



**COUNCIL OF  
THE EUROPEAN UNION**

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**NOTE**

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from : General Secretariat  
to : Permanent Representatives Committee / Council

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Subject : 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  
– Outcome of the European Parliament's first reading  
(Strasbourg, 2 to 5 June 2003)

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**I. INTRODUCTION**

The Rapporteur, Mr. Horst SCHNELLDHARDT (PPE/DE, D) introduced his report, containing 126 amendments, on behalf of the Committee on the Environment, Public Health and Consumer Policy. Other groups of MEPs tabled a further 17 amendments to the Commission proposal. In his speech to the plenary the Rapporteur pointed out that it is essential that official veterinarians play the central role in the control of products of animal origin. It is furthermore essential that the supervisory authorities are able to act in all independence if a successful system of controls is to be established. Particular attention has however to be paid, the Rapporteur added, to small artisanal businesses. While high hygiene standards ought to be required in these cases, a degree of flexibility is needed in order to avoid over burdening of these small-scale businesses.

For the Commission, Commissioner DIAMANTOPOULOU, reiterated the aims of the proposal and reassured MEPs that there is no danger of privatisation of the system of official controls and that some flexibility regarding small businesses is provided for by the legislation. The main responsibility for carrying inspections, the Commissioner explained, will be with public authorities. In this light the Commissioner welcomed as particularly constructive the proposal contained in amd.

87 to separate production and control responsibilities. On the question of small business flexibility the Commission could accept amds 3, 11, 12 and 138 - subject to rewording - as well as 134, 141 and 142 (on risk analysis). It could however not accept amds 85 and 86 as they restrict flexibility unjustifiably. The same applied to point 6 of amd 21, which, the Commissioner explained, is incompatible with Annex I of the proposal.

In Plenary, 12 Members of Parliament took the floor to welcome the improved food safety brought about by the food hygiene package legislation and this regulation in particular. They stressed the importance of putting into place a rigorous control system both for foods within the EU and for products imported from third countries. The recurrent issues mentioned in the debate related to the need to preserve the independence of official controls, the need to include some flexibility to deal with small artisan establishments, and the need to take into account the particular challenges posed by fisheries and aquaculture products to which the control systems cannot be simply transposed without taking account of their specific nature.

### III. VOTE

The Plenary adopted 135 amendments to the Commission proposal.

Of the adopted amendments the Commission:

- a. can accept amendements 1, 8, 9, 13, 16, 17, 20, 39, 40, 42, 43, 48, 50, 52, 53, 54, 74, 79, 82, 84, 89, 91, 92, 93, 94, 95, 97, 98, 99, 108, 111, 113, 115, 124, 138.
  
- b. can accept the following amendments wholly or partly subject to editorial amendment: 3, 5, 7, 11, 12, 18, 19, 21, 22, 23, 24, 26, 27, 28, 29, 32, 34, 35, 41, 45, 47, 49, 51, 56, 57, 61, 66, 85, 104, 116, 120, 121, 130, 131, 132, 133, 134.
  
- c. cannot accept amendments: 2, 4, 6, 14, 15, 21 (point 6), 25, 30, 31, 33, 36, 37, 38, 44, 46, 55, 58, 59, 60, 62, 63, 64, 65, 67, 68, 69, 70, 71, 72, 73, 75, 76, 77, 78, 80, 81, 83, 87 (amendments 2 and 3), 88 (first part), 100, 101, 102, 103, 105, 106, 107, 109, 112, 114, 117, 118, 119, 122 (first part), 123, 125, 126, 128, 129, 135, 136, 137, 139, 140.

**European Parliament legislative resolution on the proposal for a European Parliament and Council regulation laying down specific rules for the organisation of official controls on products of animal origin intended for human consumption (COM(2002) 377 – C5-0340/2002 – 2002/0141(COD))**

**(Codecision procedure: first reading)**

*The European Parliament,*

- having regard to the Commission proposal to the European Parliament and the Council (COM(2002) 377<sup>1</sup>),
  - having regard to Article 251(2) and Articles 152(4) of the EC Treaty, pursuant to which the Commission submitted the proposal to Parliament (C5-0340/2002),
  - having regard to Rule 67 of its Rules of Procedure,
  - having regard to the report of the Committee on the Environment, Public Health and Consumer Policy and the opinions of the Committee on Agriculture and Rural Development and the Committee on Fisheries (A5-0156/2003),
1. Approves the Commission proposal as amended;
  2. Asks for the matter to be referred to it again, should the Commission intend to amend its proposal substantially or replace it with another text;
  3. Instructs its President to forward its position to the Council and Commission.

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<sup>1</sup> OJ C 262, 29.10.2002, p. 449

## Amendment 1

## Recital 4

(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.

(4) Official controls on products of animal origin should cover all aspects which are important for protecting public health, animal health and animal welfare. They should be based on the most recent information available and should therefore be adapted as relevant new information becomes available.

## Amendment 2

## Recital 5

(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**.

(5) Community legislation on food safety should have a sound, **verifiable** scientific basis. To that end, the European Food Safety Authority should be consulted **on a regular basis to ensure that scientific advice is up-to-date, independent and properly assessed**.

## Amendment 3

## Recital 6

(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.

(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. **The official controls should take into account the flexible provision for artisanal businesses, and small and medium-sized businesses in Regulation (EC) No. .../2003 [on food hygiene], and Regulation (EC) No. .../2003 [laying down specific hygiene rules for food of animal origin]. Such flexible treatment should not entail any restriction on hygiene.**

Amendment 4  
Recital 6a (new)

***(6a) Producers and operators who perform better with regard to food safety and whose products present less risk should receive a reward for their investment in the form of lower inspection costs.***

Amendment 5  
Recital 7

(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.

(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 *food* business operators. These official controls should consist of audits of the operators' activities, and of inspection activities, ***including checks on the businesses' own controls.*** *The term 'meat business' should be replaced by the term 'food business' throughout the text.*

Amendment 6  
Recital 8

(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.

(8) Official controls on the production of live bivalve molluscs and on fishery products, ***which should be differentiated according to the different species involved,*** 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.

