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*(Acts whose publication is obligatory)*

**REGULATION (EC) No 852/2004 OF THE EUROPEAN PARLIAMENT  
AND OF THE COUNCIL  
of 29 April 2004**

on the hygiene of foodstuffs

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty establishing the European Community, and in particular Articles 95 and 152(4)(b) thereof,

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

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

Having consulted the Committee of the Regions,

Acting in accordance with the procedure laid down in Article 251 of the Treaty<sup>3</sup>,

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<sup>1</sup> OJ C 365 E, 19.12.2000, p. 43.

<sup>2</sup> OJ C 155, 29.5.2001, p. 39.

<sup>3</sup> Opinion of the European Parliament of 15 May 2002 (OJ C 180 E, 31.7.2003, p. 267), Council Common Position of 27 October 2003 (OJ C 48 E, 24.2.2004, p. 1), Position of the European Parliament of 30 March 2004 (not yet published in the Official Journal) and Council Decision of 16 April 2004.

Whereas:

- (1) The pursuit of a high level of protection of human life and health is one of the fundamental objectives of food law, as laid down in Regulation (EC) No 178/2002<sup>1</sup>. That Regulation also lays down other common principles and definitions for national and Community food law, including the aim of achieving free movement of food within the Community.
- (2) Council Directive 93/43/EEC of 14 June 1993 on the hygiene of foodstuffs<sup>2</sup> laid down the general rules of hygiene for foodstuffs and the procedures for verification of compliance with these rules.
- (3) Experience has shown that these rules and procedures constitute a sound basis for ensuring food safety. In the context of the common agricultural policy, many Directives have been adopted to establish specific health rules for the production and placing on the market of the products listed in Annex I to the Treaty. These health rules have reduced trade barriers for the products concerned, contributing to the creation of the internal market while ensuring a high level of protection of public health.
- (4) With regard to public health, these rules and procedures contain common principles, in particular in relation to the manufacturers' and competent authorities' responsibilities, structural, operational and hygiene requirements for establishments, procedures for the approval of establishments, requirements for storage and transport and health marks.

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<sup>1</sup> Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 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 (OJ L 31, 1.2.2002, p. 1). Regulation as amended by Regulation (EC) No 1642/2003 (OJ L 245, 29.9.2003, p. 4).

<sup>2</sup> OJ L 175, 19.7.1993, p. 1. Directive as amended by Regulation (EC) No 1882/2003 of the European Parliament and of the Council (OJ L 284, 31.10.2003, p. 1).

- (5) These principles constitute a common basis for the hygienic production of all food, including products of animal origin listed in Annex I to the Treaty.
- (6) In addition to this common basis, specific hygiene rules are necessary for certain foodstuffs. Regulation (EC) No        /2004 of the European Parliament and of the Council of ..... laying down specific hygiene rules for food of animal origin <sup>1</sup> lays down these rules.
- (7) The principal objective of the new general and specific hygiene rules is to ensure a high level of consumer protection with regard to food safety.
- (8) An integrated approach is necessary to ensure food safety from the place of primary production up to and including placing on the market or export. Every food business operator along the food chain should ensure that food safety is not compromised.
- (9) Community rules should not apply either to primary production for private domestic use, or to the domestic preparation, handling or storage of food for private domestic consumption. Moreover, they should apply only to undertakings, the concept of which implies a certain continuity of activities and a certain degree of organisation.

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<sup>1</sup> See page    of this Official Journal.

- (10) Food hazards present at the level of primary production should be identified and adequately controlled to ensure the achievement of the objectives of this Regulation. However, in the case of the direct supply of small quantities of primary products, by the food business operator producing them, to the final consumer or to a local retail establishment, it is appropriate to protect public health through national law, in particular because of the close relationship between the producer and the consumer.
- (11) The application of hazard analysis and critical control point (HACCP) principles to primary production is not yet generally feasible. However, guides to good practice should encourage the use of appropriate hygiene practices at farm level. Where necessary, specific hygiene rules for primary production should supplement these guides. It is appropriate for the hygiene requirements applicable to primary production and associated operations to differ from those for other operations.
- (12) Food safety is a result of several factors: legislation should lay down minimum hygiene requirements; official controls should be in place to check food business operators' compliance and food business operators should establish and operate food safety programmes and procedures based on the HACCP principles.
- (13) Successful implementation of the procedures based on the HACCP principles will require the full cooperation and commitment of food business employees. To this end, employees should undergo training. The HACCP system is an instrument to help food business operators attain a higher standard of food safety. The HACCP system should not be regarded as a method of self-regulation and should not replace official controls.

- (14) While the requirement of establishing procedures based on the HACCP principles should not initially apply to primary production, the feasibility of its extension will be one element of the review that the Commission will carry out following implementation of this Regulation. It is, however, appropriate for Member States to encourage operators at the level of primary production to apply such principles as far as possible.
- (15) The HACCP requirements should take account of the principles contained in the Codex Alimentarius. They should provide sufficient flexibility to be applicable in all situations, including in small businesses. In particular, it is necessary to recognise that, in certain food businesses, it is not possible to identify critical control points and that, in some cases, good hygienic practices can replace the monitoring of critical control points. Similarly, the requirement of establishing "critical limits" does not imply that it is necessary to fix a numerical limit in every case. In addition, the requirement of retaining documents needs to be flexible in order to avoid undue burdens for very small businesses.
- (16) Flexibility is also appropriate to enable the continued use of traditional methods at any of the stages of production, processing or distribution of food and in relation to structural requirements for establishments. Flexibility is particularly important for regions that are subject to special geographical constraints, including the outermost regions referred to in Article 299(2) of the Treaty. However, flexibility should not compromise food hygiene objectives. Moreover, since all food produced in accordance with the hygiene rules will be in free circulation throughout the Community, the procedure allowing Member States to exercise flexibility should be fully transparent. It should provide, where necessary to resolve disagreements, for discussion within the Standing Committee on the Food Chain and Animal Health established by Regulation (EC) No 178/2002.

