

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

(2002/C 262 E/33)

COM(2002) 377 final — 2002/0141(COD)

(Submitted by the Commission on 11 July 2002)

EXPLANATORY MEMORANDUM

I. Introduction

1. On 14 July 2000 the Commission adopted a package of 5 proposals that constitute a recast of existing Community legislation on food hygiene and veterinary legislation that is currently contained in 17 Directives (document COM(2000) 438). These proposals are:

- A proposal for a Regulation of the European Parliament and of the Council on the hygiene of foodstuffs (2000/0178(COD)).
- A proposal for a Regulation of the European Parliament and of the Council laying down specific hygiene rules for food of animal origin (2000/179(COD)).
- A proposal for a Regulation of the European Parliament and of the Council laying down detailed rules for the organisation of official controls on products of animal origin intended for human consumption (2000/180(COD)).
- A proposal for a Council Regulation laying down the animal health rules governing the production, placing on the market and importation of products of animal origin intended for human consumption (2000/181(CNS)).
- A proposal for a Directive of the European Parliament and of the Council repealing certain Directives on the hygiene of foodstuffs and the health conditions for the production and placing on the market of certain products of animal origin intended for human consumption, and amending Directives 89/662/EEC and 91/67/EEC (2000/182(COD)).

These proposals are at present under discussion in the European Parliament and in the Council in accordance with the procedures laid down for that purpose.

2. Since the time these proposals were made new developments have taken place and notably:

- New scientific advice has become available, in particular on issues that relate to meat safety. This information allows for meat inspection to be organised on a basis that takes account of hazards that threaten human health today, thus making it more science-based and risk-based. It also allows the full integration of the stable-to-table approach, an element that is believed to be of great importance with regard to meat safety.
- The Commission is preparing, as announced in the White Paper on Food Safety (document COM(1999) 719), a proposal for a Regulation laying down in a horizontal way the principles that are the basis for official feed and food controls. These principles will also be applicable to the organisation of meat inspection.

These developments require that the Commission's proposal for a Regulation of the European Parliament and of the Council laying down detailed rules for the organisation of official controls on products of animal origin intended for human consumption (2000/180(COD)) be revised in a fundamental way.

3. The Commission therefore decided, on 11 December 2001, to withdraw the proposal contained in Document 2000/180(COD), and to submit a revised proposal.

4. This proposal contains a revised version of document 2000/180(COD) and replaces completely this document. The revision concerns mainly official controls of fresh meat. At the same time, the risk management measures for live bivalve molluscs, as well as for milk and milk products, have been strengthened. This proposal is fully consistent with the proposal for a Directive of the European Parliament and of the Council repealing certain Directives on the hygiene of foodstuffs and the health conditions for the production and placing on the market of certain products of animal origin intended for human consumption, and amending Directives 89/662/EEC and 91/67/EEC (2000/182(COD)).

II. Official controls on meat

5. The proposed system for official controls on fresh meat production is characterised by the following:
 - it is science-based;
 - it addresses all known hazards that are relevant for the safety of the meat;
 - the official veterinarian plays a central role in the system;
 - it consists of official audits of the systems put in place by the operator, and also of official inspection activities;
 - it clearly integrates the stable-to-table approach;
 - it deals with the relevant animal health and animal welfare issues;
 - the frequency and intensity of official controls is risk-based;
 - it contains, for certain sectors and on certain conditions, the possibility of involvement of staff of the establishment;
 - it contains training requirements for all staff carrying out official controls.

These characteristics are further elaborated below.

6. Science-based

The proposal has been developed on the basis of the latest opinions of the Scientific Committee on Veterinary Measures relating to Public Health (http://europa.eu.int/comm/food/fs/sc/scv/index_en.html). The requirements concerning inspection procedures can be adapted in a flexible way in order to take into account scientific opinions as soon as they are released. This may concern, among other things, new scientific data on emerging hazards, the use of technology and specific inspection procedures.

7. Relevant hazards

The proposed system contains procedures for controls on all relevant microbiological, chemical and physical food safety hazards. The proposal contains standards for a number of these hazards, and makes reference to standards stated in other Community legislation, especially concerning microbiological and chemical hazards. Only healthy meat, that is in line with the standards in Community legislation, can be declared fit for human consumption.

8. The official veterinarian

The official veterinarian plays a central role in the system. He/she carries out audits and inspection activities and takes all relevant decisions. To function optimally in the proposed, risk-based meat inspection system, the official veterinarian needs specific training. The proposal contains clear requirements in this respect. The proposal also specifies the training requirements for the official auxiliaries, that can assist the official veterinarian.