Amendment 7  
Recital 10

(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, they should be adopted by use of the regulatory procedure provided for in Article 5 of that Decision,***

(10) ***The implementing provisions for the Annexes to this Regulation should be adopted by use of the regulatory procedure provided for in Article 5 of Council Decision 1999/468/EC of 28 June 1999 laying down the procedures for the exercise of implementing powers conferred on the Commission,***

Amendment 8  
Chapter I (new), Heading

**CHAPTER I**  
**GENERAL PROVISIONS**

Amendment 9  
Article 1, Heading (new)

**Scope**

Amendment 10  
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].

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 .../2003 of the European Parliament and of the Council of... [on official feed and food controls] **and Regulation (EC) No 178/2002 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<sup>1</sup>.**

<sup>1</sup> **OJ L 31, 1.2.2002, p. 1.**

Amendment 11  
Article 1, paragraph 1a (new)

***This Regulation shall apply only to activities and persons to which Regulation (EC) No. .../2003 [on food hygiene] and Regulation (EC) No. .../2003 [laying down specific hygiene rules for food of animal origin] apply.***

Amendment 12  
Article 1, paragraph 1b (new)

***This Regulation shall not apply to:***  
***(a) the primary production of foodstuffs for private domestic use;***  
***(b) the domestic preparation of foodstuffs for private consumption;***

*(c) the direct supply by the producer of small quantities of primary products to the final consumer or to local shops and restaurants; such operations shall be subject to national rules.*

Amendment 13  
Article 2, Heading (new)

***Definitions***

Amendment 14  
Article 2, paragraph 2, point (b)

(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.

(b) 'Official auxiliary' means ***a member of staff*** 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.

Amendment 15  
Article 2, paragraph 2, point (ca) (new)

***(ca) 'Artisanal small business' means a registered business which produces exclusively for a limited local market;***

Amendment 16  
Chapter II (new) Heading

***CHAPTER II  
OFFICIAL CONTROLS OF  
COMMUNITY ESTABLISHMENTS***

Amendment 17  
Article 3, Heading (new)

***Approval of establishments***

#### Amendment 18

##### Article 3, paragraph 1, subparagraph 1

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.

1. Where 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 ***comply with the provisions of Regulation (EC) No. .../2003 [on food hygiene] and Regulation (EC) No. .../2003 [laying down specific hygiene rules for food of animal origin]*** and the relevant requirements of food law.

#### Amendment 128

##### Article 3, paragraph 1, subparagraph 2

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 3 months after the conditional approval has been given that the other requirements of relevant feed and food law are complied with.***

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. ***The duration of the validity of the conditional approval shall be determined by the competent authority and cannot be extended.***

#### Amendment 19

##### Article 3, paragraph 3

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

3. Member States shall maintain lists of approved establishments with their respective approval numbers. ***These lists should be available online for consultation by all the Member States in the single format defined by the Commission.***

#### Amendment 20

##### Article 4

###### ***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.***

###### ***Deleted***

Amendment 129  
Article 4a (new)

**Article 4a**

**General Principles of Official Controls**  
**Business operators shall give all assistance needed to ensure that official controls carried out by the competent authority can be performed efficiently.**

**They shall in particular:**

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

Amendment 21  
Article 4b (new)

**Article 4b**

**Official controls of establishments processing fresh meat**

**1. Member States shall ensure that official controls are carried out in accordance with Annex I at slaughterhouses, game handling establishments and cutting plants.**

**2. Official controls shall be carried out at these establishments in accordance with Annex I, Chapter 1, Section I.1 by official veterinarians, who shall in particular check**  
**(a) good hygienic practice,**  
**(b) procedures based on the principles of Hazard Analysis Critical Control Point (HACCP).**

**3. The official veterinarian shall carry out inspections at these establishments in accordance with Annex I, Chapter 1, Section I.2 with particular reference to the following aspects:**

- (a) information about the food chain,**
- (b) ante-mortem inspection,**
- (c) animal welfare.**
- (d) post-mortem inspection,**
- (e) specifically designated risk materials and other animal by-products,**
- (f) laboratory tests,**

*4. After having performed the inspections referred to in paragraphs 2 and 3, the official veterinarian shall carry out the appropriate measures in accordance with Annex I, Chapter 1, Section II.*

*5. Official auxiliaries may assist the official veterinarian in accordance with Annex I, Chapter 2, Section I.*

*6. Member States shall ensure that they have sufficient staff for inspections to enable official controls to be executed as frequently as required by Annex I, Chapter 2, Section II.*

*7. Member States may permit staff at a slaughterhouse to perform certain official control duties relating to the production of poultry meat and rabbit meat.*

*8. Member States may permit staff at a slaughterhouse to perform certain official control duties relating to the taking of samples and the performance of tests in accordance with Annex I, Chapter 2, Section III.*

*9. Member States shall ensure that official veterinarians and official auxiliaries can obtain the required qualifications and appropriate training in accordance with Annex I, Chapter 2, Section IV.*

Amendment 22  
Article 4c (new)

*Article 4c*

*Official controls of establishments  
producing live bivalve molluscs*

*Member States shall ensure that establishments producing live bivalve molluscs are subject to official controls in accordance with Annex II.*

Amendment 23  
Article 4d (new)

*Article 4d*

*Official controls of establishments  
processing fishery products*

*Member States shall ensure that establishments processing fishery products are subject to official controls in accordance with Annex III.*

Amendment 24  
Article 4e (new)

**Article 4e**  
***Official controls of establishments  
producing or processing milk or milk  
products***  
***Member States shall ensure that  
establishments producing or processing  
milk or milk products are subject to  
official controls in accordance with  
Annex IV.***

Amendment 25  
Article 4f (new)

**Article 4f**  
***Sanctions***  
***Should a body responsible for carrying out  
controls detect a failure to observe the  
hygiene principles relating to animal  
products intended for human consumption,  
uniform sanctions identical in all the  
Member States shall be imposed on  
offenders. Where necessary they may take  
the form (following validation by the  
appropriate control body) of a shut-down of  
the offending business by the authorities  
and may require a description of the  
offences detected to be displayed in public.***