- (17) The setting of objectives such as pathogen reduction targets or performance standards may guide the implementation of hygiene rules. It is therefore necessary to provide procedures for that purpose. Such objectives would supplement existing food law, such as Council Regulation (EEC) No 315/93 of 8 February 1993 laying down Community procedures for contaminants in food <sup>1</sup>, which provides for the establishment of maximum tolerances for specific contaminants, and Regulation (EC) No 178/2002, which prohibits the placing on the market of unsafe food and provides a uniform basis for the use of the precautionary principle.
- (18) To take account of technical and scientific progress, close and effective cooperation should be ensured between the Commission and the Member States within the Standing Committee on the Food Chain and Animal Health. This Regulation takes account of international obligations laid down in the WTO Sanitary and Phytosanitary Agreement and the international food safety standards contained in the Codex Alimentarius.
- (19) The registration of establishments and the cooperation of food business operators are necessary to allow the competent authorities to perform official controls efficiently.
- (20) The traceability of food and food ingredients along the food chain is an essential element in ensuring food safety. Regulation (EC) No 178/2002 contains rules to ensure the traceability of food and food ingredients and provides a procedure for the adoption of implementing rules to apply these principles in respect of specific sectors.

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<sup>1</sup> OJ L 37, 13.2.1993, p. 1. Regulation as amended by Regulation (EC) No 1882/2003.

- (21) Food imported into the Community is to comply with the general requirements laid down in Regulation (EC) No 178/2002 or satisfy rules that are equivalent to Community rules. The present Regulation defines certain specific hygiene requirements for food imported into the Community.
- (22) Food exported to third countries from the Community is to comply with the general requirements laid down in Regulation (EC) No 178/2002. The present Regulation defines certain specific hygiene requirements for food exported from the Community.
- (23) Scientific advice should underpin Community legislation on food hygiene. To this end, the European Food Safety Authority should be consulted whenever necessary.
- (24) Since this Regulation replaces Directive 93/43/EEC, the latter should be repealed.
- (25) The requirements of this Regulation should not apply until all parts of the new legislation on food hygiene have entered into force. It is also appropriate to provide for at least 18 months to elapse between entry into force and the application of the new rules, to allow the affected industries time to adapt.
- (26) The measures necessary for the implementation of this Regulation should be adopted in accordance with Council Decision 1999/468/EC of 28 June 1999 laying down the procedures for the exercise of implementing powers conferred on the Commission <sup>1</sup>,

HAVE ADOPTED THIS REGULATION:

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<sup>1</sup> OJ L 184, 17.7.1999, p. 23.

## CHAPTER I

### GENERAL PROVISIONS

#### Article 1

##### Scope

1. This Regulation lays down general rules for food business operators on the hygiene of foodstuffs, taking particular account of the following principles:
  - (a) primary responsibility for food safety rests with the food business operator;
  - (b) it is necessary to ensure food safety throughout the food chain, starting with primary production;
  - (c) it is important, for food that cannot be stored safely at ambient temperatures, particularly frozen food, to maintain the cold chain;
  - (d) general implementation of procedures based on the HACCP principles, together with the application of good hygiene practice, should reinforce food business operators' responsibility;



- (e) guides to good practice are a valuable instrument to aid food business operators at all levels of the food chain with compliance with food hygiene rules and with the application of the HACCP principles;
- (f) it is necessary to establish microbiological criteria and temperature control requirements based on a scientific risk assessment;
- (g) it is necessary to ensure that imported foods are of at least the same hygiene standard as food produced in the Community, or are of an equivalent standard.

This Regulation shall apply to all stages of production, processing and distribution of food and to exports, and without prejudice to more specific requirements relating to food hygiene.

2. This Regulation shall not apply to:

- (a) primary production for private domestic use;
- (b) the domestic preparation, handling or storage of food for private domestic consumption;
- (c) the direct supply, by the producer, of small quantities of primary products to the final consumer or to local retail establishments directly supplying the final consumer;

(d) collection centres and tanneries which fall within the definition of food business only because they handle raw material for the production of gelatine or collagen.

3. Member States shall establish, under national law, rules governing the activities referred to in paragraph 2(c). Such national rules shall ensure the achievement of the objectives of this Regulation.

## Article 2

### Definitions

1. For the purposes of this Regulation:

(a) "food hygiene", hereinafter called "hygiene", means the measures and conditions necessary to control hazards and to ensure fitness for human consumption of a foodstuff taking into account its intended use;

(b) "primary products" means products of primary production including products of the soil, of stock farming, of hunting and fishing;

(c) "establishment" means any unit of a food business;

(d) "competent authority" means the central authority of a Member State competent to ensure compliance with the requirements of this Regulation or any other authority to which that central authority has delegated that competence; it shall also include, where appropriate, the corresponding authority of a third country;

- (e) "equivalent" means, in respect of different systems, capable of meeting the same objectives;
- (f) "contamination" means the presence or introduction of a hazard;
- (g) "potable water" means water meeting the minimum requirements laid down in Council Directive 98/83/EC of 3 November 1998 on the quality of water intended for human consumption <sup>1</sup>;
- (h) "clean seawater" means natural, artificial or purified seawater or brackish water that does not contain micro-organisms, harmful substances or toxic marine plankton in quantities capable of directly or indirectly affecting the health quality of food;
- (i) "clean water" means clean seawater and fresh water of a similar quality;
- (j) "wrapping" means the placing of a foodstuff in a wrapper or container in direct contact with the foodstuff concerned, and the wrapper or container itself;
- (k) "packaging" means the placing of one or more wrapped foodstuffs in a second container, and the latter container itself;
- (l) "hermetically sealed container" means a container that is designed and intended to be secure against the entry of hazards;

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<sup>1</sup> OJ L 330, 5.12.1998, p. 32. Directive as modified by Regulation (EC) No 1882/2003.

