, and the direct supervision of, the official veterinarian; **the competent authority shall determine the measures and conditions under which those animals are to be slaughtered.** The animals must be slaughtered under conditions such that other animals and/or the meat of other animals cannot be contaminated.

8. Once animals have arrived within the perimeter of slaughterhouse premises, they shall not leave those premises alive except in the case of a serious breakdown of the slaughter facilities. In those circumstances, only direct movements to another slaughterhouse shall be allowed.

D. Decisions concerning animal welfare

1. When the rules concerning the protection of animals at the time of slaughter or killing are not respected, the official veterinarian shall ensure that the food business operator immediately takes the necessary corrective measures and prevents any recurrence. Depending on the nature of the breach, measures such as slowing down or stopping the slaughter process, may be taken by the official veterinarian. Where appropriate, the official veterinarian shall inform other competent authorities.
2. When the official veterinarian discovers that rules concerning the protection of animals during transport are not being respected, he shall take the necessary measures in accordance with the relevant Community legislation.

E. Decisions concerning meat

The following meat shall be declared unfit for human consumption:

- (a) meat from animals which have not undergone ante-mortem inspection, except for hunted wild game;
- (b) meat from animals the offal of which has not undergone post-mortem inspection, unless otherwise provided for under this Regulation **or Regulation (EC) No. .../... [laying down specific rules for food of animal origin]**;
- (c) meat from animals which are dead before slaughter, stillborn, unborn or slaughtered under the age of 7 days;
- (d) meat resulting from the trimming of the sticking points;
- (e) meat from animals affected by an OIE list A or, where appropriate, OIE list B disease, unless otherwise provided for in Chapter 3;
- (f) meat from animals affected by generalised disease, septicaemia, pyaemia, toxæmia or viraemia;
- (g) meat that is not in conformity with the relevant microbiological criteria laid down in Community legislation;
- (h) meat found to exhibit parasitic infestation, unless otherwise provided for in Chapter 3;

- (i) meat containing residues or contaminants in excess of the levels laid down in Community legislation. Such excess shall lead to additional analyses whenever appropriate;
- (j) without prejudice to more specific Community legislation, meat from animals or carcasses containing residues of substances prohibited under Community legislation and all meat from animals that have been treated with such substances;
- (k) the liver and kidneys of animals more than two years old from regions where plans implemented under Article 5 of Directive 96/23/EC have revealed the generalised presence of heavy metals in the environment;
- (l) meat that has been treated illegally with decontaminating substances;
- (m) meat that has been treated illegally with ionising or UV-rays;
- (n) meat containing foreign bodies, except in the case of wild-game meat where it concerns material used to hunt the animal;
- (o) meat exceeding the maximum permitted radioactive levels laid down in Community legislation;
- (p) meat with patho-physiological changes, anomalies in consistency, insufficient bleeding, organoleptic anomalies, **in particular a pronounced sexual odour,** or from emaciated animals;
- (q) meat containing Specified Risk Material except as provided for under Community legislation;
- (r) meat showing soiling, faecal or other contamination;
- (s) the blood of an animal whose carcass has been declared unfit for human consumption in accordance with the points (a) to (r), and blood contaminated by stomach contents or any other substance;
- (t) all meat that, in the opinion of the official veterinarian, after examination of all the relevant information, may constitute a public or animal health danger or is for any other reasons not suitable for human consumption.

## **Chapter 2**

### **Responsibilities and frequency of official controls**

#### **I. THE INSPECTION TEAM**

In carrying out the official controls, the official veterinarian may be assisted by official auxiliaries placed under his authority and responsibility. The official auxiliaries may carry out the following activities:

- (a) collecting information regarding good hygienic practices and the HACCP-based procedures;
- (b) helping with ante-mortem inspections in the slaughterhouse **or at the holding of provenance**. In that case the official auxiliary's role shall be to make an initial check on the animals and to help with purely practical tasks;
- (c) checks concerning the welfare of animals;
- (d) post-mortem inspections, provided that the official veterinarian is supervising the work of the official auxiliaries;
- (e) checks on the removal, separation, staining and, where appropriate, marking of Specified Risk Material;
- (f) checks on cut and stored meat;
- (g) sampling; and
- (h) inspection and supervision of establishments, means of transport.

#### **II. THE FREQUENCY OF OFFICIAL CONTROLS**

1. The competent authority shall guarantee appropriate official supervision in meat establishments. The nature and intensity of the official supervision shall be based on a regular assessment of the public and animal health risks, the animal welfare aspects and the product suitability aspects related to the species and category of animals slaughtered, the type of process and the food business operator concerned. In the calculation of staffing on the slaughterline, a scientific approach shall be followed where appropriate. The number of official staff involved shall be such that all the requirements of this Regulation may be applied.

2. Care shall be taken to ensure that in slaughterhouses ~~and game handling establishments~~, at least one official veterinarian is present throughout both the ante-mortem and the post-mortem inspection **and in game handling establishments throughout post-mortem inspection.**

~~Some flexibility may be applied for small slaughterhouses and small game handling establishments:~~ **The competent authority may exercise a more flexible approach in slaughterhouses with a low throughput and in game handling establishments identified on the basis of risk analysis as follows:**

- (i) ante-mortem inspection shall be carried out by the official veterinarian, but may take place at the holding of provenance;
- (ii) the permanent presence of the official veterinarian during post-mortem inspection is not required, provided that an official auxiliary carries out post-mortem inspection, and that meat with abnormalities is put aside and inspected by the official veterinarian; a documented control system shall be put in place that allows the official veterinarian to be satisfied that standards are being met.

When necessary to ensure the uniform implementation a definition of slaughterhouse with a small throughput shall be approved in accordance with the procedure defined in **Article 19(2)**.

3. In the case of poultry, the flexible approach provided for in point 2 may, on the basis of a case-by-case analysis of the risks by the competent authority, be applied in other slaughterhouses than small ones.
4. The flexible approach provided for in points 2 and 3 shall not apply:
- (i) for emergency slaughtered animals and animals suspected of having a disease or condition which may adversely affect human health;
  - (ii) for bovine animals coming from herds that have not been declared officially tuberculosis-free;
  - (iii) for bovine animals, sheep and goats coming from herds that have not been declared officially brucellosis-free;
  - (iv) in case of an outbreak of a disease listed on List A or, where appropriate, List B of the OIE this provision shall apply to animals susceptible to the particular disease in question and coming from the particular region as defined in Article 2 of Directive 64/432/EEC;
  - (v) when considered necessary, to take into account emerging diseases or certain List B diseases.

5. Care shall be taken in cutting plants to ensure that a member of the inspection team is regularly present, ~~but at least once a week~~, when meat is being worked on **in accordance with an inspection schedule drawn up by the competent authority on the basis of a risk analysis.**

### III. INVOLVEMENT OF SLAUGHTERHOUSE STAFF

1. Member States may allow staff of the establishment to carry out activities of official auxiliaries in the control on the production of poultry and rabbit meat under the following conditions:

- (a) Where the establishment has successfully been operating, for at least 12 months, good hygienic practices and HACCP-based procedures, the competent authority may permit staff of the establishment, having received a training equivalent to the training of official auxiliaries, and having passed the same test, to carry out tasks of official auxiliaries under the supervision of the official veterinarian.

In that case, the official veterinarian shall be present throughout ante- and post-mortem inspection, shall supervise those activities and carry out regular performance tests to ascertain that the performance of the staff of the establishment meets specific criteria set by the competent authority, and shall document the results of those performance tests. When necessary, detailed rules concerning the performance tests shall be adopted in accordance with the procedure referred to in **Article 19(2)**.