9. Audits of the systems put in place by the operator

On the basis of the new European legislation in the field of hygiene, the operator has to ensure, through the application of good hygienic practices (GHP) and procedures based on the principles of Hazard Analysis and Critical Control Points (HACCP), that the meat produced is in line with the standards mentioned in Community legislation. The official veterinarian carries out audits to check whether the GHP and the HACCP-based procedures of the operator achieve the required standards. These audits are carried out on an ongoing basis.

10. Inspection activities

Besides carrying out audits of the systems put in place by the operator, the official veterinarian carries out inspection activities. These inspection activities cover the following issues:

- the relevant records from the holding of provenance of the animals;
- ante-mortem inspection;
- animal welfare;
- post-mortem inspection;
- specified risk materials;
- laboratory testing;
- health marking.

In carrying out his inspection activities, the official veterinarian takes into account the results of the audits mentioned above.

11. Stable-to-table approach

Animals are not accepted for slaughter if they are not accompanied by relevant food safety information from the farm. The official veterinarian carries out his inspection activities taking into account this information. The results of these inspections are communicated to the person responsible for raising the animals on the farm. Where appropriate, part of the ante-mortem inspection can take place on the farm.

12. Animal health and welfare

Ante-mortem inspection is carried out by the official veterinarian. He checks among other things whether any animal disease is present and whether the relevant animal welfare rules are being respected. Animals showing clinical signs of systemic disease or emaciation, shall not be slaughtered for human consumption. Only healthy animals, that are clean, identified in accordance with Community rules and accompanied by the relevant information from the farm shall be accepted for slaughter.

13. Frequency and intensity of official controls is risk-based

The frequency and intensity of official controls is based on an assessment of the health risks, represented by the type of animals and the type of process. At least one official veterinarian shall be present throughout ante- and post-mortem inspection. However, some flexibility exists for small enterprises and for the poultry sector.

14. Involvement of staff of the establishment

Member States may, under specific conditions, allow staff of the establishment to carry out certain inspection activities (normally carried out by official auxiliaries) in the control of poultry, rabbits, fattening pigs and fattening veal; the staff of the establishment must have received prior training equivalent to the training of official auxiliaries.

Only operators that have a good record in meeting the legal requirement, and are motivated to do so, can be allowed, under strict conditions, to have their staff carrying out activities of auxiliaries. By doing so, responsibilities are more clearly divided between operator and competent authority: the operator can better fill in the primary responsibility that he has for the safety of the meat and the official veterinarian can carry out his control activities in a more independent way.

III. Live bivalve molluscs

15. Live bivalve molluscs may present, as a consequence of their special physiological characteristics, certain risks for human health. As filter-feeders, they have the capacity to concentrate in their tissues micro-organisms (bacteria and viruses), toxins from algae that are present in the aquatic environment, and other contaminants. Special risk management measures including close monitoring of the environment are therefore required so as to ensure that live bivalve molluscs do not present a hazard to human health.
16. The present proposal aims to identify better the actions that must be undertaken by the competent authority in order to ensure the safety of the products. These actions include the establishment of a monitoring programme of harvesting areas in order to check:
- the microbiological quality of live bivalve molluscs,
 - the presence of toxin-producing plankton,
 - the presence of chemical contamination.

If these monitoring programmes show that Community levels have been exceeded, prompt action must be taken in order to prevent molluscs from reaching the consumer.

The proposal also imposes upon Member States the establishment of control systems for Pectinidae harvested outside classified production areas.

IV. Milk and milk products

17. It was felt that there was a need to specify more precisely the responsibilities of the competent authorities with regard to official controls for milk and dairy products. In the milk sector, there is in several Member States a close cooperation between the sector itself and the competent authority, especially with regard to checking health and quality criteria of raw milk upon collection.

Within that context, the present proposal aims at enshuring that where raw milk fails to meet the health standards, corrective action is taken at farm level, and that milk that might constitute a hazard to human health is not delivered for human consumption.

V. Feed and food controls: the coherence of Community legislation

18. The controls in the present proposal must be seen in the wider context of the Community legislation that is being developed as a consequence of the adoption of the White Paper on Food Safety and in particular:
- the recently adopted Regulation laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety, and
 - the establishment of a proposal for a Regulation of the European Parliament and of the Council on official feed and food controls (Action 4 of the Annex to the White Paper on Food Safety).