- (m) "processing" means any action that substantially alters the initial product, including heating, smoking, curing, maturing, drying, marinating, extraction, extrusion or a combination of those processes;
- (n) "unprocessed products" means foodstuffs that have not undergone processing, and includes products that have been divided, parted, severed, sliced, boned, minced, skinned, ground, cut, cleaned, trimmed, husked, milled, chilled, frozen, deep-frozen or thawed;
- (o) "processed products" means foodstuffs resulting from the processing of unprocessed products. These products may contain ingredients that are necessary for their manufacture or to give them specific characteristics.

2. The definitions laid down in Regulation (EC) No 178/2002 shall also apply.

3. In the Annexes to this Regulation the terms "where necessary", "where appropriate", "adequate" and "sufficient" shall mean respectively where necessary, where appropriate, adequate or sufficient to achieve the objectives of this Regulation.

## CHAPTER II

### FOOD BUSINESS OPERATORS' OBLIGATIONS

#### Article 3

##### General obligation

Food business operators shall ensure that all stages of production, processing and distribution of food under their control satisfy the relevant hygiene requirements laid down in this Regulation.

#### Article 4

##### General and specific hygiene requirements

1. Food business operators carrying out primary production and those associated operations listed in Annex I shall comply with the general hygiene provisions laid down in Part A of Annex I and any specific requirements provided for in Regulation (EC) No ...../2004 \*.
2. Food business operators carrying out any stage of production, processing and distribution of food after those stages to which paragraph 1 applies shall comply with the general hygiene requirements laid down in Annex II and any specific requirements provided for in Regulation (EC) No ...../2004 \*.

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\* Note to Official Journal: insert No of Regulation laying down specific hygiene rules for food of animal origin.

3. Food business operators shall, as appropriate, adopt the following specific hygiene measures:

- (a) compliance with microbiological criteria for foodstuffs;
- (b) procedures necessary to meet targets set to achieve the objectives of this Regulation;
- (c) compliance with temperature control requirements for foodstuffs;
- (d) maintenance of the cold chain;
- (e) sampling and analysis.

4. The criteria, requirements and targets referred to in paragraph 3 shall be adopted in accordance with the procedure referred to in Article 14(2).

Associated sampling and analysis methods shall be laid down in accordance with the same procedure.

5. When this Regulation, Regulation (EC) No ...../2004 \* and their implementing measures do not specify sampling or analysis methods, food business operators may use appropriate methods laid down in other Community or national legislation or, in the absence of such methods, methods that offer equivalent results to those obtained using the reference method, if they are scientifically validated in accordance with internationally recognised rules or protocols.
6. Food business operators may use the guides provided for in Articles 7, 8 and 9 as an aid to compliance with their obligations under this Regulation.

#### Article 5

##### Hazard analysis and critical control points

1. Food business operators shall put in place, implement and maintain a permanent procedure or procedures based on the HACCP principles.
2. The HACCP principles referred to in paragraph 1 consist of the following:
  - (a) identifying any hazards that must be prevented, eliminated or reduced to acceptable levels;
  - (b) identifying the critical control points at the step or steps at which control is essential to prevent or eliminate a hazard or to reduce it to acceptable levels;

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\* Note to Official Journal: insert number of Regulation laying down specific hygiene rules for food of animal origin.

- (c) establishing critical limits at critical control points which separate acceptability from unacceptability for the prevention, elimination or reduction of identified hazards;
- (d) establishing and implementing effective monitoring procedures at critical control points;
- (e) establishing corrective actions when monitoring indicates that a critical control point is not under control;
- (f) establishing procedures, which shall be carried out regularly, to verify that the measures outlined in subparagraphs (a) to (e) are working effectively; and
- (g) establishing documents and records commensurate with the nature and size of the food business to demonstrate the effective application of the measures outlined in subparagraphs (a) to (f).

When any modification is made in the product, process, or any step, food business operators shall review the procedure and make the necessary changes to it.

3. Paragraph 1 shall apply only to food business operators carrying out any stage of production, processing and distribution of food after primary production and those associated operations listed in Annex I.



4. Food business operators shall:

- (a) provide the competent authority with evidence of their compliance with paragraph 1 in the manner that the competent authority requires, taking account of the nature and size of the food business;
- (b) ensure that any documents describing the procedures developed in accordance with this Article are up-to-date at all times;
- (c) retain any other documents and records for an appropriate period.

5. Detailed arrangements for the implementation of this Article may be laid down in accordance with the procedure referred to in Article 14(2). Such arrangements may facilitate the implementation of this Article by certain food business operators, in particular by providing for the use of procedures set out in guides for the application of HACCP principles, in order to comply with paragraph 1. Such arrangements may also specify the period during which food business operators shall retain documents and records in accordance with paragraph 4(c).

## Article 6

### Official controls, registration and approval

1. Food business operators shall cooperate with the competent authorities in accordance with other applicable Community legislation or, if it does not exist, with national law.

2. In particular, every food business operator shall notify the appropriate competent authority, in the manner that the latter requires, of each establishment under its control that carries out any of the stages of production, processing and distribution of food, with a view to the registration of each such establishment.

Food business operators shall also ensure that the competent authority always has up-to-date information on establishments, including by notifying any significant change in activities and any closure of an existing establishment.

3. However, food business operators shall ensure that establishments are approved by the competent authority, following at least one on-site visit, when approval is required:

- (a) under the national law of the Member State in which the establishment is located;
- (b) under Regulation (EC) No ...../2004<sup>\*</sup>; or
- (c) by a decision adopted in accordance with the procedure referred to in Article 14(2).