However, when the level of hygiene in the establishment decreases due to the functioning of the staff, or when tasks are not properly carried out by the staff, or, in general, when the staff carries out their activities in a manner that is not satisfactory according to the competent authority, they shall be replaced by official auxiliaries.

- (b) The competent authority of the Member State shall decide in principle and on a case by case basis whether to allow for the implementation of the system provided for in point (a). If the Member State decides to do so in principle, it should inform the Commission of its decision and the conditions thereof.

For meat establishments in a Member State where that system is implemented, the actual use of the system shall be optional. Meat establishments shall not be forced by the competent authority to introduce the system.

When the competent authority is not convinced that the meat establishment meets the requirements of point (a), the system shall not be implemented.

To assess whether a meat establishment meets the requirements of point (a), the competent authority shall conduct an analysis of production and inspection records, the type of activities undertaken in the meat establishment, its history of compliance with legislation, expertise, professional attitude and sense of responsibility as regards food safety of the staff of the establishment and any other relevant information.

2. Member States with at least five years of experience with staff of establishments carrying out inspections in the poultry sector, may extend the system provided for in point 1(a) to the fattening pig and the fattening veal sectors under the following conditions:
  - (a) the Member State concerned shall submit an evaluation report to the Commission and the Member States proving that the system has, during those five years, operated successfully in the poultry sector.
  - (b) the Food and Veterinary Office of the Commission shall, when deemed necessary by the Commission, carry out an audit of the system in the Member State to confirm its successful operation;
  - (c) the Commission may require that the Member State returns to inspection of fattening pigs or fattening veal calves by official auxiliaries or takes any other appropriate measure, when a report of the Food and Veterinary Office or other information indicates that the Member State may not be able to guarantee adequate hygiene or inspection in the pig or veal meat establishments.

The conditions applying to the implementation of the system in the poultry sector, set out in points 1 (a) and 1 (b), shall also apply to the implementation of the system in the fattening pig and fattening veal sectors.

3. Staff of the establishment having received specific training, under the supervision of the official veterinarian, may, under the responsibility and the supervision of the official veterinarian, carry out specific sampling and testing.

#### **IV. PROFESSIONAL QUALIFICATIONS**

##### **A. Professional qualifications of the official veterinarian**

1. Only veterinarians who have passed a test organised by the competent authority, as defined by Regulation (EC) No .../... [on official feed and food controls], or by the organisation designated for that purpose by the competent authority, may be appointed as official veterinarians.

2. The test referred to in point 1 **shall confirm knowledge of the following subjects to the extent necessary depending on the veterinarian's background and qualifications** ~~should cover at least the following subjects:~~
- (a) Community and national legislation on veterinary public health, food safety, animal health, animal welfare and pharmaceutical substances;
  - (b) principles of the Common Agricultural Policy, market measures, export refunds and frauds, including in the global context: WTO, SPS, Codex Alimentarius, OIE;
  - (c) essentials of food processing and food technology;
  - (d) principles, concepts and methods of good manufacturing practice and quality management;
  - (e) pre-harvest quality management ('good farming practices');
  - (f) promotion and use of food hygiene, food related safety ('good hygienic practices');
  - (g) principles, concepts and methods of risk-analysis;
  - (h) principles, concepts and methods of HACCP, use of HACCP throughout the food production food chain;
  - (i) prevention and control of food-borne hazards related to human health;
  - (j) population dynamics of infections and intoxications;
  - (k) diagnostic epidemiology;
  - (l) monitoring and surveillance systems;
  - (m) auditing and regulatory assessment of food safety management systems;
  - (n) principles and diagnostic applications of modern testing methods;
  - (o) information and communication technology as related to veterinary public health;
  - (p) data-handling and applications of biostatistics;
  - (q) investigations of outbreaks of foodborne diseases in humans;

- (r) relevant aspects concerning transmissible spongiform encephalopathies;
- (s) animal welfare at the level of production, transport and slaughter;
- (t) environmental issues related to food production, including waste management;
- (u) precautionary principle and consumer concerns;
- (v) principles of training of personnel working in the production chain.

3. **Candidates for the test referred to in point 1 may have acquired the required knowledge as part of their basic veterinary training, or through training undertaken, or professional experience acquired, after qualifying as veterinarians. The competent authority may arrange for different tests to take account of candidates' background. However, when the competent authority is satisfied that a candidate has acquired all the required knowledge as part of a university degree, or through continuing education resulting in a post-graduate qualification, it may waive the requirement for a test.**
4. **Veterinarians already appointed as official veterinarians must have adequate knowledge of the subjects referred to in point 2. Where necessary, they shall be required to acquire such knowledge through continuing education activities. The competent authority shall make adequate provision for such continuing education activities.**
5. Official veterinarians shall **be capable of** ~~prepared for~~ multidisciplinary co-operation.
6. Detailed rules concerning the content of the test referred to in point 1 shall be adopted, where appropriate, in accordance with the procedure referred to in **Article 19(2)**.
7. In addition, a veterinarian shall receive at least 200 hours of practical training before being appointed as an official veterinarian. The practical training shall:
  - (a) be provided by official veterinarians;
  - (b) take place in slaughterhouses, cutting plants, inspection posts for fresh meat and holdings; and
  - (c) concern, among other things, auditing of food safety management systems.

8. The official veterinarian shall maintain up-to-date knowledge and keep abreast of new developments through annual continuing education activities and professional literature.
9. Veterinarians already appointed as official veterinarians and part-time official veterinarians shall, where necessary, acquire the required knowledge on the subjects referred to in point 2 through continuing education activities. Adequate provisions shall be made by the competent authority for such continuing educational activities.

B. Professional qualifications of the official auxiliaries

1. Only persons who have passed a test organised by the competent authority of the Member States, or by the organisation designated for that purpose by the central competent authority, may be appointed as official auxiliaries.
2. In order to be eligible for the test referred to in point 1, candidates must prove that they have:
  - (a) followed at least 600 hours of theoretical training, including laboratory demonstrations; and
  - (b) received at least 300 hours of practical training under the supervision of an official veterinarian.

The practical training referred to in (b) shall take place under the supervision of an official veterinarian, in slaughterhouses, cutting plants, inspection posts for fresh meat and holdings.

3. The practical training and tests referred to in point 1 shall focus either on red meat or poultry meat. However, persons who were trained for one of those two categories and passed the test, may undergo a shortened practical training course in order to pass the test for the other category.
4. The tests for official auxiliaries referred to in point 1 shall consist of a theoretical part and a practical part and shall cover the following subjects:
  - (a) for the inspection of holdings:
    - (i) theoretical part:
      - familiarity with the farming industry including the organisation, production methods, and international trade;
      - pre-harvest quality management

- basic knowledge of diseases, in particular zoonotic diseases - viruses, bacteria, and parasites.;
- monitoring for disease, use of medicines and vaccines, residue testing;
- hygiene and health inspection;
- animal welfare on the farm, during transport and at the slaughterhouse;
- environmental requirements - in buildings, on farms and in general;
- relevant laws, regulations and administrative provisions applicable;
- consumer concerns and quality control.

(ii) practical part:

- visits to farms of different types and using different rearing methods;
- visits to production establishments;
- loading and unloading of means of transport;
- visits to laboratories;
- veterinary checks;
- documentation.