19. The basic principles related to responsibilities of the Member States authorities are already laid down in the Regulation laying down the general principles of food law, establishing the European Food Authority and laying down procedures in matters of food safety. This Regulation stipulates in particular that 'Member States shall enforce food law and monitor and verify that the relevant requirements of food law are fulfilled by food and feed business operators at all stages of production, processing and distribution. For that purpose they shall maintain a system of official controls and other activities as appropriate to the circumstances, including public communication on food and feed safety and risk, food and feed safety surveillance and other monitoring activities covering all stages of production, processing and distribution. Member States shall also lay down the rules on measures and penalties applicable to infringements of food and feed law. The measures and penalties provided for shall be effective, proportionate and dissuasive'.

20. In the White Paper on Food Safety it is stated that:

'There is a clear need for a Community framework of national control systems, which will improve the quality of controls at Community level, and consequently raise food safety standards across the European Union. The operation of such control systems would remain a national responsibility. This Community framework would have three core elements.

- The first element would be operational criteria set up at Community level, which national authorities would be expected to meet. These criteria would form the key reference points against which the competent authorities would be audited by the FVO, thereby allowing it to develop a consistent, complete approach to the audit of national systems.
- The second element would be the development of Community control guidelines. These would promote coherent strategies, and identify risk-based priorities and the most effective control procedures. A Community strategy would take a comprehensive, integrated approach to the operation of controls. These guidelines would also provide advice on the development of systems to record the performance and results of control actions, as well as setting Community indicators of performance.
- The third element of the framework would be enhanced administrative cooperation in the development and operation of control systems. There would be a reinforced Community dimension to the exchange of best practice between national authorities. This would also include promoting mutual assistance between the Member States by integrating and completing the existing legal framework.'

The preparation of a Commission proposal on such a Community framework of national control systems is well advanced and this proposal will formally be submitted by the Commission in 2002. It covers in a horizontal way for all feed and food those issues that are important for the organisation of official controls at a national and at Community level.

21. In addition to the principles and rules referred to in paragraphs 19 and 20 it must be considered that for a number of issues more specific rules must be laid down, so as to describe in a more precise manner what the duties of the competent authorities are with regard to these issues. Examples of specific control requirements already exist in Community legislation: residue controls, controls of zoonotic diseases, controls of certain transmissible spongiform encephalopathies, etc. Likewise, it must be envisaged that for products of animal origin such as meat, milk, fishery products and live bivalve molluscs more specific controls are necessary. These products present a number of hazards that fully justify the definition of such specific controls. These specific controls must be seen in the more general context described above.

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,

Having regard to the opinion of the Economic and Social
Committee,

Having regard to the opinion of the Committee of the Regions,

Acting in accordance with the procedure laid down in Article
251 of the Treaty,

Whereas:

- (1) Regulation (EC) No ... of the European Parliament and of the Council of ... on the hygiene of foodstuffs 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.
- (2) Regulation (EC) No ... of the European Parliament and of the Council of ... on official feed and food controls lays down the general rules for performing official controls of foodstuffs.
- (3) 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.
- (4) 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.
- (5) Community legislation on food safety should have a sound scientific basis. To that end, the European Food Safety Authority should be consulted whenever necessary.
- (6) 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.
- (7) 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 business operators. These official controls should consist of audits of the operators' activities, and of inspection activities.
- (8) 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.
- (9) 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 dairy products.
- (10) 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⁽¹⁾, they should be adopted by use of the regulatory procedure provided for in Article 5 of that Decision,

HAVE ADOPTED THIS REGULATION:

Article 1

This Regulation lays down the specific rules for the organisation of official controls of products of animal origin intended for human consumption. It shall apply in addition to Regulation (EC) No ... [on official feed and food controls].

Article 2

For the purposes of this Regulation, the definitions laid down in the following Regulations shall apply as appropriate:

- (a) Regulation (EC) No 178/2002⁽²⁾,
- (b) Regulation (EC) No ... [on official feed and food controls],
- (c) Regulation (EC) No ... [on the hygiene of foodstuffs],

⁽¹⁾ OJ L 184, 17.7.1999, p. 23.

⁽²⁾ OJ L 31, 1.2.2002, p. 1.

- (d) Regulation (EC) No ... [laying down specific hygiene rules for food of animal origin].