Any Member State requiring the approval of certain establishments located on its territory under national law, as provided for in subparagraph (a), shall inform the Commission and other Member States of the relevant national rules.

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\* Note to Official Journal: insert number of Regulation laying down specific hygiene rules for food of animal origin.

## CHAPTER III

### GUIDES TO GOOD PRACTICE

#### Article 7

##### Development, dissemination and use of guides

Member States shall encourage the development of national guides to good practice for hygiene and for the application of HACCP principles in accordance with Article 8. Community guides shall be developed in accordance with Article 9.

The dissemination and use of both national and Community guides shall be encouraged. Nevertheless, food business operators may use these guides on a voluntary basis.

#### Article 8

##### National guides

1. When national guides to good practice are developed, they shall be developed and disseminated by food business sectors:
  - (a) in consultation with representatives of parties whose interests may be substantially affected, such as competent authorities and consumer groups;

- (b) having regard to relevant codes of practice of the Codex Alimentarius; and
  - (c) when they concern primary production and those associated operations listed in Annex I, having regard to the recommendations set out in Part B of Annex I.
2. National guides may be developed under the aegis of a national standards institute referred to in Annex II to Directive 98/34/EC<sup>1</sup>.
3. Member States shall assess national guides in order to ensure that:
- (a) they have been developed in accordance with paragraph 1;
  - (b) their contents are practicable for the sectors to which they refer; and
  - (c) they are suitable as guides to compliance with Articles 3, 4 and 5 in the sectors and for the foodstuffs covered.
4. Member States shall forward to the Commission national guides complying with the requirements of paragraph 3. The Commission shall set up and run a registration system for such guides and make it available to Member States.
5. Guides to good practice drawn up under Directive 93/43/EEC shall continue to apply after the entry into force of this Regulation, provided that they are compatible with its objectives.

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<sup>1</sup> Directive 98/34/EC of the European Parliament and of the Council of 22 June 1998 laying down a procedure for the provision of information in the field of technical standards and regulations (OJ L 204, 21.7.1998, p. 37). Directive as amended by Directive 98/48/EC (OJ L 217, 5.8.1998, p. 18).

## Article 9

### Community guides

1. Before Community guides to good practice for hygiene or for the application of the HACCP principles are developed, the Commission shall consult the Committee referred to in Article 14. The objective of this consultation shall be to consider the case for such guides, their scope and subject matter.
  
2. When Community guides are prepared, the Commission shall ensure that they are developed and disseminated:
  - (a) by or in consultation with appropriate representatives of European food business sectors, including SMEs, and other interested parties, such as consumer groups;
  - (b) in collaboration with parties whose interests may be substantially affected, including competent authorities;
  - (c) having regard to relevant codes of practice of the Codex Alimentarius; and
  - (d) when they concern primary production and those associated operations listed in Annex I, having regard to the recommendations set out in Part B of Annex I.

3. The Committee referred to in Article 14 shall assess draft Community guides in order to ensure that:

- (a) they have been developed in accordance with paragraph 2;
- (b) their contents are practicable for the sectors to which they refer throughout the Community;  
and
- (c) they are suitable as guides to compliance with Articles 3, 4 and 5 in the sectors and for the foodstuffs covered.

4. The Commission shall invite the Committee referred to in Article 14 periodically to review any Community guides prepared in accordance with this Article, in cooperation with the bodies mentioned in paragraph 2.

The aim of this review shall be to ensure that the guides remain practicable and to take account of technological and scientific developments.

5. The titles and references of Community guides prepared in accordance with this Article shall be published in the C series of the Official Journal of the European Union.

## CHAPTER IV

### IMPORTS AND EXPORTS

#### Article 10

##### Imports

As regards the hygiene of imported food, the relevant requirements of food law referred to in Article 11 of Regulation (EC) No 178/2002 shall include the requirements laid down in Articles 3 to 6 of this Regulation.

#### Article 11

##### Exports

As regards the hygiene of exported or re-exported food, the relevant requirements of food law referred to in Article 12 of Regulation (EC) No 178/2002 shall include the requirements laid down in Articles 3 to 6 of this Regulation.

## CHAPTER V

### FINAL PROVISIONS

#### Article 12

##### Implementing measures and transitional arrangements

Implementing measures and transitional arrangements may be laid down in accordance with the procedure referred to in Article 14(2).

#### Article 13

##### Amendment and adaptation of Annexes I and II

1. Annexes I and II may be adapted or updated in accordance with the procedure referred to in Article 14(2), taking into account:
  - (a) the need to revise the recommendations set out in Annex I, Part B, paragraph 2;
  - (b) the experience gained from the implementation of HACCP-based systems pursuant to Article 5;
  - (c) technological developments and their practical consequences and consumer expectations with regard to food composition;



(d) scientific advice, particularly new risk assessments;

(e) microbiological and temperature criteria for foodstuffs.

2. Derogations from Annexes I and II may be granted, in particular in order to facilitate the implementation of Article 5 for small businesses, in accordance with the procedure referred to in Article 14(2), taking into account the relevant risk factors, provided that such derogations do not affect the achievement of the objectives of this Regulation.

3. Member States may, without compromising achievement of the objectives of this Regulation, adopt, in accordance with paragraphs 4 to 7 of this Article, national measures adapting the requirements laid down in Annex II.

4.(a) The national measures referred to in paragraph 3 shall 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 situated in regions that are subject to special geographical constraints.

(b) In other cases, they shall apply only to the construction, layout and equipment of establishments.

5. Any Member State wishing to adopt national measures as referred to in paragraph 3 shall notify the Commission and 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 foodstuffs and 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.