Amendment 26  
Chapter III (new), heading

**CHAPTER III**  
***IMPORTATION OF PRODUCTS OF  
ANIMAL ORIGIN FROM THIRD  
COUNTRIES***

Amendment 27  
Article 4g (new)

**Article 4g**

**Basic provisions**

*The provisions of the Annexes to this Regulation shall apply without prejudice to the animal health requirements for the importation of products of animal origin laid down in Council Directive 2002/99/EC of 16 December 2002 laying down the animal health rules governing the production, processing, distribution and introduction of products of animal origin for human consumption<sup>1</sup>.*

<sup>1</sup> **OJ L 18, 23.1.2003, p. 11.**

Amendment 28  
Article 4h (new), Introduction

**Article 4h**

*Provisions for drawing up lists of third countries or regions of third countries from which imports of products of animal origin are permitted*

*1. In order to ensure compliance with the general provisions referred to in Article 12 of Regulation (EC) No .../2003 [on the hygiene of foodstuffs], the provisions of this Article shall apply.*

Amendment 29  
Article 4i (new), paragraph 2

*2. In accordance with the procedure referred to in Article 6, the Commission shall draw up lists of the third countries from which imports of products of animal origin are permitted. These lists are to be drawn up after a Community inspection visit.*

*When drawing up these lists, particular account must be taken of:*  
*(a) the legislation of the third country;*

- (b) the organisation of the competent authority of the third country and of its inspection services, of the powers of these services and the supervision to which they are subject, as well as the authority that these services have to monitor effectively the application of their legislation;*
- (c) the hygiene conditions of production, manufacture, handling, storage and dispatch actually applied to products of animal origin destined for the Community;*
- (d) assurances which the third country can give regarding compliance or equivalence with the relevant health conditions;*
- (e) experience of marketing of the product from the third country and the results of import controls carried out;*
- (f) the results of Community inspection and/or audits carried out in the third country, in particular the results of the assessment of the competent authorities;*
- (g) the state of health of the livestock, other domestic animals and wildlife in the third country and the general health situation in the country, which might endanger public health in the Community;*
- (h) the regularity and rapidity of communication of the information supplied by the third country relating to the presence of biological hazards, including the presence of marine biotoxins in fishing or aquaculture zones;*
- (i) the existence, implementation and communication of a zoonoses control programme;*
- (j) the legislation of the third country on the use of substances and veterinary medicinal products, including rules on their prohibition or authorisation, their distribution, their marketing and the rules covering administration and inspection;*
- (k) the existence, implementation and communication of a residue control programme;*

*(l) the legislation of the third country on the preparation and use of feedingstuffs, including the procedures for using additives and the preparation and use of medicated feedingstuffs, as well as the hygiene quality of the raw materials used for preparing feedingstuffs and of the final product.*

Amendment 30

Article 4j (new), paragraph 3

*3. In accordance with the procedure referred to in Article 6, the Commission shall lay down, for each product or group of products, special import conditions for each third country or group of third countries, having regard to the health situation of the third country or countries concerned.*

*The special import conditions shall include:*

*(a) identification of the competent authority responsible for official controls on the products concerned and for signing health certificates,*

*(b) details of the health certification which must accompany consignments destined for the Community; these certificates must:*

*- be drawn up in at least one of the languages of the country of dispatch and of destination and one of those of the Member State in which the inspections at the border inspection post are carried out,*  
*- accompany the products in their original version,*

*- consist of a single sheet of paper,*

*- be made out for a single consignee;*

*Certificates must be issued on the day on which the products are loaded with a view to dispatch to the country of destination.*

*(c) affixing of a health mark identifying products of animal origin, in particular by identification of the third country of dispatch (the country's full name or its ISO abbreviation) and the approval number, name and address of the establishment of origin;*

Amendment 31

Article 4j (new), paragraph 4

*4. In accordance with the procedure referred to in Article 6, the Commission shall, where appropriate, lay down general import conditions for a given product.*

Amendment 32

Article 4l (new), Introduction

*Article 4l*

*Conditions for drawing up and updating lists of establishments, including factory vessels and freezer vessels*

*An establishment, factory vessel or freezer vessel and, with regard to live bivalve molluscs, production and harvesting areas shall only dispatch products of animal origin to the Community when it figures on a list to be established and kept up-to-date in accordance with the following procedures:*

Amendment 33

Article 4l (new), point 1

*1. Equivalence agreements  
Drawing up and updating the lists of establishments must comply with the provisions of the relevant equivalence agreement.*

Amendment 34  
Article 41 (new), point 2

**2. By the Commission.**

***In the case of a favourable outcome of the Commission controls referred to under Article 4 g:***

***(a) Lists must be drawn up by the Commission in accordance with the procedure referred to in Article 6 on the basis of a communication from the competent authorities of the third country to the Commission.***

***(i) An establishment may be placed on a list only if it is officially approved by the competent authority of the third country exporting to the Community. Such approval is subject to***

***- compliance with Community requirements;***

***- supervision by an official inspection service in the third country.***

***(ii) A production or harvesting area for live bivalve molluscs must comply with the relevant legislation applicable within the Community.***

***(iii) The approval of factory vessels and freezer vessels must be carried out:***

***- by the competent authority of the third country of which the vessel is flying the flag,***

***- by the competent authority of another third country, on condition that such third country figures on the Community list of third countries authorised to import fishery products into the Community and the fishery products are landed regularly on its territory and inspected by its competent authority, which must also apply health marks to the products and issue the health certificates, or***

***- by a Member State***

***(b) Approved lists shall be amended as follows:***

***- the Commission shall inform the Member States of the modifications proposed by the third country concerned to the lists of establishments within five working days of the receipt of the proposed modifications;***

*- the Member States shall have seven working days, from receipt of the modifications to the lists of establishments referred to above to send any written comments to the Commission;*  
*- where written comments are made by at least one Member State, the Commission shall inform the Member States within five working days and include the point on the next meeting of the Standing Veterinary Committee for decision in accordance with the procedure referred to in Article 6;*  
*- where no comments are received from the Member States within the time limit referred to in the second indent, the modifications to the list shall be considered to have been accepted by the Member States. The Commission shall inform the Member States within five working days, and imports shall be authorised from such establishments five working days after receipt of this information by the Member States;*  
*- the Commission shall publish the lists in the Official Journal of the European Union.*