The following definitions shall also apply:

- (a) 'Official veterinarian' means a veterinarian qualified, in accordance with this Regulation, to act in such a capacity and appointed by the competent authority.
- (b) 'Official auxiliary' means an officer qualified, in accordance with this Regulation, to act in such a capacity, appointed by the competent authority and working under the authority and responsibility of an official veterinarian.
- (c) 'Health mark' means a mark applied by or under the responsibility of the official veterinarian indicating that all the requirements of the present Regulation have been met.

Article 3

1. Where national or Community legislation requires establishments to be approved, the competent authority shall make an on-site visit. They shall approve establishments only if it has been demonstrated that they meet the relevant requirements of food law.

In establishments starting up their activities, the competent authority shall grant a conditional approval if it appears from an on-site visit that all of the infrastructure and equipment requirements are adhered to. A final approval can only be granted if it appears from a new on-site visit carried out within three months after the conditional approval has been given 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 respective approval numbers.

Article 4

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.

Article 5

In accordance with the procedure referred to in Article 6 and where necessary after having obtained the opinion of the European Food Safety Authority:

- (a) Annexes I to IV shall be amended or supplemented in order to take account of scientific and technical progress;
- (b) implementing rules needed to ensure uniform implementation of this Regulation shall be adopted;
- (c) microbiological criteria for the control of hygiene in production facilities may be laid down.

Article 6

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 Article 5 of Decision 1999/468/EC shall apply, in compliance with Article 7 and Article 8 thereof.

3. The period provided for in Article 5(6) of Decision 1999/468/EC shall be three months.

Article 7

This Regulation shall enter into force on the date of its publication in the *Official Journal of the European Communities*.

It shall apply [one year after its entry into force] ⁽¹⁾.

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

⁽¹⁾ 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

The specific rules mentioned in this Annex apply 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. Auditing tasks of the official veterinarian

The official veterinarian shall carry out audits in meat establishments with a view to checking whether the 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 are carried out to verify the continuous compliance with the 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 and storage of animal by-products not intended for human consumption, including Specified Risk Materials.

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

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

guarantee 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 EU welfare requirements.

guarantee, 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, in general, been produced in accordance with the relevant Community legislation on transmissible spongiform encephalopathies;
- (i) is in conformity with the relevant Community requirements concerning traceability of meat.

C. *Audits of the use of guides*

Where the operator, to comply with legal requirements, uses national or Community guides to good practice, the correct use of these guides shall be audited.

D. *Performance of these audits*

Special care shall be taken in carrying out the different audits in regard to:

- (a) keeping oversight of the activities carried out by the staff of the establishment on an ongoing basis, and at all stages of the slaughtering and cutting process. Supporting the audit, the official veterinarian may carry out performance tests, 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 6;
- (b) verification of all the relevant records of the operator;
- (c) taking samples for laboratory analysis whenever deemed necessary;
- (d) documenting the elements taken into account and the findings of the audit.

1.2. **Inspection tasks of the official veterinarian**

The results of the audits carried out under 1.1 shall be taken into account by the official veterinarian in carrying out his inspection tasks and shall affect, where appropriate, the way these tasks are carried out.

The following issues shall be covered by the inspection tasks:

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 of the previous six months), date(s) of administration and the withdrawal period(s);
 - (d) the occurrence of diseases which may affect the safety of the meat;
 - (e) the results of any analysis carried out on samples taken from the animals or other samples taken 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.
 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 this information.
 4. In carrying out his inspection tasks, 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 foreseen by Article 14 of Directive 64/432/EEC ⁽¹⁾, as last amended by Decision 2001/298/EC ⁽²⁾.
 5. When the 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 these measures are documented and the animals covered by these schemes clearly identifiable, the official veterinarian may take this into account in carrying out his inspection tasks and in reviewing the HACCP-based procedures.
- B. *Ante-mortem inspection* ⁽³⁾
 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.
 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 (World organisation for animal health, OIE) and other notifiable diseases.
 3. The official veterinarian shall, at the slaughterhouse, also carry out clinical inspection of all animals that the 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 can 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 rules on the welfare of animals, such as the rules concerning the protection of animals at the time of slaughter and the rules concerning the protection of animals during transport.

⁽¹⁾ OJ 121, 29.7.1964, p. 1977/64.

⁽²⁾ OJ L 102, 12.4.2001, p. 63.

⁽³⁾ The following rules do not apply to hunted wild game.

D. *Post-mortem inspection*

1. The carcase and 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 carcase 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 lengthwise into half carcasses down the spinal column. If the inspection so necessitates, the official veterinarian may require any head or any carcase to be split lengthwise. 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 6, replace specific post-mortem inspection procedures described in Chapter 3 when these give at least equivalent guarantees.