6. The other Member States shall have three months from the receipt of a notification referred to in paragraph 5 to send written comments to the Commission. In the case of the adaptations arising from paragraph 4(b), this period shall, at the request of any Member State, be extended to four months. The Commission may, and when it receives written comments from one or more Member States shall, consult Member States within the committee referred to in Article 14(1). The Commission may decide, in accordance with the procedure referred to in Article 14(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 paragraph 1 or 2.

7. A Member State may adopt national measures adapting the requirements of Annex II only:
- (a) in compliance with a decision adopted in accordance with paragraph 6; or
  - (b) if, one month after the expiry of the period referred to in paragraph 6, the Commission has not informed Member States that it has received written comments or that it intends to propose the adoption of a decision in accordance with paragraph 6.

#### Article 14

##### Committee procedure

1. The Commission shall be assisted by the Standing Committee on the Food Chain and Animal Health.
2. Where reference is made to this paragraph, Articles 5 and 7 of Decision 1999/468/EC shall apply, having regard to the provisions of Article 8 thereof.

The period laid down in Article 5(6) of Decision 1999/468/EC shall be set at three months.

3. The Committee shall adopt its rules of procedure.

## Article 15

### Consultation of the European Food Safety Authority

The Commission shall consult the European Food Safety Authority on any matter falling within the scope of this Regulation that could have a significant impact on public health and, in particular, before proposing criteria, requirements or targets in accordance with Article 4(4).

## Article 16

### Report to the European Parliament and the Council

1. The Commission shall, not later than .....<sup>\*</sup>, submit a report to the European Parliament and the Council.
2. The report shall, in particular, review the experience gained from the application of this Regulation and consider whether it would be desirable and practicable to provide for the extension of the requirements of Article 5 to food business operators carrying out primary production and those associated operations listed in Annex I.
3. The Commission shall, if appropriate, accompany the report with relevant proposals.

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<sup>\*</sup> Five years after the entry into force of this Regulation.

## Article 17

### Repeal

1. Directive 93/43/EEC shall be repealed with effect from the date of application of this Regulation.
2. References to the repealed Directive shall be construed as being made to this Regulation.
3. However, decisions adopted pursuant to Articles 3(3) and 10 of Directive 93/43/EEC shall remain in force pending their replacement by decisions adopted in accordance with this Regulation or Regulation (EC) No 178/2002. Pending the setting of the criteria or requirements referred to in Article 4(3), points (a) to (e) of this Regulation, Member States may maintain any national rules establishing such criteria or requirements that they had adopted in accordance with Directive 93/43/EEC.
4. Pending the application of new Community legislation laying down rules for official controls on food, Member States shall take all appropriate measures to ensure the fulfilment of the obligations laid down in or under this Regulation.

## Article 18

### Entry into force

This Regulation shall enter into force twenty days after the date of its publication in the Official Journal of the European Union.

It shall apply 18 months after the date on which all of the following acts have entered into force:

- (a) Regulation (EC) No .../2004 \*;
- (b) Regulation (EC) No .../2004 of the European Parliament and of the Council of ..... laying down specific rules for the organisation of official controls on products of animal origin intended for human consumption <sup>1</sup>; and
- (c) Directive 2004/41/EC of the European Parliament and of the Council of ..... repealing certain Directives concerning food hygiene and health conditions for the production and placing on the market of certain products of animal origin intended for human consumption <sup>2</sup>.

However, it shall apply no earlier than 1 January 2006.

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

Done at Strasbourg, 29 April 2004.

For the European Parliament  
The President  
P. COX

For the Council  
The President  
M. McDOWELL

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\* Note to Official Journal: insert number of Regulation laying down specific hygiene rules for food of animal origin.

<sup>1</sup> See p. of this Official Journal.

<sup>2</sup> See p. of this Official Journal.

PRIMARY PRODUCTION

PART A: GENERAL HYGIENE PROVISIONS FOR PRIMARY PRODUCTION AND ASSOCIATED OPERATIONS

I. SCOPE

1. This Annex applies to primary production and the following associated operations:
  - (a) the transport, storage and handling of primary products at the place of production, provided that this does not substantially alter their nature;
  - (b) the transport of live animals, where this is necessary to achieve the objectives of this Regulation; and
  - (c) in the case of products of plant origin, fishery products and wild game, transport operations to deliver primary products, the nature of which has not been substantially altered, from the place of production to an establishment.

II. HYGIENE PROVISIONS

2. As far as possible, food business operators are to ensure that primary products are protected against contamination, having regard to any processing that primary products will subsequently undergo.

3. Notwithstanding the general duty laid down in paragraph 2, food business operators are to comply with appropriate Community and national legislative provisions relating to the control of hazards in primary production and associated operations, including:
  - (a) measures to control contamination arising from the air, soil, water, feed, fertilisers, veterinary medicinal products, plant protection products and biocides and the storage, handling and disposal of waste; and
  - (b) measures relating to animal health and welfare and plant health that have implications for human health, including programmes for the monitoring and control of zoonoses and zoonotic agents.
  
4. Food business operators rearing, harvesting or hunting animals or producing primary products of animal origin are to take adequate measures, as appropriate:
  - (a) to keep any facilities used in connection with primary production and associated operations, including facilities used to store and handle feed, clean and, where necessary after cleaning, to disinfect them in an appropriate manner;
  - (b) to keep clean and, where necessary after cleaning, to disinfect, in an appropriate manner, equipment, containers, crates, vehicles and vessels;



- (c) as far as possible to ensure the cleanliness of animals going to slaughter and, where necessary, production animals;
- (d) to use potable water, or clean water, whenever necessary to prevent contamination;
- (e) to ensure that staff handling foodstuffs are in good health and undergo training on health risks;
- (f) as far as possible to prevent animals and pests from causing contamination;
- (g) to store and handle waste and hazardous substances so as to prevent contamination;
- (h) to prevent the introduction and spread of contagious diseases transmissible to humans through food, including by taking precautionary measures when introducing new animals and reporting suspected outbreaks of such diseases to the competent authority;
- (i) to take account of the results of any relevant analyses carried out on samples taken from animals or other samples that have importance to human health; and
- (j) to use feed additives and veterinary medicinal products correctly, as required by the relevant legislation.