Amendment 35

Article 41 (new), point 3

*3. Authorisation to a third country to draw up and update lists of establishments*  
*Following a Commission on-the-spot inspection and/or audit for the criteria listed in Article 4g, the competent authority of a third country may be granted the possibility to draw up and update lists, on the following conditions:*  
*(a) An establishment may be placed on a list only if it is officially approved by the competent authority of the third country exporting to the Community. Such approval is subject to:*  
*- compliance with Community requirements;*  
*- supervision by an official inspection service in the third country.*

*Each establishment must be given an approval number.*

*(b) The approval of factory vessels and freezer vessels is to be carried out by the competent authority of the third country of which the vessel is flying the flag.*

*(c) The approval of production and harvesting areas for live bivalve molluscs is subject to compliance with the rules applicable for that purpose within the Community.*

*(d) In the event of non-compliance with the Community requirements, the competent authority must have real powers to ensure:*

*- correction of deficiencies within an appropriate time-limit and*

*- suspension of the activities for export to the Community or withdrawal of approval of establishments, factory and freezer vessels, and production and harvesting areas of live bivalve molluscs under its responsibility, where it is not possible to correct deficiencies within an appropriate time-limit or where a risk to public health has been identified.*

*(e) An up-to-date list is to be transmitted by the competent authority in a third country to the Commission, which makes it available to any interested third party on a dedicated site on the Internet.*

*Only establishments appearing on this list may dispatch products of animal origin to the Community.*

Amendment 36

Article 41 (new), point 4

*4. Case-by-case decisions.*

*To deal with specific situations and in accordance with the procedure referred to in Article 6, imports may be authorised directly from an establishment of a third country where the latter is unable to provide the guarantees referred to under Article 4g. In this event, the establishment in question must receive special approval following a Commission inspection. The approval decision must fix the specific import conditions to be followed for products coming from that establishment.*

Amendment 37  
Article 4m (new)

**Article 4i**  
**Other provisions**

- 1. Only products from a third country which**
- are prepared in the third country of dispatch or, with regard to fishery products, on factory vessels or freezer vessels of the third country of dispatch;**
  - are obtained or prepared in a third country other than the third country of dispatch, provided the product comes from an approved establishment in a third country appearing on a Community list; or, where appropriate,**
  - are prepared in the Community or manufactured therein, may be imported into the Community.**
- 2. If necessary, special conditions for the importation of products intended for specific purposes may be adopted by the Commission in accordance with the procedure referred to in Article 6.**

Amendment 38  
Article 5

**Article 5**

**Deleted**

***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.***

Amendment 130  
Article 5a (new)

**Article 5a**  
**Amendment of the Annexes,  
implementing rules and transitional  
measures**

**1. Annexes I to IV may be amended or supplemented to take account of scientific and technical progress in accordance with the procedure referred to in Article 6, paragraph 2. Whenever necessary, the Commission shall consult the European Food Safety Authority before making a proposal.**

**2. Implementing rules to ensure uniform implementation of this Regulation may be adopted in accordance with the procedure referred to in Article 6, paragraph 2. Whenever necessary, the Commission shall consult the European Food Safety Authority before making a proposal.**

**3. Transitional measures may be laid down in accordance with the procedure referred to in Article 6, paragraph 2.**

Amendment 131  
Article 5b (new)

**Article 5b**  
**Implementing rules**

**The implementing rules referred to in Article 5a may specify, in particular:**

- (a) technical arrangements at the inspection sites;**
- (b) the method of communicating inspection results;**
- (c) the circumstances in which the permanent presence of the official veterinarian is not required in certain slaughterhouses and game handling establishments;**
- (d) rules concerning the content of tests for official veterinarians and official auxiliaries;**
- (e) microbiological criteria for the control of hygiene in establishments;**

- (f) alternative procedures, serological or other laboratory tests that provide guarantees at least equivalent to specific post-mortem inspection procedures described in Annex 1, Section IV, and may therefore replace them;*
- (g) circumstances in which certain of the specific post-mortem inspection procedures described in Annex 1, Section IV, are not necessary, depending on the holding, region or country of origin and based on the principles of risk analysis;*
- (h) rules for laboratory testing, including methods to be applied when examining for sexual odour;*
- (i) the cold treatment to be applied to meat in relation to Cysticercosis and Trichinosis;*
- (j) the heat treatment to be applied to meat in relation to Tuberculosis;*
- (k) conditions under which holdings can be certified as officially free of Cysticercosis and Trichinosis;*
- (l) methods to be applied when examining for the conditions referred to in Annex 1, Section IV, Chapter IX;*
- (m) freshness criteria for the organoleptic evaluation of fishery products;*
- (n) analytical limits, methods of analysis and sampling plans for the official controls on fishery products required under Annex III;*
- (o) procedures which must be observed for the eradication or control of animal diseases, such as brucellosis or tuberculosis or other zoonotic agents such as salmonella, in particular when these animals are slaughtered;*
- (p) the number of official staff and official auxiliaries for the slaughter line.*

**Article 5c**  
**Flexibility**

**1. Member States may, without compromising the objectives of this Regulation, adopt national measures adapting the requirements laid down in the Annexes in accordance with paragraphs 2 to 5.**

**2. The national measures referred to in paragraph 1 shall:**

**(a) have the aim of:**

**(i) enabling the continued use of traditional methods at any of the stages of production, processing or distribution of food; or**

**(ii) accommodating the needs of food businesses with a small throughput and of those situated in regions suffering from special geographic constraints.**

**(b) concern in particular the following elements of the Annexes :**

**(i) food chain information;**

**(ii) the presence of the competent authority depending on the risk analysis.**

**3. Any Member State wishing to adopt national measures as referred to in paragraph 2 shall notify the Commission and the other Member States. The notification shall:**

**(a) provide a detailed description of the requirements that that Member State considers need to be adapted and the nature of the adaptation sought;**

**(b) describe the establishments concerned;**

**(c) explain the reasons for the adaptation, including, where relevant, by providing a summary of the hazard analysis carried out and any measures to be taken to ensure that the adaptation will not compromise the objectives of this Regulation; and**