(b) for inspections at slaughterhouses:

(i) theoretical part:

- familiarity with the meat industry including the organisation, production methods, international trade, **slaughter and cutting technology**;
- basic knowledge of hygiene and good hygienic practices, and in particular industrial hygiene, slaughter, cutting and storage hygiene, hygiene of work;
- HACCP and the audit of HACCP-based procedures;

- basic knowledge of the anatomy and physiology of slaughtered animals;
- basic knowledge of the pathology of slaughtered animals;
- basic knowledge of the pathological anatomy of slaughtered animals;

– **knowledge of microbiology;**

– **examination for trichinosis;**

- relevant knowledge concerning transmissible spongiform encephalopathies;
- knowledge of methods and procedures for the slaughter, inspection, preparation, wrapping, packaging and transport of fresh meat;
- knowledge of the relevant laws, regulations and administrative provisions applicable;

– **ante-mortem inspections;**

– **post-mortem inspections;**

- sampling procedures;
- fraud aspects;

– **administrative tasks.**

(ii) practical part:

- animal identification;
- age checks;
- **recording the results of ante-mortem inspections;**
- inspections and assessments of slaughtered animals;
- post-mortem inspections in a slaughterhouse;
- **examination for trichinosis;**

- identification of animal species by examination of typical parts of the animal;
- identification of a number of parts of slaughtered animals in which changes have occurred, and comments thereon;
- hygiene control, including the audit of the good hygienic practices and the HACCP-based procedures;
- sampling;
- traceability of meat.

Detailed rules concerning the content of the test referred to point 1 shall be adopted, where appropriate, in accordance with the procedure referred to in **Article 19(2)**.

The total duration of the training of official auxiliaries shall gradually increase towards 1400 hours in by 2010, **which shall include practical and theoretical training in ante-mortem inspections, HACCP and plant management** ~~including theoretical and practical training~~.

Official auxiliaries shall maintain up-to-date knowledge and keep abreast of new developments through annual continuing education activities and professional literature.

## **Chapter 3**

### **Specific requirements**

The specific requirements laid down in this Chapter shall apply in addition to the requirements of the Chapters 1 and 2.

#### **I. DOMESTIC BOVINE ANIMALS**

##### **I.1 Bovine animals over six weeks old**

###### **A. Food chain information**

For the slaughter of a lot of bovine animals from the same holding of provenance that are sent directly for slaughter, the food chain information, covering the matters referred to under Section I.2.A of Chapter 1, shall be sent to the food business operator of the slaughterhouse 24 to 72 hours before the arrival of the lot at the slaughterhouse.

When the food business operator decides to accept the lot for slaughter, he shall without delay give a copy of the food chain information to the official veterinarian, but in any case at least 24 hours before the arrival of the lot.

B. Post-mortem inspections

Carcases and offal of bovine animals over six weeks old shall undergo the following post-mortem inspection procedures:

- (a) visual inspection of the head and throat; incision and examination of the sub-maxillary, retropharyngeal and parotid lymph nodes (*Lnn retropharyngiales, mandibulares and parotidei*); examination of the external masseters, in which two incisions must be made parallel to the mandible, and the internal masseters (internal pterygoid muscles), which must be incised along one plane; the tongue must be freed to permit a detailed visual inspection of the mouth and the fauces and must itself be visually inspected and palpated; the tonsils must be removed;
- (b) inspection of the trachea and oesophagus; visual examination and palpation of the lungs; incision and examination of the bronchial and mediastinal lymph nodes (*Lnn. bifurcationes, eparteriales and mediastinales*); the trachea and the main branches of the bronchi must be opened lengthwise and the lungs must be incised in their posterior third, perpendicular to their main axes; these incisions are not necessary where the lungs are excluded from human consumption;
- (c) visual inspection of the pericardium and heart, the latter being incised lengthwise so as to open the ventricles and cut through the interventricular septum;
- (d) visual inspection of the diaphragm;
- (e) visual inspection and palpation of the liver and the hepatic and pancreatic lymph nodes, (*Lnn portales*); incision of the gastric surface of the liver and at the base of the caudate lobe to examine the bile ducts;
- (f) visual inspection of the gastro-intestinal tract, the mesentery, the gastric and mesenteric lymph nodes (*Lnn. gastrici, mesenterici, craniales and caudales*); palpation and, if necessary, incision of the gastric and mesenteric lymph nodes;
- (g) visual inspection and, if necessary, palpation of the spleen;

- (h) visual inspection of the kidneys and incision, if necessary, of the kidneys and the renal lymph nodes (*Lnn. renales*);
- (i) visual inspection of the pleura and the peritoneum;
- (j) visual inspection of the genital organs;
- (k) visual inspection and, if necessary, palpation and incision of the udder and its lymph nodes (*Lnn. supramammarii*); in cows, each half of the udder must be opened by a long, deep incision as far as the lactiferous sinuses (*sinus lactiferes*) and the lymph nodes of the udder must be incised, except when the udder is excluded from human consumption.

## **I.2 Bovine animals under six weeks old**

Carcases and offal of bovine animals under six weeks old shall undergo the following post-mortem inspection procedures:

- (a) visual inspection of the head and throat; incision and examination of the retropharyngeal lymph nodes (*Lnn. retropharyngiales*); inspection of the mouth and fauces; palpation of the tongue; removal of the tonsils;
- (b) visual inspection of the lungs, trachea and oesophagus; palpation of the lungs; incision and examination of the bronchial and mediastinal lymph nodes (*Lnn. bifurcationes, eparteriales and mediastinales*); the trachea and the main branches of the bronchi must be opened lengthwise and the lungs must be incised in their posterior third, perpendicular to their main axes; those incisions shall not be necessary where the lungs are excluded from human consumption;
- (c) visual inspection of the pericardium and heart, the latter being incised lengthwise so as to open the ventricles and cut through the interventricular septum;
- (d) visual inspection of the diaphragm;
- (e) visual inspection of the liver and the hepatic and pancreatic lymph nodes, (*Lnn. portales*); palpation and, if necessary, incision of the liver and its lymph nodes;
- (f) visual inspection of the gastro-intestinal tract, the mesentery, the gastric and mesenteric lymph nodes (*Lnn. gastrici, mesenterici, craniales and caudales*); palpation and, if necessary, incision of the gastric and mesenteric lymph nodes;
- (g) visual inspection and, if necessary, palpation of the spleen;

- (h) visual inspection of the kidneys; incision, if necessary, of the kidneys and the renal lymph nodes (*Lnn. renales*);
- (i) visual inspection of the pleura and peritoneum;
- (j) visual inspection and palpation of the umbilical region and the joints; in the event of doubt, the umbilical region must be incised and the joints opened; the synovial fluid must be examined.

## II. DOMESTIC SHEEP AND GOATS

### A. Food chain information

For the slaughter of a lot of sheep or goats from the same holding of provenance that are sent directly for slaughter, the food chain information, covering the matters referred to under Section 1.2.A of Chapter 1, shall be sent to the food business operator of the slaughterhouse 24 to 72 hours before the arrival of the lot at the slaughterhouse.

When the food business operator decides to accept the lot for slaughter, he shall without delay give a copy of the information to the official veterinarian, but in any case at least 24 hours before the arrival of the lot.