5. Food business operators producing or harvesting plant products are to take adequate measures, as appropriate:
  - (a) to keep clean and, where necessary after cleaning, to disinfect, in an appropriate manner, facilities, equipment, containers, crates, vehicles and vessels;
  - (b) to ensure, where necessary, hygienic production, transport and storage conditions for, and the cleanliness of, plant products;
  - (c) to use potable water, or clean water, whenever necessary to prevent contamination;
  - (d) to ensure that staff handling foodstuffs are in good health and undergo training on health risks;
  - (e) as far as possible to prevent animals and pests from causing contamination;
  - (f) to store and handle wastes and hazardous substances so as to prevent contamination;
  - (g) to take account of the results of any relevant analyses carried out on samples taken from plants or other samples that have importance to human health; and
  - (h) to use plant protection products and biocides correctly, as required by the relevant legislation.

6. Food business operators are to take appropriate remedial action when informed of problems identified during official controls.

### III. RECORD-KEEPING

7. Food business operators are to keep and retain records relating to measures put in place to control hazards in an appropriate manner and for an appropriate period, commensurate with the nature and size of the food business. Food business operators are to make relevant information contained in these records available to the competent authority and receiving food business operators on request.
8. Food business operators rearing animals or producing primary products of animal origin are, in particular, to keep records on:
  - (a) the nature and origin of feed fed to the animals;
  - (b) veterinary medicinal products or other treatments administered to the animals, dates of administration and withdrawal periods;
  - (c) the occurrence of diseases that may affect the safety of products of animal origin;
  - (d) the results of any analyses carried out on samples taken from animals or other samples taken for diagnostic purposes, that have importance for human health; and
  - (e) any relevant reports on checks carried out on animals or products of animal origin.

9. Food business operators producing or harvesting plant products are, in particular, to keep records on:
  - (a) any use of plant protection products and biocides;
  - (b) any occurrence of pests or diseases that may affect the safety of products of plant origin;  
and
  - (c) the results of any relevant analyses carried out on samples taken from plants or other samples that have importance to human health.
  
10. The food business operators may be assisted by other persons, such as veterinarians, agronomists and farm technicians, with the keeping of records.

## PART B: RECOMMENDATIONS FOR GUIDES TO GOOD HYGIENE PRACTICE

1. National and Community guides referred to in Articles 7 to 9 of this Regulation should contain guidance on good hygiene practice for the control of hazards in primary production and associated operations.
2. Guides to good hygiene practice should include appropriate information on hazards that may arise in primary production and associated operations and actions to control hazards, including relevant measures set out in Community and national legislation or national and Community programmes. Examples of such hazards and measures may include:
  - (a) the control of contamination such as mycotoxins, heavy metals and radioactive material;
  - (b) the use of water, organic waste and fertilisers;
  - (c) the correct and appropriate use of plant protection products and biocides and their traceability;
  - (d) the correct and appropriate use of veterinary medicinal products and feed additives and their traceability;
  - (e) the preparation, storage, use and traceability of feed;

- (f) the proper disposal of dead animals, waste and litter;
  - (g) protective measures to prevent the introduction of contagious diseases transmissible to humans through food, and any obligation to notify the competent authority;
  - (h) procedures, practices and methods to ensure that food is produced, handled, packed, stored and transported under appropriate hygienic conditions, including effective cleaning and pest-control;
  - (i) measures relating to the cleanliness of slaughter and production animals;
  - (j) measures relating to record-keeping.
-

GENERAL HYGIENE REQUIREMENTS FOR ALL FOOD BUSINESS OPERATORS  
(EXCEPT WHEN ANNEX I APPLIES)

INTRODUCTION

Chapters V to XII apply to all stages of production, processing and distribution of food and the remaining Chapters apply as follows:

- Chapter I applies to all food premises, except premises to which Chapter III applies;
- Chapter II applies to all rooms where food is prepared, treated or processed, except dining areas and premises to which Chapter III applies;
- Chapter III applies to those premises listed in the heading to the Chapter;
- Chapter IV applies to all transportation.

CHAPTER I

GENERAL REQUIREMENTS FOR FOOD PREMISES  
(OTHER THAN THOSE SPECIFIED IN CHAPTER III)

1. Food premises are to be kept clean and maintained in good repair and condition.

2. The layout, design, construction, siting and size of food premises are to:
  - (a) permit adequate maintenance, cleaning and/or disinfection, avoid or minimise air-borne contamination, and provide adequate working space to allow for the hygienic performance of all operations;
  - (b) be such as to protect against the accumulation of dirt, contact with toxic materials, the shedding of particles into food and the formation of condensation or undesirable mould on surfaces;
  - (c) permit good food hygiene practices, including protection against contamination and, in particular, pest control; and
  - (d) where necessary, provide suitable temperature-controlled handling and storage conditions of sufficient capacity for maintaining foodstuffs at appropriate temperatures and designed to allow those temperatures to be monitored and, where necessary, recorded.
3. An adequate number of flush lavatories are to be available and connected to an effective drainage system. Lavatories are not to open directly into rooms in which food is handled.
4. An adequate number of washbasins is to be available, suitably located and designated for cleaning hands. Washbasins for cleaning hands are to be provided with hot and cold running water, materials for cleaning hands and for hygienic drying. Where necessary, the facilities for washing food are to be separate from the hand-washing facility.