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 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) specific laboratory testing for the diagnosis of transmissible spongiform encephalopathies referred to in Regulation (EC) No 999/2001 ⁽¹⁾;
 - (c) the detection of unauthorised substances or products, the control on regulated substances and in particular in the framework of the National Residue Plans referred to in Directive 96/23/EC ⁽²⁾;
 - (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.

⁽¹⁾ OJ L 147, 31.5.2001, p. 1.

⁽²⁾ OJ L 125, 23.5.1996, p. 10.

2. Where necessary, detailed rules for laboratory testing shall be laid down in accordance with the procedure referred to in Article 6. This includes 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 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.
2. For this purpose, the official veterinarian shall supervise:
 - (a) the health marking;
 - (b) the marks and wrapping material when marked as provided for in this section.
3. The health mark can only be applied when the animal (from which the meat has been obtained) has been inspected ante-mortem by the official veterinarian ⁽¹⁾ and when all the other requirements of this Regulation have been met.
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 (i.e. one of the following): AT — B — DK — D — EL — E — FI — F — IRL — I — L — NL — P — SE — UK, followed by the veterinary approval number of the establishment,
 - (ii) on the lower part, one of the following sets of initials: CEE, EEC, EEG, EOK, EØF, ETY, or EWG;
 - (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: CEE, EEC, EEG, EOK, EØF, ETY, or EWG;

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. Carcasses 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 carcasses must bear at least two stamps, one on each side of the carcass, on the shoulder or on the external surface of the thighs,
 - (c) other carcasses 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 carcasses, 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.

⁽¹⁾ This requirement does not apply to hunted wild game.

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 referred to above 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 6.
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 inspection activities. If this reveals the presence of any disease or condition which might affect public or animal health, or compromised animal welfare, this information shall be communicated to the operator of the meat establishment. When the problem arises during primary production, this information shall also be communicated to the competent authority responsible for supervising the holding of provenance of the animals or the hunting area, the private veterinarian attending the holding of provenance and the person responsible for the holding of provenance⁽¹⁾. Following such communication, action must be taken by the person responsible 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 operator of the meat establishment and to the central competent authority of the Member State where the meat establishment is located. The latter shall inform the Commission in case 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 mentioned on 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. This includes 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 6.

⁽¹⁾ Where there is the necessity to find evidence for not respecting 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.

II. DECISIONS FOLLOWING CONTROLS

Where, following controls, deficiencies, non-compliance or irregularities are found, appropriate measures shall be taken. These include:

A. Decisions following audit of the good hygienic practices and the HACCP-based procedures

1. When audit of the good hygienic practices or the HACCP-based procedures reveals non-compliance, the official veterinarian shall ensure that the 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, according to heading II.E of this sub-chapter, is to be considered unfit for human consumption, and the 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 operator is not able to prevent recurrence, the competent authority shall start the procedure of 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 these 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 can 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 also applies 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;

these 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 these animals are already present at the slaughterhouse, they shall be killed separately and declared unfit for human consumption, taking precautions 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 act upon the person responsible for the holding of provenance of the animals, or any other person involved, among others by carrying out extra controls. The costs of these extra controls shall be born by the 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. These 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, this information shall be supplied before the carcass can be approved for human consumption. This also applies in 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. These 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. Animals which might have residues of veterinary medicinal products in excess of the levels laid down in Community legislation, or residues of forbidden substances, shall be dealt with in accordance with Directive 96/23/EC.
7. The slaughter of animals under a specific scheme for the eradication or control of a specific disease such as brucellosis or tuberculosis or other zoonotic agents such as salmonellosis shall be carried out under the conditions imposed by, and the direct supervision of, the official veterinarian; 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 these premises alive except in the case of a serious breakdown of the slaughter facilities. In these circumstances, only movements direct 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 operator immediately takes the necessary corrective measures and prevents recurrence. Depending on the nature of the deficiency, 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;
- (c) meat from animals which are dead before slaughter, stillborn, unborn or slaughtered under the age of seven days;
- (d) meat resulting from the trimming of the sticking points;
- (e) meat from animals affected by a notifiable animal disease, unless stated differently under 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 stated differently in Chapter 3;
- (i) without prejudice to more specific Community legislation, meat containing residues of veterinary medicinal products, contaminants or other chemical residues in excess of the permitted Community level in that edible tissue; an excess of this Community level should lead to additional analyses whenever appropriate;
- (j) without prejudice to more specific Community legislation, all meat from animals or carcasses containing residues of forbidden substances and all meat from animals that have been treated with forbidden 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 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 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 preceding points, and blood contaminated by stomach contents or any other substance;
- (t) all meat that, in the opinion of the veterinarian, after examination of all the relevant information, may constitute a public or animal health danger or is for other reasons not suitable for human consumption.