### B. Post-mortem inspections

Carcases and offal of sheep and goats shall undergo the following post-mortem inspection procedures:

- (a) visual inspection of the head after flaying and, in the event of doubt, examination of the throat, mouth, tongue and retropharyngeal and parotid lymph nodes; however, without prejudice to animal-health rules, such examinations shall not be necessary if the competent authority is able to guarantee that the head, including the tongue and the brains, is to be excluded from human consumption;
- (b) visual inspection of the lungs, trachea and oesophagus; palpation of the lungs and the bronchial and mediastinal lymph nodes (*Lnn. bifurcationes, eparteriales and mediastinales*); in the event of doubt, those organs and lymph nodes must be incised and examined;
- (c) visual inspection of the pericardium and heart; in the event of doubt, the heart must be incised and examined;
- (d) visual inspection of the diaphragm;
- (e) visual inspection of the liver and the hepatic and pancreatic lymph nodes, (*Lnn portales*); palpation of the liver and its lymph nodes; incision of the gastric surface of the liver to examine the bile ducts;

- (f) visual inspection of the gastro-intestinal tract, the mesentery and the gastric and mesenteric lymph nodes (*Lnn. gastrici, mesenterici, craniales* and *caudales*);
- (g) visual inspection and, if necessary, palpation of the spleen;
- (h) visual inspection of the kidneys; incision, if necessary, of the kidneys and the renal lymph nodes (*Lnn. renales*);
- (i) visual inspection of the pleura and peritoneum;
- (j) visual inspection of the genital organs;
- (k) visual inspection of the udder and its lymph nodes;
- (l) visual inspection and palpation of the umbilical region and joints of young animals; in the event of doubt, the umbilical region must be incised and the joints opened; the synovial fluid must be examined.

### III. DOMESTIC SOLIPEDS

#### A. Food chain information

The original passport accompanying the animal to slaughter shall be checked by the official veterinarian to ascertain whether the animal is intended to be slaughtered for human consumption.

#### B. Post-mortem inspections

Carcases and offal of solipeds shall undergo the following post-mortem inspection procedures:

- (a) visual inspection of the head and, after freeing the tongue, the throat; palpation and, if necessary, incision of the sub-maxillary, retropharyngeal and parotid lymph nodes (*Lnn. retropharyngiales, mandibulares and parotidei*); the tongue must be freed to permit a detailed visual inspection of the mouth and the fauces and must itself be visually examined and palpated; the tonsils must be removed;
- (b) visual inspection of the lungs, trachea and oesophagus; palpation of the lungs; palpation and, if necessary, incision of the bronchial and mediastinal lymph nodes (*Lnn. bifurcationes, eparteriales and mediastinales*); the trachea and the main branches of the bronchi must be opened lengthways and the lungs must be incised in their posterior third, perpendicular to their main axes; however, those incisions shall not be necessary where the lungs are excluded from human consumption;

- (c) visual inspection of the pericardium and the heart, the latter being incised lengthways so as to open the ventricles and cut through the interventricular septum;
- (d) visual inspection of the diaphragm;
- (e) visual inspection, palpation and, if necessary, incision of the liver and the hepatic and pancreatic lymph nodes, (*Lnn portales*);
- (f) visual inspection of the gastro-intestinal tract, the mesentery and the gastric and mesenteric lymph nodes (*Lnn. gastrici, mesenterici, craniales* and *caudales*); incision, if necessary, of the gastric and mesenteric lymph nodes;
- (g) visual inspection and, if necessary, palpation of the spleen;
- (h) visual inspection and palpation of the kidneys; incision, if necessary, of the kidneys and the renal lymph nodes (*Lnn. renales*);
- (i) visual inspection of the pleura and peritoneum;
- (j) visual inspection of the genital organs of stallions and mares;
- (k) visual inspection of the udder and its lymph nodes (*Lnn. supramammarii*) and, if necessary, incision of the supramammary lymph nodes;
- (l) visual inspection and palpation of the umbilical region and joints of young animals; in the event of doubt, the umbilical region must be incised and the joints opened; the synovial fluid must be examined;
- (m) all grey or white horses must be inspected for melanosis and melanomata by examination of the muscles and lymph nodes (*Lnn. subrhomboidei*) of the shoulders beneath the scapular cartilage after loosening the attachment of one shoulder; the kidneys must be exposed and examined by incision through the entire kidney.

#### IV. DOMESTIC PIGS

##### A. Ante-mortem inspections

1. Slaughter of a lot of pigs from a holding may be authorised only when:
  - (a) either the pigs intended for slaughter have been submitted to an ante-mortem inspection at the holding of provenance and are accompanied by the health certificate provided for under Section X of Chapter 3; or

- (b) the food chain information, covering the matters referred to under Section 1.2. A of Chapter 1, has been sent to the food business operator of the slaughterhouse 24 to 72 hours before the arrival of the pigs at the slaughterhouse.

When the food business operator decides to accept the lot for slaughter, he shall without delay give a copy of the information to the official veterinarian, but in any case at least 24 hours before arrival of the lot.

- 2. The ante-mortem inspection at the holding of provenance shall comprise:
  - (a) checking the records or documentation of the holding, including the food chain information as referred to in Section 1.2.A of Chapter 1;
  - (b) examination to determine whether the pigs:
    - (i) have a disease or condition which may be transmitted to animals or humans through handling or eating the meat, or are behaving, individually or collectively, in a manner indicating that such a disease may occur;
    - (ii) show disturbance of general behaviour or signs of disease which may make the meat unfit for human consumption;
    - (iii) show evidence that they may contain chemical residues in excess of the levels laid down in Community legislation, or residues of substances prohibited under Community legislation.

In addition, the following shall be carried out:

- (a) regular sampling of water and feed to check compliance with withdrawal periods; and where appropriate, sampling of the animals;
  - (b) where appropriate, tests for zoonotic agents.
- 3. Ante-mortem inspections at the holding shall be carried out by the official veterinarian, or by an approved veterinarian taking part in a surveillance network system, as provided for by Article 14 of Directive 64/432/EEC; the pigs shall be sent directly to slaughter and not be mixed with other pigs.

4. Where an ante-mortem inspection has been carried out at the holding, the ante-mortem inspection at the slaughterhouse may be limited to a control on the identification and a screening to ascertain whether animal welfare rules have been complied with and signs of any condition which might adversely affect human or animal health are present.
5. Where an ante-mortem inspection has not been carried out at the holding, the official veterinarian shall carry out ante-mortem inspection as provided for under Section 1.2.B of Chapter 1.
6. Where the pigs are not slaughtered within three days of the issue of the health certificate provided for in point 1(a), the following rules shall apply:
  - (a) where the pigs have not left the holding of provenance, **the procedure set out in point 1 (a) shall be repeated** ~~the pigs shall be re-examined and a new health certificate shall be issued;~~
  - (b) where the pigs are already at the slaughterhouse, slaughter may be authorised once the reason for the delay has been assessed, provided the pigs are subjected to a further veterinary ante-mortem inspection.

**B. Post-mortem inspection**

1. Carcasses and offal of pigs, other than fattening pigs raised:
  - (a) under controlled housing conditions, in integrated production systems;
  - (b) with a flow of information between holding of provenance and slaughterhouse considered satisfactory by the competent authority;
 shall undergo the post-mortem inspection procedures set out in point 2.
  - (a) visual inspection of the head and throat; incision and examination of the submaxillary lymph nodes (*Lnn mandibulares*); visual inspection of the mouth, fauces and tongue;
  - (b) visual inspection of the lungs, trachea and oesophagus; palpation of the lungs and the bronchial and mediastinal lymph nodes (*Lnn. bifurcationes, eparteriales and mediastinales*); the trachea and the main branches of the bronchi must be opened lengthways and the lungs must be incised in their posterior third, perpendicular to their main axes; those incisions are not necessary where the lungs are excluded from human consumption;

- (c) visual inspection of the pericardium and heart, the heart being incised lengthways so as to open the ventricles and cut through the interventricular septum;
  - (d) visual inspection of the diaphragm;
  - (e) visual inspection of the liver and the hepatic and pancreatic lymph nodes, (*Lnn portales*); palpation of the liver and its lymph nodes;
  - (f) visual inspection of the gastro-intestinal tract, the mesentery, the gastric and mesenteric lymph nodes (*Lnn. gastrici, mesenterici, craniales* and *caudales*); palpation and, if necessary, incision of the gastric and mesenteric lymph nodes;
  - (g) visual inspection and, if necessary, palpation of the spleen;
  - (h) visual inspection of the kidneys; incision, if necessary, of the kidneys and the renal lymph nodes (*Lnn. renales*);
  - (i) visual inspection of the pleura and peritoneum;
  - (j) visual inspection of the genital organs;
  - (k) visual inspection of the udder and its lymph nodes (*Lnn. supramammarii*); incision of the supramammary lymph nodes in sows;
  - (l) visual inspection and palpation of the umbilical region and joints of young animals; in the event of doubt, the umbilical region must be incised and the joints opened.
3. Fattening pigs raised under controlled housing conditions, in integrated production systems, with a flow of information between holding and slaughterhouses considered satisfactory by the competent authority, shall undergo visual inspection only. The competent authority may however, on the basis of epidemiological or other data, decide that some or all of the procedures referred to in point 2 shall be applied to the fattening pigs.