5. There is to be suitable and sufficient means of natural or mechanical ventilation. Mechanical airflow from a contaminated area to a clean area is to be avoided. Ventilation systems are to be so constructed as to enable filters and other parts requiring cleaning or replacement to be readily accessible.
6. Sanitary conveniences are to have adequate natural or mechanical ventilation.
7. Food premises are to have adequate natural and/or artificial lighting.
8. Drainage facilities are to be adequate for the purpose intended. They are to be designed and constructed to avoid the risk of contamination. Where drainage channels are fully or partially open, they are to be so designed as to ensure that waste does not flow from a contaminated area towards or into a clean area, in particular an area where foods likely to present a high risk to the final consumer are handled.
9. Where necessary, adequate changing facilities for personnel are to be provided.
10. Cleaning agents and disinfectants are not to be stored in areas where food is handled.

## CHAPTER II

### SPECIFIC REQUIREMENTS IN ROOMS WHERE FOODSTUFFS ARE PREPARED, TREATED OR PROCESSED (EXCLUDING DINING AREAS AND THOSE PREMISES SPECIFIED IN CHAPTER III)

1. In rooms where food is prepared, treated or processed (excluding dining areas and those premises specified in Chapter III, but including rooms contained in means of transport) the design and layout are to permit good food hygiene practices, including protection against contamination between and during operations. In particular:
  - (a) floor surfaces are to be maintained in a sound condition and be easy to clean and, where necessary, to disinfect. This will require the use of impervious, non-absorbent, washable and non-toxic materials unless food business operators can satisfy the competent authority that other materials used are appropriate. Where appropriate, floors are to allow adequate surface drainage;
  - (b) wall surfaces are to be maintained in a sound condition and be easy to clean and, where necessary, to disinfect. This will require the use of impervious, non-absorbent, washable and non-toxic materials and require a smooth surface up to a height appropriate for the operations unless food business operators can satisfy the competent authority that other materials used are appropriate;
  - (c) ceilings (or, where there are no ceilings, the interior surface of the roof) and overhead fixtures are to be constructed and finished so as to prevent the accumulation of dirt and to reduce condensation, the growth of undesirable mould and the shedding of particles;

- (d) windows and other openings are to be constructed to prevent the accumulation of dirt. Those which can be opened to the outside environment are, where necessary, to be fitted with insect-proof screens which can be easily removed for cleaning. Where open windows would result in contamination, windows are to remain closed and fixed during production;
  - (e) doors are to be easy to clean and, where necessary, to disinfect. This will require the use of smooth and non-absorbent surfaces unless food business operators can satisfy the competent authority that other materials used are appropriate; and
  - (f) surfaces (including surfaces of equipment) in areas where foods are handled and in particular those in contact with food are to be maintained in a sound condition and be easy to clean and, where necessary, to disinfect. This will require the use of smooth, washable corrosion-resistant and non-toxic materials, unless food business operators can satisfy the competent authority that other materials used are appropriate.
2. Adequate facilities are to be provided, where necessary, for the cleaning, disinfecting and storage of working utensils and equipment. These facilities are to be constructed of corrosion-resistant materials, be easy to clean and have an adequate supply of hot and cold water.
  3. Adequate provision is to be made, where necessary, for washing food. Every sink or other such facility provided for the washing of food is to have an adequate supply of hot and/or cold potable water consistent with the requirements of Chapter VII and be kept clean and, where necessary, disinfected.

## CHAPTER III

### REQUIREMENTS FOR MOVABLE AND/OR TEMPORARY PREMISES (SUCH AS MARQUEES, MARKET STALLS, MOBILE SALES VEHICLES), PREMISES USED PRIMARILY AS A PRIVATE DWELLING HOUSE BUT WHERE FOODS ARE REGULARLY PREPARED FOR PLACING ON THE MARKET, AND VENDING MACHINES

1. Premises and vending machines are, so far as is reasonably practicable, to be so sited, designed, constructed and kept clean and maintained in good repair and condition as to avoid the risk of contamination, in particular by animals and pests.
2. In particular, where necessary:
  - (a) appropriate facilities are to be available to maintain adequate personal hygiene (including facilities for the hygienic washing and drying of hands, hygienic sanitary arrangements and changing facilities);
  - (b) surfaces in contact with food are to be in a sound condition and be easy to clean and, where necessary, to disinfect. This will require the use of smooth, washable, corrosion-resistant and non-toxic materials, unless food business operators can satisfy the competent authority that other materials used are appropriate;
  - (c) adequate provision is to be made for the cleaning and, where necessary, disinfecting of working utensils and equipment;

- (d) where foodstuffs are cleaned as part of the food business' operations, adequate provision is to be made for this to be undertaken hygienically;
- (e) an adequate supply of hot and/or cold potable water is to be available;
- (f) adequate arrangements and/or facilities for the hygienic storage and disposal of hazardous and/or inedible substances and waste (whether liquid or solid) are to be available;
- (g) adequate facilities and/or arrangements for maintaining and monitoring suitable food temperature conditions are to be available;
- (h) foodstuffs are to be so placed as to avoid the risk of contamination so far as is reasonably practicable.

## CHAPTER IV

### TRANSPORT

1. Conveyances and/or containers used for transporting foodstuffs are to be kept clean and maintained in good repair and condition to protect foodstuffs from contamination and are, where necessary, to be designed and constructed to permit adequate cleaning and/or disinfection.

2. Receptacles in vehicles and/or containers are not to be used for transporting anything other than foodstuffs where this may result in contamination.
3. Where conveyances and/or containers are used for transporting anything in addition to foodstuffs or for transporting different foodstuffs at the same time, there is, where necessary, to be effective separation of products.
4. Bulk foodstuffs in liquid, granulate or powder form are to be transported in receptacles and/or containers/tankers reserved for the transport of foodstuffs. Such containers are to be marked in a clearly visible and indelible fashion, in one or more Community languages, to show that they are used for the transport of foodstuffs, or are to be marked "for foodstuffs only".
5. Where conveyances and/or containers have been used for transporting anything other than foodstuffs or for transporting different foodstuffs, there is to be effective cleaning between loads to avoid the risk of contamination.
6. Foodstuffs in conveyances and/or containers are to be so placed and protected as to minimise the risk of contamination.
7. Where necessary, conveyances and/or containers used for transporting foodstuffs are to be capable of maintaining foodstuffs at appropriate temperatures and allow those temperatures to be monitored.