Chapter 2

Responsibilities and frequency of controls

I. THE INSPECTION TEAM

In carrying out the controls referred to in Chapter 1, the official veterinarian may be assisted by official auxiliaries placed under his authority and responsibility. The official auxiliaries shall form part of an independent inspection team under the authority and responsibility of the official veterinarian. The official auxiliaries may carry out the following activities:

- (a) collecting information regarding the good hygienic practices and the HACCP-based procedures;
- (b) helping with ante-mortem inspection in the slaughterhouse. In this case the official auxiliary's role is 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 inspection, provided that the 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, etc. . . .

II. THE FREQUENCY OF 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 operator concerned. In the calculation of staffing on the slaughter line, a scientific approach shall be followed where appropriate. The number of official staff involved shall be such that all the requirements of this Regulation can be applied.

2. Care shall be taken to ensure that:

- (a) in slaughterhouses and game handling establishments, at least one official veterinarian is present throughout both the ante-mortem and the post-mortem inspection.

Some flexibility may be applied for small slaughterhouses and small game handling establishments:

- (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.

In the case of poultry, this flexibility can, on the basis of a case-by-case analysis of the risks by the competent authority, be applied in other slaughterhouses than small ones.

The flexibility mentioned above 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 concerns animals susceptible to the particular disease in question and coming from the particular region as defined in Article 2 of Directive 64/432/EEC, as last amended by Decision 2001/298/EC;
- (v) when considered necessary, to take into account emerging diseases or particular List B diseases. Where appropriate, rules shall be adopted in accordance with the procedure mentioned in Article 6.

When necessary to assure the uniform implementation of this rule, a definition of small establishment shall be approved in accordance with the procedure defined in Article 6.

- (b) in cutting plants, a member of the inspection team is regularly present, but at least once a week, when meat is being worked on.

III. INVOLVEMENT OF STAFF OF THE ESTABLISHMENT

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. The following conditions apply:

- (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. The official veterinarian then shall be present throughout ante- and post-mortem inspection, shall supervise these 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 these performance tests. When necessary, detailed rules concerning the performance tests shall be adopted in accordance with the procedure referred to in Article 6. When the level of hygiene in the establishment decreases due to the functioning of this staff, or when tasks are not properly carried out by this staff, or, in general, when this staff carries out its activities in a manner that is not satisfactory according to the competent authority, this staff 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 described above. If the Member State decides to do so in principle, it should inform the Commission about this decision and the conditions thereof. For meat establishments in a Member State where the system described above is implemented, the actual use of the system is optional. Meat establishments shall not be forced by the competent authority to introduce the system described above. When the competent authority is not convinced that the meat establishment meets the requirements, the system shall not be implemented in the establishment. To assess this, the competent authority shall conduct an analysis of production and inspection records, the type of activities undertaken in the establishment, history of compliance with legislation, expertise, professional attitude and sense of responsibility as regards food safety of the staff of the establishment and other relevant information.

2. Member States with at least five years of experience with staff of establishments carrying out inspection tasks in the poultry sector, may extend the system 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 these 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 can 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, mentioned under 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 should cover at least the following subjects:
 - (a) national and Community 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 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 food-borne 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. The veterinarian shall be prepared for multidisciplinary cooperation.

4. Detailed rules concerning the content of the test referred to above shall be adopted, where appropriate, in accordance with the procedure referred to in Article 6.

5. In addition, the veterinarian shall receive at least 200 hours of practical training to be appointed as an official veterinarian. The practical training shall be provided by official veterinarians, shall take place in slaughterhouses, cutting plants, inspection posts for fresh meat and holdings and shall concern, among other things, auditing of food safety management systems.

6. The official veterinarian shall maintain up-to-date knowledge and keep abreast of new developments through annual continuing education activities and professional literature.

7. Veterinarians already appointed as official veterinarians and part-time official veterinarians shall, where necessary, acquire the required knowledge on the subjects mentioned above through continuing education activities. Adequate provisions should be made by the competent authority in this respect.

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 that central authority, may be appointed as official auxiliaries.