**(d) give any other relevant information.**

**4. The other Member States shall have three months from the receipt of a notification as referred to in paragraph 3 to send written comments to the Commission. The Commission may, and if it receives written comments from one or more Member States shall, consult Member States within the committee referred to in Article 6(1). The Commission may decide, in accordance with the procedure referred to in Article 6(2), whether the envisaged measures may be implemented subject, if necessary, to appropriate amendments. Where appropriate, the Commission may propose general measures in accordance with paragraphs 1 or 2.**

**5. A Member State may adopt national measures adapting the requirements of Annex I only:**  
**(a) in compliance with a decision adopted in accordance with paragraph 4;**  
**(b) if, one month after the expiry of the period referred to in paragraph 4, the Commission has not informed Member States that it has received written comments or that it intends to propose the adoption of a decision as referred to in subparagraph (a).**

Amendment 39  
Chapter 4 (new), Heading

**CHAPTER IV  
FINAL PROVISIONS**

Amendment 40  
Article 6, Heading (new)  
**Standing committee procedure**

Amendment 41  
Article 6, paragraph 2

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.

2. Where reference is made to this paragraph, **Articles 5 and 7** of Decision 1999/468/EC shall apply, **having regard to** Article 8 thereof.

Amendment 42  
Article 6, paragraph 3a (new)

**3a. The committee shall adopt its rules of procedure.**

Amendment 43  
Annex I, Chapter 1, Section I.1, Introduction

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:

The official veterinarian shall carry out audits in meat establishments with a view to checking whether the **food business** operator complies with the requirements of Regulation (EC) No .../... [on the hygiene of foodstuffs], Regulation (EC) No .../... [laying down specific hygiene rules for food of animal origin] and Regulation (EC) No 1774/2002 of the European Parliament and of the Council of 3 October 2003 laying down health rules concerning animal by-products not intended for human consumption<sup>1</sup>, and consequently has taken all appropriate measures to ensure good hygienic practices and safe meat. These audits include:

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

The term 'operator' should be expanded to 'food business operator' throughout the text. (This change applies to the entire legislative text.)

Amendment 44

Annex I, Chapter 1, Section I.1.A., point (a)

(a) design and maintenance of plant **structure** and equipment;

(a) design and maintenance of plant **infrastructure** and equipment;

Amendment 45

Annex I, Chapter 1, Section I.1.A., point (i)

(i) handling, collection and storage of animal by-products not intended for human consumption, including Specified Risk Materials.

(i) handling, collection, **transport, processing, disposal** and storage of animal by-products not intended for human consumption, including Specified Risk Materials **while they remain on the premises.**

Amendment 46

Annex I, Chapter I., Section I.1.B., subparagraph 2, introductory part  
**guarantee that** the animals entering the slaughter process: **create the conditions under which** the animals entering the slaughter process:

Amendment 47

Annex I, Chapter 1, Section I.2.A, paragraph 1, point (c)  
(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)**; (c) the details of veterinary medicinal products administered to the animals **with the** date(s) of administration and **the waiting periods. Details should be given only of veterinary medicinal products which provide for a waiting period;**

Amendment 48

Annex I, Chapter 1, Section I.2.A, paragraph 1, point (d)  
(d) **the occurrence of** diseases which may affect the safety of the meat; (d) diseases **which have occurred and** which may affect the safety of the meat;

Amendment 49

Annex I, Chapter 1, Section I.2.A, paragraph 1, point (e)  
(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; (e) the results of any analysis carried out on samples taken from the animals, samples taken **to diagnose diseases which have an effect on the quality of meat**, including samples taken - **if they are of significance from the point of view of human health** - in the framework of the monitoring and control of zoonoses and residues;

Amendment 50

Annex I, Chapter 1, Section I.2.A, paragraph 1, point (f)  
(f) the relevant reports from slaughterhouses about previous ante- and post-mortem findings in animals from the same holding of provenance; *Does not concern the English text.*

Amendment 51

Annex I, Chapter 1, Section I.2.A, paragraph 2

*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.*

*2. The following shall be laid down in accordance with the procedure in Article 6:*

*(a) rules concerning the way this information shall be established and presented;*

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

Amendment 52

Annex I, Chapter 1, Section I.2.C

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.

The official veterinarian shall verify compliance with the relevant Community **and national** 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.

Amendments 53 and 54

Annex I, Chapter 1, Section 1.2.D., paragraph 1

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.

1. The carcase and **accompanying** offal shall be subjected without delay to 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.

Amendment 55

Annex I, Chapter 1, Section 1.2.D., paragraph 2

**2. Whenever considered necessary to reach a definitive diagnosis, or to detect the presence of an animal disease or an excess of chemical residues or non-compliance with microbiological criteria,** additional examination shall take place, such as palpation and incision of parts of the carcass and offal, and laboratory tests.

2. Additional examination shall take place, such as palpation and incision of parts of the carcass and offal, and laboratory tests:

- (a) in order to reach a definitive diagnosis, or**
- (b) to detect the presence of an animal disease, or**
- (c) to detect an excess of chemical residues or non-compliance with microbiological criteria.**

Amendment 56

Annex I, Chapter 1, Section 1.2.D., paragraph 5

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.

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. ***The decision to use alternative procedures shall be taken by the competent authority.***

Amendment 57

Annex I, Chapter I, Section I.2.D, paragraph 5a (new)

***5a. In the event of emergency slaughter, the carcass shall be subjected as soon as possible to a post-mortem inspection, in accordance with paragraphs 1 to 5, before being declared fit for human consumption.***

Amendment 58

Annex I, Chapter 1, Section 1.2.F. paragraph 1, introduction

1. In the framework of:

**1. *The official veterinarian shall carry out 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*** in the framework of:

Amendment 59

Annex I, Chapter 1, Section 1.2.F. paragraph 1, point (e)

(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.***

(e) laboratory testing of animals considered suspect by the official veterinarian, or laboratory testing for the official veterinarian to reach a definitive diagnosis;

Amendment 60

Annex I, Chapter 1, Section 1.2.G. paragraph 1

**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.

1. 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.