## V. POULTRY

### A. Ante-mortem inspections

- 1. Slaughter of a flock of poultry from a holding may be authorised only when:
  - (a) either the birds intended for slaughter have been submitted to an ante-mortem inspection at the holding of provenance and are accompanied by the health certificate as provided for under Section X of this Chapter; or

- (b) the food chain information, covering the matters provided for under Section 1.2.A of Chapter 1, , has been sent to the food business operator of the slaughterhouse 24 to 72 hours before the arrival of the birds at the slaughterhouse.

Where the operator decides to accept the birds for slaughter, he shall without delay give a copy of the information to the official veterinarian, but in any case at least 24 hours before the arrival of the birds.

2. The ante-mortem inspection on the holding of provenance shall comprise:
  - (a) checking the records or documentation of the holding, including the food chain information as provided for under Section 1.2.A of Chapter 1;
  - (b) examination to determine whether the birds:
    - (i) have a disease or condition which may be transmitted to animals or humans through handling or eating the meat, or are behaving, individually or collectively, in a manner indicating that such a disease may occur;
    - (ii) show disturbance of general behaviour or signs of disease which may make the meat unfit for human consumption;
    - (iii) show evidence that they may contain chemical residues in excess of the levels laid down in Community legislation, or residues of substances prohibited under Community legislation.
3. The following shall be carried out at the holding of provenance:
  - (a) regular sampling of water and feed to check compliance with withdrawal periods; where appropriate, sampling of the animals;
  - (b) where appropriate, tests for zoonotic agents.
4. Ante-mortem inspection at the holding shall be carried out by the official veterinarian.
5. Where ante-mortem inspection has been carried out at the holding, ante-mortem inspection at the slaughterhouse may be limited to a control on the identification and a screening to ascertain whether animal welfare rules have been complied with and signs of any condition which might adversely affect human or animal health are present; the screening may be carried out by an official auxiliary.

6. Where ante-mortem inspection has not been carried out at the holding, the official veterinarian shall carry out an examination to determine whether the birds:
- (a) have a disease or condition transmissible to humans or animals or are behaving, individually or collectively, in a manner indicating that such a disease may occur;
  - (b) show disturbance of general behaviour or signs of disease which may make the meat unfit for human consumption;
  - (c) show evidence that they may contain chemical residues in excess of the levels laid down in Community legislation, or residues of substances prohibited under Community legislation

Where appropriate, the official veterinarian shall carry out tests for zoonotic agents.

7. Where the birds are not slaughtered within three days of the issue of the health certificate, as set out in Section X of this Chapter, the following rules shall apply:
- (a) where the birds have not left the holding of provenance, **the procedure set out in point 1 (a) shall be repeated** ~~the birds shall be re-examined and a new health certificate shall be issued;~~
  - (b) where the birds are already at the slaughterhouse, slaughter may be authorised once the reason for the delay has been assessed, provided the birds are re-examined.
8. If the birds show clinical symptoms of a disease, their slaughter for human consumption shall be prohibited. However, the killing of those birds on the slaughterline shall be authorised at the end of the normal slaughter process provided precautions are taken to avoid the risk of spreading pathogenic organisms and to clean and disinfect the facilities immediately after slaughter.
9. In the case of poultry reared for the production of *foie gras* and in the case of delayed eviscerated poultry obtained at the holding of production, ante-mortem inspection shall be carried out in accordance with points 2 and 3.

B. Post-mortem inspection

All birds shall undergo post-mortem inspection. As part of the post-mortem inspection, the official veterinarian shall:

- (a) inspect the viscera and body cavities of a representative number of birds from each batch of birds from the same origin;
- (b) subject to a detailed inspection a random sample of parts of birds or entire birds which were declared unfit for human consumption following a post-mortem inspection;
- (c) carry out any further investigations deemed necessary where there is reason to suspect that the meat from the birds concerned could be unfit for human consumption;
- (d) in the case of poultry reared for the production of *foie gras* and delayed eviscerated poultry obtained at the holding of production, control the health certificate as set out in point C that shall accompany the carcasses.

C. Specimen health certificate

**HEALTH CERTIFICATE**

for poultry intended for the production of *foie gras* and delayed eviscerated poultry obtained at the holding of provenance, stunned, bled and plucked at the holding and transported to a cutting plant equipped with a separate room for evisceration

Competent service:..... No: .....

**1. Identification of uneviscerated carcasses**

Species:.....

Number:.....

**2. Provenance of uneviscerated carcasses**

Address of holding:.....

**3. Destination of uneviscerated carcasses**

The uneviscerated carcasses will be transported to the following cutting plant: .....

.....

#### 4. Declaration

I, the undersigned official veterinarian, declare that:

- the uneviscerated carcasses described above are of birds which were examined before slaughter on the above-mentioned holding at ..... (time) on ..... (date) and found to be healthy;
- the records and documentation concerning these animals were in accordance with the legal requirements and do not prohibit slaughter of the birds.

Done at ....., on .....  
(Place) (Date)

Stamp

.....  
(Signature of the official veterinarian)

#### VI. FARMED LAGOMORPHS

The requirements applicable to poultry shall apply.

#### VII. FARMED GAME

##### A. Ante-mortem inspection

1. Ante-mortem inspection may be carried out at the holding of provenance; it shall be carried out by the official veterinarian **or by the approved veterinarian.** Ante-mortem inspection at the holding shall include checking the records or documentation of the holding, including the food chain information as provided for in Section 1.2.A of Chapter 1, regular sampling of water and feed and, where appropriate, tests for zoonotic agents. When an ante-mortem inspection has taken place at the holding, the ante-mortem inspection at the slaughterhouse may be restricted to detecting injuries sustained during transport and a check of the identification of the animals.
2. Live animals inspected at the holding must be accompanied by a health certificate drawn up in accordance with the specimen set out in Section X of Chapter 3 stating that the animals were inspected at the holding and found to be healthy.

B. Post-mortem inspection

1. The post-mortem inspection shall include palpation and, where judged necessary, incision of those parts of the animal which have undergone any change or are suspect for any other reason.
2. Post-mortem inspection procedures provided for in Section 1.B for bovine and ovine animals, in Section IV.B for domestic pigs and in Section V.B for poultry shall be applied to the corresponding species of farmed game.
3. When the animals have been slaughtered at the holding, the official veterinarian shall check the certificate issued and signed by the official veterinarian **or the approved veterinarian** attesting to a favourable result of ante-mortem inspection, correct slaughter and bleeding and the time of slaughter.