2. Only candidates who 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 supervision of an official veterinarian,

shall be eligible for the above test. The practical training shall take place under the supervision of an official veterinarian, in slaughterhouses, cutting plants, inspection posts for fresh meat and holdings.

3. The training and tests shall focus either on red meat or poultry meat. However, persons who were trained for one of the two categories and passed the test, may undergo a shortened training to pass the test for the other category.

4. The tests for official auxiliaries 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 — organisation, production methods, international trade, etc.;
- pre-harvest quality management (good farming practices);
- basic knowledge of diseases, in particular zoonotic diseases — viruses, bacteria, parasites, etc.;
- 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 inspection at slaughterhouses:
- (i) theoretical part:
- familiarity with the meat industry — organisation, production methods, international trade, etc.;
 - 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;
 - 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;
 - sampling procedures;
 - fraud aspects.
- (ii) practical part:
- animal identification;
 - age checks;
 - inspection and assessment of slaughtered animals;
 - post-mortem inspection in a slaughterhouse;
 - 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 above shall be adopted, where appropriate, in accordance with the procedure referred to in Article 6.

The total duration of the training of official auxiliaries shall gradually increase towards 1 400 hours in 2010, including theoretical and practical training.

The 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 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 items mentioned under Chapter 1, heading I.2.A, shall be sent to the slaughterhouse operator 24 to 72 hours before the arrival of the lot at the slaughterhouse. When the 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 24 hours before the arrival of the lot.

B. Post-mortem inspection

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. supra-mammarii*). 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; 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 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 items mentioned under Chapter 1, heading I.2.A, shall be sent to the slaughterhouse operator 24 to 72 hours before the arrival of the lot at the slaughterhouse. When the 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 24 hours before the arrival of the lot.

B. Post-mortem inspection

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. Without prejudice to animal-health rules, these examinations are not necessary if the competent authority is able to guarantee that the head, including the tongue and the brains, will 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, these 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 inspection

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 lengthwise and the lungs must be incised in their posterior third, perpendicular to their main axes; however, these incisions are not necessary where the lungs are excluded from human consumption;
- (c) visual inspection of the pericardium and the 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, 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 SWINE

A. Ante-mortem inspection

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 Chapter 3, heading X, or

(b) the food chain information, covering the items mentioned under Chapter 1, heading I.2.A, has been sent to the slaughterhouse operator 24 to 72 hours before the arrival of the pigs at the slaughterhouse. When the 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 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 mentioned in Chapter 1, heading I.2.A;
- (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 forbidden substances.

Besides, the following shall be carried out:

- (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.
3. Ante-mortem inspection at the holding shall be carried out by the official veterinarian, or by an approved veterinarian taking part in a surveillance network system, as foreseen 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 ante-mortem inspection has been carried out at the holding, ante-mortem inspection at the slaughterhouse can 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 ante-mortem inspection has not been carried out at the holding, the official veterinarian shall carry out ante-mortem inspection as described in Chapter 1, heading I.2.B.
6. Where the pigs are not slaughtered within three days of the issue of the health certificate provided for in point 1(a):
- (a) where the pigs have not left the holding of provenance, 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 following post-mortem inspection procedures:

- (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 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 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.
2. 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 above described procedures shall be applied to these fattening pigs.

V. POULTRY

A. Ante-mortem inspection

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 provided for in Chapter 3, heading X, or
 - (b) the food chain information, covering the items mentioned under Chapter 1, heading I.2.A, has been sent to the slaughterhouse operator 24 to 72 hours before the arrival of the birds at the slaughterhouse. When 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 24 hours before 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 mentioned in Chapter 1, heading I.2.A;
 - (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 forbidden substances.

Besides, the following shall be carried out:

- (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.
3. Ante-mortem inspection at the holding shall be carried out by the official veterinarian.
4. Where ante-mortem inspection has been carried out at the holding, ante-mortem inspection at the slaughterhouse can 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. This screening may be carried out by an official auxiliary.
5. Where ante-mortem inspection has not been carried out at the holding, the official veterinarian shall carry out an examination to determine whether:
- (a) the birds 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 forbidden substances;
- and, where appropriate, tests for zoonotic agents.
6. Where the birds are not slaughtered within three days of the issue of the health certificate provided for in point 1(a):
- (a) where the birds have not left the holding of provenance, 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.
7. If the birds show clinical symptoms of a disease, their slaughter for human consumption shall be prohibited. Killing of these birds on the slaughterline is however 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.
8. 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 Chapter 3, heading VI.2.