#### Amendment 61

##### Annex I, Chapter I., Section I.2. G., paragraph 3

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 and when all the other requirements of this Regulation have been met.

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 and when all the other requirements of this Regulation have been met. ***If the carcass is identifiable up until the moment that the result of the trichinosis inspection or the residue inspection is available, the health mark may be applied beforehand. The carcass or the products manufactured therefrom may not, however, be placed on the market before the results of the trichinosis inspection are available.***

#### Amendment 62

##### Annex I, Chapter I., Section I.2. G., paragraph 4, subparagraph 2

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.

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, ***rabbits*** and piglets.

#### Amendment 63

##### Annex I, Chapter 1, Section 1.2.G. paragraph 5, point (b)

(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,

(b) lamb, kid, ***rabbit*** 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,

#### Amendment 64

##### Annex I, Chapter 1, Section 1.2.G. paragraph 6

6. The livers of bovine animals, swine and solipeds must be ***hot-branded*** in accordance with point 4.

6. The livers of bovine animals, swine and solipeds must be ***marked immediately*** in accordance with point 4, ***either directly on the product by hot-branding, 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.***

Amendment 65

Annex I, Chapter 1, Section 1.2.G. paragraph 13

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.

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. ***Traceability shall be ensured by means of documentation.***

Amendment 66

Annex I, Chapter 1, Section 1.2.H. paragraph 1

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. Following such communication, action must be taken by the ***person responsible for the holding of provenance***, to remedy the situation ***where appropriate***.

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:

- (a) the operator of the meat establishment,
- (b) the competent authority responsible for supervising the holding of provenance of the animals or the hunting area,
- (c) the private veterinarian attending the holding of provenance, and
- (d) the person responsible for the holding of provenance.

***The official veterinarian may withhold certain information if it is not relevant to a particular person.***

Following such communication, action must be taken by the ***persons*** responsible ***in their sphere of competence*** to remedy the situation.

Amendment 67

Annex I, Chapter 1, Section II.A, paragraph 1

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.

1. When audit of the good hygienic practices or the HACCP-based procedures reveals non-compliance, the official veterinarian shall **require** 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 **or suspending** the process may be taken by the official veterinarian.

Amendment 68

Annex I, Chapter 1, Section II.A, paragraph 2

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**.

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 **also apply** whenever considered necessary by the official veterinarian.

Amendment 69

Annex I, Chapter 1, Section II.A, paragraph 4

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.

4. When the process has to be stopped repeatedly **for the same or other causes**, and the operator is not able to prevent recurrence, the competent authority shall start the procedure of withdrawal of the approval of the establishment. **The decision to do so shall be published without delay.**

Amendment 70

Annex I, Chapter I, Section II. A, paragraph 4a (new)

**4a. Member States shall ensure that adequate appeal procedures are available to operators. Resort to appeal may not result in any delay or postponement of the implementation of the measures laid down in this Regulation.**

Amendment 71

Annex I, Chapter I., Section II B., paragraph 1

**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.***

**1. *Where the records of the holding of provenance of the animals do not contain the relevant food safety information, although they could be produced, the animals shall not be authorised for slaughter. The operator of the slaughterhouse shall take measures to ensure that the necessary information is forwarded as quickly as possible and shall, in agreement with the official veterinarian, take measures to ensure the welfare of the animals. The cost of those measures shall be borne by the establishment which has caused the delay. Should all these measures not result in the necessary information for food safety being obtained, the animals shall be killed separately and declared unfit for human consumption.***

Amendment 72

Annex I, Chapter I., Section II B., paragraph 2

**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.***

**2. *In the case of emergency slaughter outside the slaughterhouse, the food chain information shall also 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. Otherwise, where the information is lacking, the carcass shall be condemned as unfit for human consumption.***

Amendment 73

Annex I, Chapter 1, Section II.C, paragraph 1

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.

1. ***When animals are not properly identified, or where their provenance or classification cannot be established by other means, the official veterinarian shall decide whether they may be slaughtered.*** Whenever considered necessary by the official veterinarian ***to avoid health hazards for humans and animals, these animals shall be killed. The official veterinarian may also decide that*** official controls shall be carried out on the holding of provenance.

Amendment 74

Annex 1, Chapter 1, Section II C, paragraph 7

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.***

7. The ***treatment*** 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 competent authority shall determine the measures and conditions under which these animals will be slaughtered.***

Amendment 75

Annex I, Chapter I, Section II. C, paragraph 8

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.

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, ***and only if this is necessary in the interests of animal welfare and the animals are in such a condition that there is a greater than normal risk of contamination of the meat during slaughter.***

Amendment 76

Annex 1, Chapter 1, Section II D, paragraph 1

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.

1. When the rules concerning the protection of animals at the time of slaughter or killing are not respected, the official veterinarian shall *stipulate* 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.

Amendment 77

Annex I, Chapter I., Section II D., paragraph 2

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.

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. ***The decision to do so shall be published without delay.***

Amendment 78

Annex 1, Chapter 1, Section II E, Introduction

The following meat shall be declared unfit for human consumption:

***1.*** The following meat shall be declared unfit for human consumption:

Amendment 79

Annex I, Chapter I., Section II. E, point (b)

(b) meat from animals the offal of which has not undergone post-mortem inspection, unless otherwise provided for under this Regulation;

(b) meat from animals the offal of which has not undergone post-mortem inspection, unless otherwise provided for under this Regulation ***or Regulation (EC) No. .../2003 [laying down specific hygiene rules for food of animal origin];***

Amendment 132

Annex I, Chapter 1, Section II.E, point (ta) (new)

***(ta) Meat of hermaphrodites and cryptorchides unless it can be established by means of an objective testing method that it is free of odour;***

Amendment 133  
Annex I, Chapter 1, Section II.E, (tb) (new)

*(tb) Meat of uncastrated male fattening pigs unless it can be established by means of an objective testing method that it is free of odour;*

Amendment 80  
Annex 1, Chapter 1, Section II E, paragraph 1a (new)

*1a. The official veterinarian shall stipulate which products may be marketed in the pet food sector in the light of Regulation (EC) No 1774/2002.*

Amendment 81  
Annex I, Chapter 2, Section I, introduction

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

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

Amendment 82  
Annex I, Chapter 2, Section I, point (b)

(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;

(b) helping with ante-mortem inspection in the slaughterhouse **or at the holding of provenance**. In this case the official auxiliary's role is to make an initial check on the animals and to help with purely practical tasks;

#### Amendment 83

##### Annex I, Chapter 2, Section II., paragraph 1

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 slaughterline, a scientific approach shall be followed *where appropriate*. The number of official staff involved shall be such that all the requirements of this Regulation can be applied.