VIII. **WILD GAME**

A. Post-mortem inspection

1. Wild game shall be inspected as soon as possible after admission to the game handling establishment.
2. The official veterinarian shall check whether the wild game is accompanied by a declaration of the trained person, as defined in Annex III, Chapter II, point 4(a) of Regulation (EC) No .../... [laying down specific hygiene rules for food of animal origin]. Where the wild game is accompanied by that declaration, he shall take this declaration into account in carrying out the post-mortem inspection.
3. During the post-mortem inspection, the official veterinarian shall carry out:
  - (a) a visual examination of the carcase, its cavities and where appropriate organs with a view to:
    - (i) detecting any abnormalities **not caused by the hunting process;** for this purpose, the diagnosis may be based on any information provided by the hunter concerning the behaviour of the animal before killing;
    - (ii) checking that death was not caused by reasons other than hunting;

however, if an assessment cannot be made of the matters referred to in (i) and (ii) on the basis of visual examination alone, a more extensive inspection must be carried out in a laboratory;

- (b) an investigation of organoleptic abnormalities;
  - (c) palpation of organs, where appropriate;
  - (d) an analysis of residues including environmental contaminants by sampling, where there are serious grounds for suspecting the presence of residues or contaminants; where a more extensive inspection is made on the basis of such suspicions, the official veterinarian must wait until that inspection has been concluded before assessing all the game killed during a specific hunt, or those parts which are suspected of showing the same abnormalities;
  - (e) examination for characteristics indicating that the meat presents a health risk, including:
    - (i) abnormal behaviour or disturbance of the general condition of the live animal, as reported by the hunter;
    - (ii) the generalised presence of tumours or abscesses affecting different internal organs or muscles;
    - (iii) arthritis, orchitis, pathological changes in the liver or the spleen, inflammation of the intestines or the umbilical region;
    - (iv) the presence of foreign bodies, **not resulting from the hunting process**, in the body cavities, stomach or intestines or in the urine, where the pleura or peritoneum are discoloured;
    - (v) the presence of parasites;
    - (vi) formation of a significant amount of gas in the gastro-intestinal tract with discolouring of the internal organs;
    - (vii) significant abnormalities of colour, consistency or odour of muscle tissue or organs;
    - (viii) aged open fractures;
    - (ix) emaciation and/or general or localised oedema;
    - (x) recent pleural or peritoneal adhesions;
    - (xi) other obvious extensive changes, such as putrefaction.
4. Where the official veterinarian so requires, the vertebral column and the head shall be split lengthways.

5. In the case of small wild game not eviscerated immediately after killing, the official veterinarian shall carry out a post-mortem inspection on a representative sample of animals from the same source; where the post-mortem inspection reveals a disease transmissible to man or defects as referred to in point 3, the veterinarian shall carry out more checks on the entire batch to determine whether it must be declared unfit for human consumption or whether each carcass must be inspected individually.
6. In the event of doubt, the official veterinarian may perform any further cuts and inspections of the relevant parts of the animals necessary to reach a final diagnosis.

B. Decisions following controls

In addition to the decisions concerning meat provided for in Section II.E of Chapter 1, meat presenting characteristics during post-mortem inspection as listed in point A of that Section, shall be declared unfit for human consumption.

## IX. SPECIFIC HAZARDS

A. Transmissible spongiform encephalopathies

1. ~~Inspection of bovine animals over six weeks old, sheep or goats shall be carried out taking into account Regulation (EC) No 999/2001, and all other relevant Community legislation concerning transmissible spongiform encephalopathies. This concerns at least the following aspects:~~
  - ~~(a) Where appropriate, the status of the dam shall be checked before slaughter of the animal.~~
  - ~~(b) When there is any indication that the age as mentioned in the accompanying information is not correct, a dentition check shall be carried out by the official veterinarian.~~
  - ~~(c) Special care shall be taken that all bovine animals, sheep or goats suspected of suffering from a transmissible spongiform encephalopathy, as defined in Regulation (EC) No 999/2001, are treated in accordance with the specifications of that Regulation. These suspect animals shall be slaughtered separately from the other animals, taking all necessary precautions to limit to a minimum the risk of contamination of other carcasses, the slaughter line and the staff present in the slaughterhouse.~~

- ~~2. Specific tests for the diagnosis of transmissible spongiform encephalopathies shall be carried out according to the specific Community legislation on this issue.~~

**Official controls carried out in relation to TSEs are to take into account the requirement of Regulation (EC) No 999/2001 and other relevant Community legislation.**

B. Cysticercosis

1. The post-mortem inspection procedures set out under Sections I and IV of Chapter 3, shall be the minimum requirements for the examination for cysticercosis in bovine animals over 6 weeks old and swine. In addition, specific serological tests may be used. In the case of bovines over 6 weeks old, incision of the masseters at post-mortem inspection shall not be compulsory when a specific serological test is used or when bovine animals over 6 weeks old have been raised on a holding officially certified to be free of cysticercosis.
2. Meat infected with cysticercus shall be declared unfit for human consumption. However, when the animal is not generally infected with cysticercus, the parts not infected may be declared fit for human consumption after having undergone a cold treatment.

C. Trichinosis

1. Carcasses of swine (domestic, farmed game and wild game), solipeds and other species susceptible to trichinosis shall be examined for trichinosis unless the animals were raised on a holding officially certified to be free of trichinosis, or a cold treatment has been applied.
2. Meat from animals infected with trichinae shall be declared unfit for human consumption.

D. Glanders

1. Where appropriate, solipeds shall be examined for glanders. Examination for glanders in solipeds shall include a careful examination of mucous membranes from the trachea, larynx, nasal cavities and sinuses and their ramifications, after splitting the head in the median plane and excising the nasal septum.
2. Meat from horses in which glanders has been diagnosed shall be declared unfit for human consumption.

E. Tuberculosis

1. Animals which have reacted positively or inconclusively to tuberculin shall be slaughtered separately from the other animals, taking precautions as to avoid the risk of contamination of other carcasses, the slaughter line and the staff present in the slaughterhouse.
2. Meat from animals which have produced a positive or inconclusive reaction to tuberculin and in which the post-mortem inspection has revealed localised tuberculous lesions located in a number of organs or areas of the carcass shall be declared unfit for human consumption. Pending an opinion of the European Food Safety Authority, meat from animals which have produced a positive or inconclusive reaction to tuberculin and in which post-mortem inspection has revealed localised tuberculous lesions in the lymph node(s) of one organ or part of the carcass, shall be declared unfit for human consumption or undergo a heat treatment.

F. Brucellosis

1. Animals which have reacted positively or inconclusively to a brucellosis test shall be slaughtered separately from the other animals, taking precautions as to avoid the risk of contamination of other carcasses, the slaughter line and the staff present in the slaughterhouse.
2. Meat from animals which have reacted positively or inconclusively to a brucellosis test, confirmed by lesions indicating infection, shall be declared unfit for human consumption. Even where no such lesion has been found, the udder, genital tract and blood must nevertheless be declared unfit for human consumption.

G. Detailed requirements

The following shall be established in accordance with the procedure referred to in **Article 19(2)**, and after the European Food Safety Authority has given its opinion:

- (a) the cold treatment to be applied to meat in relation to cysticercosis and trichinosis, and the heat treatment to be applied to meat in relation to tuberculosis;
- (b) the conditions under which holdings may be certified as officially free of cysticercus or trichinae;
- (c) where appropriate, methods to be applied when examining for the conditions referred to in this heading, **including the serological tests to examine for cysticercosis and possible procedures for examining for trichinosis.**

## **X. SPECIMEN HEALTH CERTIFICATE**

### **HEALTH CERTIFICATE**

for animals transported from the holding to the slaughterhouse

Competent service: ..... No: .....

#### **1. Identification of the animals**

Species: .....

Number of animals: .....

Identification marking: .....

#### **2. Provenance of the animals**

Address of holding of provenance: .....

Identification of house\* : .....

#### **3. Destination of the animals**

The animals will be transported to the following slaughterhouse: .....