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 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 under 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: Number:

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 (Place), on (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. Ante-mortem inspection at the holding shall include checking the records or documentation of the holding, including the food chain information as mentioned in Chapter 1, heading I.2.A, regular sampling of water and feed and, where appropriate, tests for zoonotic agents. When 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 certificate drawn up in accordance with the specimen in Chapter 3, heading X stating that the animals were inspected at the holding and found to be healthy.

B. *Post-mortem inspection*

1. This 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 described for bovine and ovine animals, domestic swine and 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 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 Regulation (EC) No . . . [laying down specific hygiene rules for food of animal origin]. Where this is the case, he shall take this declaration into account in carrying out the post-mortem inspection.
3. During post-mortem inspection, the official veterinarian shall carry out:
 - (a) a visual examination of the carcass, its cavities and where appropriate organs with a view to:
 - detecting any abnormalities. For this purpose, the diagnosis may be based on any information provided by the hunter concerning the behaviour of the animal before killing,
 - checking that death was not caused by reasons other than hunting.
 - If an assessment cannot be made 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 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 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 lengthwise.

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 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 cases provided for in Chapter 1, heading II.E, meat presenting characteristics during post-mortem inspection as listed in point A of this 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.

B. *Cysticercosis*

1. The post-mortem inspection procedures described under Chapter 3, headings I and IV are the minimum requirements for the examination for cysticercosis in bovine animals over six weeks old and swine. In addition, specific serological tests may be used. In the case of bovines over six weeks old, incision of the masseters at post-mortem inspection is not compulsory when a specific serological test is used. The same applies when bovine animals over six 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 6, 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 can 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.

X. SPECIMEN HEALTH CERTIFICATE

HEALTH CERTIFICATE

for animals transported from the holding to the slaughterhouse

Competent service: Number:

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 abovementioned 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 is 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 Annex II, Section VII, Chapter V of 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 6 000 *faecal coliforms* per 100 g of flesh or 4 600 *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 6, 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, etc.,
 - (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 paragraph 3(b), (c) and (d) above, 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:
 - the likely variation in faecal contamination,
 - the parameters referred to in paragraph 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:

- 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
- periodic toxicity tests using those molluscs from the affected area most susceptible to contamination.

The sampling frequency for toxin analysis in the molluscs should be at least weekly during the time periods for which harvesting is allowed. This frequency may occasionally be reduced in specific areas for which robust historical data on toxins or phytoplankton occurrence suggest very low risk of toxic episodes. Nevertheless, this should be periodically reviewed in order to assess the risk of toxins occurring in the shellfish from these areas.

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. This will 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 should only be allowed if further analysis on the other species shows toxin levels below the limits.

With regard to the monitoring of plankton, the samples should be representative of the water column and should 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 will be established until results of toxin analysis are obtained.

- (c) The sampling plan for checking the presence of chemical contaminants must allow to determine that the levels referred to in Regulation (EC) No 466/2001 ⁽¹⁾ 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.
7. In addition to the monitoring of relaying and production zones referred to in paragraph 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.

⁽¹⁾ OJ L 77, 16.3.2001, p. 1.

This list must be communicated to interested parties affected by this Annex, such as producers, gatherers and operators of purification centres and dispatch centres.

- (b) immediately inform the interested parties affected by the present 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 the present Annex indicate that a production area must be closed or can 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 businesses or organisation concerned.

II. OFFICIAL 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

In addition to the common control requirements, the following shall apply:

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.
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 specified in 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:

- the mean value must not exceed 100 ppm,
- two samples may have a value exceeding 100 ppm but not more than 200 ppm,
- no sample may have a value exceeding 200 ppm.

These limits apply only to fish species of the following families: Scombridae, Clupeidae, Engraulidae, Coryfenidae, Pomatomidae and Scombraesosidae. 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, such as 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 such as 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 endoparasites.

(g) 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 6, after an opinion has been given by the European Food Safety Authority:

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

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 endoparasites 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

In addition to the common control requirements, official controls shall include:

A. *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. These inspections may take place at the occasion of veterinary checks carried out pursuant to other Community provisions.

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.

2. 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.

B. *Control of raw milk upon collection*

1. The competent authority shall organise, where appropriate in cooperation 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 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 can be used under certain well defined conditions. As soon as these conditions are reached, the competent authority shall apply a procedure of re-authorisation of delivering milk.

C. *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, such as:
 - heat treatment or other physical treatment parameters, or
 - 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.
-