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 slaughterline, a scientific approach shall be followed. The number of official staff *or staff of the establishment* involved shall be such that all the requirements of this Regulation can be applied.

#### Amendment 84

##### Annex I, Chapter 2, Section II., paragraph 2, point (a), subparagraph 1

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

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

#### Amendment 85

Annex I, Chapter 2, Section II., paragraph 2, point (a), subparagraph 2, introduction  
*Some flexibility may be applied for small slaughterhouses and small game handling establishments:*

*The competent authority may exercise a more flexible approach in small slaughterhouses, small artisanal businesses and game handling establishments, identified on the basis of risk analysis:*

#### Amendment 134

##### Annex I, Chapter 2, Section II, paragraph 2(b)

(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.

(b) in cutting plants, a member of the inspection team is present when meat is being worked on *in accordance with an inspection schedule drawn up by the competent authority on the basis of a risk analysis*.

Amendment 87

Annex I, Chapter 2, Section III, paragraph 1, point (a)

(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.

(a) Where the establishment has successfully been operating, for at least 12 months, good hygienic practices **in accordance with Chapter 1 Section 1.1** 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, **authority and responsibility** of the official veterinarian **and to form part of the competent authority's independent inspection team at the establishment**. 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. 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. **In addition, responsibilities for production and inspection must be separated within the establishment and a business which wishes to make use of in-house inspectors must have internationally recognised certification.**

Amendment 135 and 139

Annex I, Chapter 2, Section III, paragraph 2

**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:**

**deleted**

*(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.*

Amendment 136 and 140

Annex I, Chapter 2, Section III, paragraph 3

*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.*

*deleted*

Amendment 88

Annex I, Chapter 2, Section IV A, paragraph 1

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.

1. Only veterinarians who have passed a test organised by the competent authority, as defined by Regulation (EC) No .../2003 [on official feed and food controls], or by the organisation designated for that purpose by the competent authority, **or who are already practising or whose professional training satisfies the requirements of this Regulation**, may be appointed as official veterinarians.

Amendment 89

Annex I, Chapter 2, Section IV A, paragraph 3

3. The veterinarian shall be ***prepared for*** multidisciplinary co-operation.

3. The veterinarian shall be ***capable of*** multidisciplinary co-operation.

Amendment 90

Annex I, Chapter 2, Section IV. A., paragraph 7a (new)

***7a. Notwithstanding the provisions of paragraphs 1 to 5, Member States may lay down special rules for part-time official veterinarians responsible for inspecting artisanal small businesses.***

Amendment 91

Annex I, Chapter 2, Section IV B, paragraph 4, point (b) (i), indent 1

– familiarity with the meat industry - organisation, production methods, international trade, ***etc.***;

– familiarity with the meat industry – organisation, production methods, international trade, ***and slaughter and cutting technology***;

Amendment 92

Annex I, Chapter 2, Section IV. B., paragraph 4, point (b)(i), indent 8a (new)

***- knowledge of microbiology;***

Amendment 93

Annex I, Chapter 2, Section IV B, paragraph 4, point (b) (i), indent 9a (new)

***- ante-mortem inspection procedures;***

Amendment 94

Annex I, Chapter 2, Section IV B, paragraph 4, point (b) (i), indent 9b (new)

***- trichinoscopic examination;***

Amendment 95

Annex I, Chapter 2, Section IV B, paragraph 4, point (b) (i), indent 10a (new)

***- post-mortem inspection procedures;***

Amendment 96

Annex I, Chapter 2, Section IV B, paragraph 4, point (b) (i), indent 11a (new)

***- administrative work;***

Amendment 97

Annex I, Chapter 2, Section IV B, paragraph 4, point (b) (ii), indent 4a (new)  
**- trichoscopic examination;**

Amendment 98

Annex I, Chapter 2, Section IV B, paragraph 4, point (b) (ii), indent 7a (new)  
**- recording the results of ante-mortem inspection;**

Amendment 99

Annex I, Chapter 2, Section IV. B., paragraph 4, point (b), subparagraph 3  
The **total duration of the** training of official auxiliaries shall **gradually** increase towards 1400 hours in 2010, **including theoretical and practical training.**

The training of official auxiliaries shall increase **to** 1400 hours **by** 2010, **which will include practical and theoretical training in ante-mortem inspection, HACCP and plant management.**

Amendment 100

Annex I, Chapter 2, Section IV. Ba (new)

**Ba. Professional qualifications of staff of the establishment**

**Staff of the establishment who carry out tasks of official auxiliaries under the supervision of the official veterinarian shall hold the same professional qualifications as set out in B above for official auxiliaries. Such staff of the establishment shall also maintain up-to-date knowledge and keep abreast of new developments through annual continuing education activities and professional literature.**

Amendment 101

Annex I, Chapter 3, Section I.1.A

*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.*

*1. Animals from the same holding of provenance may be delivered for slaughter only if the slaughterhouse operator and the official veterinarian have available the information referred to under Chapter 1, section I.2.A. Slaughter may only be carried out if the official veterinarian raises no objections. Delays to slaughter caused by late and incomplete forwarding of information and/or additional measures shall be communicated to the primary producer and any costs incurred shall be borne by the party causing the delays. In all other cases, the type and extent of the information is dependent on the type of production, the options available to the primary producer and on any uncontrollable circumstances. If the information is not clear, the official veterinarian shall decide whether to carry out additional inspections, or tests before and during slaughter. If, owing to a lack of information, there is a suspicion of a risk to humans and animals, these animals are to be killed and to be declared unfit for human consumption.*