.....

by the following means of transport: .....

#### **4. Other relevant information**

.....

#### **5. Declaration**

I, the undersigned, declare that:

- the animals described above were examined before slaughter at the above-mentioned holding at ..... (time) on ..... (date) and were found to be healthy,
- the records and documentation concerning these animals were in accordance with the legal requirements and do not prohibit slaughter of the animals.

Done at ....., on.....  
(Place) (Date)

Stamp

.....  
(Signature of veterinarian)

\* optional

## ANNEX II

### LIVE BIVALVE MOLLUSCS

#### **I. OFFICIAL CONTROLS OF PRODUCTION AREAS**

1. The competent authority must fix the location and the boundaries of production areas for bivalve molluscs. The production areas from which harvesting of bivalve molluscs shall be authorised must be classified by the competent authority in three categories according to the level of the faecal contamination as follows:
  - (a) **Class A areas:** areas from which live bivalve molluscs may be collected for direct human consumption. Live bivalve molluscs taken from these areas must meet the health standards for live bivalve molluscs referred to in Section VII of Chapter V of Annex II to Regulation (EC) No .../... [laying down specific hygiene rules for food of animal origin].
  - (b) **Class B areas:** areas from which live bivalve molluscs may be collected, but only placed on the market for human consumption after treatment in a purification centre or after relaying so as to meet the health standards referred to under (a). Live bivalve molluscs from these areas must not exceed the limits of a five-tube, three dilution Most Probable Number (MPN)-test of 6000 *Faecal coliforms* per 100 g of flesh or 4600 *E.coli* per 100 g of flesh in 90% of samples.
  - (c) **Class C areas:** areas from which live bivalve molluscs may be collected but placed on the market only after relaying over a long period (at least two months) whether or not combined with purification, or after intensive purification for a period to be fixed in accordance with the procedure referred to in **Article 19(2)**, so as to meet the health standards referred to under (a). Live bivalve molluscs from these areas must not exceed the limits of a five-tube, three dilution MPN test of 60 000 faecal coliforms per 100 g flesh.
2. In order to enable the classification of production zones and to determine the faecal contamination level of an area, the competent authority must:
  - (a) make an inventory of the sources of pollution from human or animal origin likely to be a source of contamination for the production area;
  - (b) examine the quantities of organic pollutants which are released during the different periods of the year, according to the seasonal variations of both human and animal populations in the catchment area, rainfall readings, waste water treatment;
  - (c) determine the characteristics of the circulation of pollutants by virtue of current patterns, bathymetry and the tidal cycle in the production area;

- (d) establish a sampling programme of bivalve molluscs in the production area which is based on the examination of established data, and with a number of samples, a geographical distribution of the sampling points and a sampling frequency which must ensure that the results of the analysis are as representative as possible for the area considered.
- 3. Classified relaying and production areas must be periodically monitored in order to:
  - (a) prevent any malpractice with regard to the origin, provenance and destination of live bivalve molluscs;
  - (b) check the microbiological quality of live bivalve molluscs in relation to the production and relaying areas;
  - (c) check for the presence of toxin-producing plankton in production and relaying waters and biotoxins in live bivalve molluscs;
  - (d) check for the presence of chemical contaminants in live bivalve molluscs.
- 4. For the implementation of point 3(b), (c) and (d), sampling plans must be drawn up for carrying out such checks at regular intervals or on a case-by-case basis where harvesting periods are irregular. The geographical distribution of the sampling points and the sampling frequency must ensure that the results of the analysis are as representative as possible for the area considered.
  - (a) The sampling plan for checking the microbiological quality of live bivalve molluscs must take particular account of:
    - (i) the likely variation in faecal contamination;
    - (ii) the parameters referred to in point 2.
  - (b) The sampling plan for checking the presence of toxin-producing plankton in production and relaying waters and for biotoxins in live bivalve molluscs must take particular account of possible variations in the presence of plankton containing marine biotoxins.

Sampling must be carried out as follows:

- (i) monitoring plankton: periodic sampling to detect changes in the composition of the plankton containing toxins and the geographical distribution thereof; results suggesting an accumulation of toxins in mollusc flesh must be followed by intensive sampling, by increasing the number of sampling points and number of samples taken in growing and fishing waters; and
- (ii) periodic toxicity tests using those molluscs from the affected area most susceptible to contamination; **harmonised testing methods for marine biotoxins shall be laid down following the procedure referred to in Article 19(2).**

- (c) The sampling frequency for toxin analysis in the molluscs shall be **as a general rule** ~~at least~~ weekly during the periods at which harvesting is allowed. This frequency may be **reduced** in specific areas, or for specific types of molluscs, if a risk assessment on toxins or phytoplankton occurrence suggest very low risk of toxic episodes. It is to be **increased** where such an assessment suggests that weekly sampling would not be sufficient. The risk assessment shall be periodically reviewed in order to assess the risk of toxins occurring in the live bivalve molluscs from these areas.
  - (d) When knowledge of toxin accumulation rates is available for a group of species growing in the same area, a species with the highest rate may be used as an indicator species in order to allow the exploitation of all species in the group if toxin levels in the indicator species are below the regulatory limits. When toxin levels in the indicator species are above the regulatory limits, harvesting of the other species shall only be allowed if further analysis on the other species shows toxin levels below the limits.
  - (e) With regard to the monitoring of plankton, the samples should be representative of the water column and shall provide information on the presence of toxic species as well as on population trends. If any changes in toxic populations that may lead to toxin accumulation are detected, the sampling frequency of molluscs shall be increased or precautionary closures of the areas shall be established until results of toxin analysis are obtained.
  - (f) The sampling plan to check for the presence of chemical contaminants must the detection of any overshooting of the levels laid down in Regulation (EC) No 466/2001<sup>1</sup> are exceeded.
5. Where the results of sampling show that the health standards for molluscs are exceeded, or that there may be otherwise a risk to human health, the production area concerned must be closed for the harvesting of live bivalve molluscs.
- Closed areas may only be re-opened when the health standards for molluscs comply again with Community legislation. When for reasons of the presence of plankton or excessive levels of toxins in molluscs an area has been closed, at least two consecutive results below the regulatory limit separated at least 48 hours are necessary to re-open it. Information on phytoplankton trends may be included in this decision. In those cases when there are robust data on the dynamic of the toxicity for a given area, and provided that recent data on decreasing trends of toxicity are available, the competent authority may decide to re-open the area with results below the regulatory limit obtained from one single sampling.
6. The competent authority shall monitor production areas where the harvesting of bivalve molluscs is forbidden or subject to special conditions, to ensure that products harmful to human health are not placed on the market.

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<sup>1</sup> OJ L 77, 16.3.2001, p. 1.

7. In addition to the monitoring of relaying and production zones referred to in point 3, a control system must be set up comprising laboratory tests to verify compliance with the requirements for the end product, in particular to verify that the levels of marine biotoxins and contaminants do not exceed safety limits and that the microbiological quality of the molluscs does not constitute a hazard to human health.
8. The competent authority must:
  - (a) establish and keep up-to-date a list of approved production and relaying areas, with details of their location and boundaries, as well as the class in which the area is classified, from which live bivalve molluscs may be taken in accordance with the requirements of this Annex.

That list must be communicated to interested parties affected by this Annex, including producers, gatherers and operators of purification centres and dispatch centres.
  - (b) immediately inform the interested parties affected by the requirements of Annex, and in particular the producers, gatherers and operators of purification centres and dispatch centres, about any change of the location, boundaries or class of the production area, or its closure, be it temporary or final.
  - (c) act promptly where the controls prescribed in this Annex indicate that a production area must be closed or may be re-opened.
9. For deciding on the classification, opening or closure of harvesting areas, the competent authority may take into account the results of controls carried out by the food business operators or by the organisation representing the food business operators concerned. In that event, the analysis must have been carried out in a laboratory that has been approved by the competent authority and in accordance with a protocol that has eventually been agreed between the competent authority and the food businesses or organisation concerned.