*2. If there are compelling reasons for doing so, the official veterinarian may decide that the animals shall be slaughtered in the slaughterhouse, even if the relevant food chain information is not available; however, all food chain information which the official veterinarian requires for a post-mortem examination must be available before the carcass may be released for consumption. Until a definitive decision is made, such carcasses and the by-products of slaughter shall be stored separately from other meat.*

Amendment 102  
Annex I, Chapter 3, Section II.A

**A. Food chain information**

**Deleted**

*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.*

Amendment 103  
Annex I, Chapter 3, Section IV.A, paragraph 1, point (b)

*(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.*

**Deleted**

Amendment 104  
Annex I, Chapter 3, Section IV.A, paragraph 6, point (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;*

**(a) the procedure set out in paragraph 1 (a) shall be repeated.**

Amendment 105  
Annex I, Chapter 3, Section IV.B, paragraph 1, introduction

*1. Carcasses and offal of pigs, other than fattening pigs raised:*

**1. Carcasses and offal of pigs *not* raised:**

Amendment 106  
Annex I, Chapter 3, Section IV.B, paragraph 1, point (1a) (new)

**(1a) Trichinoscopic examination**

Amendment 109

Annex I, Chapter 3, Section IV. B, paragraph 2

**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.** Deleted

Amendment 107

Annex I, Chapter 3, Section V.A, paragraph 1, point (b)

**(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.** Deleted

Amendment 108

Annex I, Chapter 3, Section V.A, paragraph 6, point (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;** (a) **the procedure set out in paragraph 1(a) shall be repeated;**

Amendment 110

Annex I, Chapter 3, Section VII.B, paragraph 3

**3. When the animals have been slaughtered at the holding, the official veterinarian shall check the certificate issued and signed by the *private* veterinarian attesting to a favourable result of ante-mortem inspection, correct slaughter and bleeding and the time of slaughter.** 3. When the animals have been slaughtered at the holding, the official veterinarian shall check the certificate issued and signed by the *private* veterinarian **or by a veterinarian authorised by the competent authority** attesting to a favourable result of ante-mortem inspection, correct slaughter and bleeding and the time of slaughter.

#### Amendment 137

##### Annex I, Chapter 3, Section VIII.A, point 2

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.

2. The official veterinarian shall check whether the wild game is accompanied by a declaration of the **expert**, 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.

#### Amendment 111

##### Annex I, Chapter 3, Section VIII. A, paragraph 3, point (a), indent 1

– 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,

– detecting any abnormalities **not caused by the hunting process**. For this purpose, the diagnosis may be based on any information provided by the hunter concerning the behaviour of the animal before killing,

#### Amendment 112

##### Annex I, Chapter 3, Section VIII. A, paragraph 3, point (d)

(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;

(d) an analysis of residues, **not resulting from the hunting process**, 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;

#### Amendment 113

##### Annex I, Chapter 3, Section VIII. A, paragraph 3, point (e) (iv)

(iv) the presence of foreign bodies in the body cavities, stomach or intestines or in the urine, where the pleura or peritoneum are discoloured;

(iv) the presence of foreign bodies, **not resulting from the hunting process**, in the body cavities, stomach or intestines or in the urine, where the pleura or peritoneum are discoloured;

Amendment 114

Annex I, Chapter 3, Section VIII.A, paragraph 5

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.

**5. For small wild game, the rules laid down in Regulation (EC) No .../2003 [laying down specific hygiene rules for food of animal origin] shall apply.** 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.

Amendment 115

Annex I, Chapter 3, Section IX.A, paragraph 1, point (a)

**(a) Where appropriate, the status of the dam shall be checked before slaughter of the animal.**

**deleted**

Amendment 116

Annex I, Chapter 3, Section IX.B, paragraph 1a (new)

**1a. The conditions under which holdings may officially be declared free of cysticercosis shall be laid down in accordance with the procedure referred to in Article 6 and after the European Food Safety Authority has given its opinion.**

Amendment 117

Annex I, Chapter 3, Section IX.C, paragraph 1

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.***

1. Carcasses of swine (domestic, farmed game and wild game) and other species susceptible to trichinosis shall be examined for trichinosis.

Amendment 118

Annex I, Chapter 3, Section IX.C, paragraph 1a (new)

***1a. The examination need not be carried out if the animals were raised on a holding officially certified to be free of trichinosis. The conditions for official recognition as trichinosis-free shall be laid down in accordance with the procedure referred to in Article 6 and after the European Food Safety Authority has given its opinion.***

Amendment 119

Annex I, Chapter 3, Section IX.F, paragraph 2

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.***

2. Meat from animals which have reacted positively or inconclusively to a brucellosis test, indicating infection, shall be declared unfit for human consumption.

Amendment 120

Annex I, Chapter 3, Section IX.G

***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.***

***Where appropriate, methods to be applied when examining for the conditions referred to in this heading, the serological tests to examine for cysticercosis and the possible procedures for examining for trichinosis shall be established*** in accordance with the procedure referred to in Article 6, and after the European Food Safety Authority has given its opinion.

Amendment 121

Annex II, Section I., paragraph 4, point (b), indent 2

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

- periodic toxicity tests using those molluscs from the affected area most susceptible to contamination. ***Harmonised methods for the test procedures including negative controls shall be established in accordance with the procedure referred to in Article 6.***

Amendment 122

Annex II, Section I., paragraph 4, point (b), subparagraph 3

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.

The sampling frequency for toxin analysis in the molluscs should be at least ***every two weeks in the calendar months April to October inclusive, and otherwise monthly***. This frequency may be ***increased or*** reduced in specific areas for which robust historical data on toxins or phytoplankton occurrence ***respectively*** suggest ***a greater or lower*** 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.

Amendment 123

Annex II, Section I., paragraph 5, subparagraph 1

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.

5. Where the results of sampling ***unambiguously*** 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.

Amendment 124

Annex III, paragraph 1

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.

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

Amendment 125

Annex III, paragraph 2, point (da) (new)

***(da) Checks on the canthaxanthine content in farmed salmon, which must be severely restricted.***

Amendment 126

Annex III, paragraph 3, point (e)

(e) fishery products or parts thereof considered dangerous to human health.

(e) fishery products or parts thereof considered dangerous to human health ***on the basis of independent, verifiable scientific advice which is updated on a regular basis.***

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