## **II. OFFICAL CONTROLS OF PECTINIDAE HARVESTED OUTSIDE CLASSIFIED PRODUCTION AREAS**

Member States shall ensure that appropriate controls are organised on pectinidae that have been harvested outside classified production areas in order to ensure that they comply with the relevant health standards, including biotoxins.

### ANNEX III

#### FISHERY PRODUCTS

1. Official controls on fishery products shall be carried out at the time of landing or before first sale at an auction or wholesale market. **Fish and other products derived from aquaculture shall also be checked before they are placed on the market.**

2. Official controls shall include:

- (a) Organoleptic surveillance testing.

Random checks must be carried out to check compliance with the freshness criteria laid down in Community legislation. Where there is doubt as to the freshness of the products, the organoleptic examination must be repeated.

- (b) Total Volatile Basic Nitrogen (TVB-N) tests.

Where the organoleptic examination reveals any doubt as to the freshness of the fishery products, samples may be taken and subjected to laboratory tests to determine the levels of TVB-N (Total Volatile Basic Nitrogen).

The TVB-N levels and the methods of analysis to be used shall be those provided for in Articles 1 to 3 of Decision 95/149/EC.

Where the organoleptic examination gives cause to suspect the presence of other conditions which may affect human health, samples may be taken for verification purposes.

- (c) Histamine testing

Surveillance testing for histamine shall be carried out to verify compliance with the permitted levels laid down in Community legislation.

The level of histamine in certain fishery products must be within the following limits in nine samples taken from a batch:

- (i) the mean value must not exceed 100 ppm;
    - (ii) two samples may have a value exceeding 100 ppm but not more than 200 ppm;
    - (iii) no sample may have a value exceeding 200 ppm.

Those limits shall apply only to fish species of the following families: Scombridae, Clupeidae, Engraulidae, Coryfenidae, Pomatomidae and Scombraesidae. However, anchovy which has undergone enzyme maturation treatment in brine may have higher histamine levels but not more than twice the above values. Examinations must be carried out in accordance with reliable methods which are recognised scientifically, including high performance liquid chromatography (HPLC).

- (d) Surveillance testing for contaminants.

Monitoring arrangements shall be set up to control the levels in fishery products of contaminants including heavy metals and organo-chlorinated substances present in the aquatic environment.

- (e) Microbiological checks, where necessary.
- (f) Surveillance testing to verify compliance with Community legislation on endo-parasites.
- (g) Official Checks on the possible presence on the market of poisonous fish species or fish containing biotoxins.

Where necessary, the following shall be established in accordance with the procedure referred to in **Article 19(2)**, after an opinion has been given by the European Food Safety Authority:

- (i) freshness criteria for the organoleptic evaluation of fishery products, in particular where such criteria have not been established under existing Community legislation;
- (ii) the analytical limits, methods of analysis and sampling plans to be used for performing those official checks .

3. The following shall be declared unfit for human consumption:

- (a) fishery products when the organoleptic, chemical, physical or microbiological checks have shown that such products are not fit for human consumption;
- (b) fish or parts of fish which have not been properly examined to detect endo-parasites in accordance with Community legislation;
- (c) fishery products which contain in their edible parts contaminants present in the aquatic environment, such as heavy metals and organochlorinated substances, at levels where the calculated dietary intake would exceed the acceptable daily or weekly intake for humans;
- (d) poisonous fish and fishery products containing biotoxins;
- (e) fishery products or parts thereof considered dangerous to human health.

## **ANNEX IV**

### **MILK AND MILK PRODUCTS**

#### **CHAPTER I: CONTROL OF HOLDINGS**

1. Animals on production holdings must undergo regular veterinary inspections to ensure that the health requirements for raw milk production, and in particular the health status of the animals and the use of veterinary medicinal products, are being complied with. Those inspections may take place at the occasion of veterinary checks carried out pursuant to other Community provisions.
2. If there are grounds for suspecting that the animal health requirements are not being complied with, the general health status of the animals shall be checked.
3. The production holdings shall undergo regular checks to ensure that hygiene requirements are being complied with. If it is shown that the hygiene is inadequate, appropriate steps shall be taken to ensure that the operator corrects the situation.

#### **CHAPTER II: CONTROL OF RAW MILK UPON COLLECTION**

1. The competent authority shall organise, where appropriate in co-operation with food business operators producing or collecting milk or with the sector representing these operators, control schemes in order to ensure compliance with the standards that apply to raw milk.
2. When the raw milk fails to meet such standards, the competent authority shall take appropriate steps to ensure that the food business operator corrects the situation.

If the situation is not corrected within three months after notification of non-compliance with those standards, the milk of the production holding shall be suspended from delivery until the food business operator has proved that the milk complies again with the standards.

3. When the raw milk fails to meet mandatory public health criteria so that food safety may be compromised, the competent authority shall define and implement procedures to suspend the delivering of the raw milk until conditions ensuring food safety are restored. At the same time, the competent authority shall instruct the farmer as to whether the milk must be destroyed, or whether it may be used under certain well defined conditions. As soon as those conditions are met, the competent authority shall apply a procedure of re-authorisation of delivering milk.

#### **CHAPTER III: CONTROL OF PROCESSED DAIRY PRODUCTS**

Official controls shall include:

1. A verification of the compliance of raw milk used for processing with the standards that apply to it.

2. A verification that food safety objectives are achieved, by appropriate checks performed on the means applied by the food business operators, including
  - (i) heat treatment or other physical treatment parameters, or
  - (ii) processing conditions in general, including those adapted to traditional methods of production
3. A verification of the compliance of final products with the standards that apply to them, in particular as regards microbiological criteria and labelling.

## ANNEX V

### ESTABLISHMENTS NOT SUBJECT TO LISTING

The following third country establishments need not appear on lists drawn up and updated in accordance with Article 9(4):

1. establishments handling products of animal origin for which Annex III to Regulation (EC) .../... [*laying down specific hygiene rules for products of animal origin*] does not lay down requirements;
2. establishments carrying out only primary production;
3. establishments carrying out only transport operations;
4. establishments carrying out only the storage of products of animal origin not requiring temperature-controlled storage conditions.

## ANNEX VI

### REQUIREMENTS FOR CERTIFICATES ACCOMPANYING IMPORTS

1. The representative of the competent authority of the third country of dispatch issuing a certificate to accompany a consignment of products of animal origin destined for the Community must sign the certificate and ensure that it bears an official stamp. This requirement applies to each sheet of the certificate if it consists of more than one. In the case of factory vessels, the competent authority may authorise the captain or another ship's officer to sign the certificate.
2. Certificates must be drawn up in the official language or languages of the third country of dispatch and the Member State in which the border inspection takes place, or be accompanied by a certified translation into that language or languages. However, a Member State may consent to the use of an official Community language other than its own.
3. The original version of the certificate must accompany consignments on entry into the Community.
4. Certificates must consist of:
  - (a) a single sheet of paper; or
  - (b) two or more pages that are part of an integrated and indivisible sheet of paper; or
  - (c) a sequence of pages numbered so as to indicate that it is a particular page in a finite sequence (for example, "page 2 of 4 pages").
5. Certificates must bear a unique identifying number. Where the certificate consists of a sequence of pages, each page must indicate this number.
6. The certificate must be issued before the consignment to which it relates leaves the control of the competent authority of the third country of dispatch.