## CHAPTER V

### EQUIPMENT REQUIREMENTS

1. All articles, fittings and equipment with which food comes into contact are to:
  - (a) be effectively cleaned and, where necessary, disinfected. Cleaning and disinfection are to take place at a frequency sufficient to avoid any risk of contamination;
  - (b) be so constructed, be of such materials and be kept in such good order, repair and condition as to minimise any risk of contamination;
  - (c) with the exception of non-returnable containers and packaging, be so constructed, be of such materials and be kept in such good order, repair and condition as to enable them to be kept clean and, where necessary, to be disinfected; and
  - (d) be installed in such a manner as to allow adequate cleaning of the equipment and the surrounding area.
2. Where necessary, equipment is to be fitted with any appropriate control device to guarantee fulfilment of this Regulation's objectives.
3. Where chemical additives have to be used to prevent corrosion of equipment and containers, they are to be used in accordance with good practice.

## CHAPTER VI

### FOOD WASTE

1. Food waste, non-edible by-products and other refuse are to be removed from rooms where food is present as quickly as possible, so as to avoid their accumulation.
2. Food waste, non-edible by-products and other refuse are to be deposited in closable containers, unless food business operators can demonstrate to the competent authority that other types of containers or evacuation systems used are appropriate. These containers are to be of an appropriate construction, kept in sound condition, be easy to clean and, where necessary, to disinfect.
3. Adequate provision is to be made for the storage and disposal of food waste, non-edible by-products and other refuse. Refuse stores are to be designed and managed in such a way as to enable them to be kept clean and, where necessary, free of animals and pests.
4. All waste is to be eliminated in a hygienic and environmentally friendly way in accordance with Community legislation applicable to that effect, and is not to constitute a direct or indirect source of contamination.

## CHAPTER VII

### WATER SUPPLY

1. (a) There is to be an adequate supply of potable water, which is to be used whenever necessary to ensure that foodstuffs are not contaminated;



- (b) Clean water may be used with whole fishery products. Clean seawater may be used with live bivalve molluscs, echinoderms, tunicates and marine gastropods; clean water may also be used for external washing. When such water is used, adequate facilities are to be available for its supply.
  
- 2. Where non-potable water is used, for example for fire control, steam production, refrigeration and other similar purposes, it is to circulate in a separate duly identified system. Non-potable water is not to connect with, or allow reflux into, potable water systems.
  
- 3. Recycled water used in processing or as an ingredient is not to present a risk of contamination. It is to be of the same standard as potable water, unless the competent authority is satisfied that the quality of the water cannot affect the wholesomeness of the foodstuff in its finished form.
  
- 4. Ice which comes into contact with food or which may contaminate food is to be made from potable water or, when used to chill whole fishery products, clean water. It is to be made, handled and stored under conditions that protect it from contamination.
  
- 5. Steam used directly in contact with food is not to contain any substance that presents a hazard to health or is likely to contaminate the food.
  
- 6. Where heat treatment is applied to foodstuffs in hermetically sealed containers it is to be ensured that water used to cool the containers after heat treatment is not a source of contamination for the foodstuff.

## CHAPTER VIII

### PERSONAL HYGIENE

1. Every person working in a food-handling area is to maintain a high degree of personal cleanliness and is to wear suitable, clean and, where necessary, protective clothing.
2. No person suffering from, or being a carrier of a disease likely to be transmitted through food or afflicted, for example, with infected wounds, skin infections, sores or diarrhoea is to be permitted to handle food or enter any food-handling area in any capacity if there is any likelihood of direct or indirect contamination. Any person so affected and employed in a food business and who is likely to come into contact with food is to report immediately the illness or symptoms, and if possible their causes, to the food business operator.

## CHAPTER IX

### PROVISIONS APPLICABLE TO FOODSTUFFS

1. A food business operator is not to accept raw materials or ingredients, other than live animals, or any other material used in processing products, if they are known to be, or might reasonably be expected to be, contaminated with parasites, pathogenic microorganisms or toxic, decomposed or foreign substances to such an extent that, even after the food business operator had hygienically applied normal sorting and/or preparatory or processing procedures, the final product would be unfit for human consumption.

2. Raw materials and all ingredients stored in a food business are to be kept in appropriate conditions designed to prevent harmful deterioration and protect them from contamination.
3. At all stages of production, processing and distribution, food is to be protected against any contamination likely to render the food unfit for human consumption, injurious to health or contaminated in such a way that it would be unreasonable to expect it to be consumed in that state.
4. Adequate procedures are to be in place to control pests. Adequate procedures are also to be in place to prevent domestic animals from having access to places where food is prepared, handled or stored (or, where the competent authority so permits in special cases, to prevent such access from resulting in contamination).
5. Raw materials, ingredients, intermediate products and finished products likely to support the reproduction of pathogenic micro-organisms or the formation of toxins are not to be kept at temperatures that might result in a risk to health. The cold chain is not to be interrupted. However, limited periods outside temperature control are permitted, to accommodate the practicalities of handling during preparation, transport, storage, display and service of food, provided that it does not result in a risk to health. Food businesses manufacturing, handling and wrapping processed foodstuffs are to have suitable rooms, large enough for the separate storage of raw materials from processed material and sufficient separate refrigerated storage.
6. Where foodstuffs are to be held or served at chilled temperatures they are to be cooled as quickly as possible following the heat-processing stage, or final preparation stage if no heat process is applied, to a temperature which does not result in a risk to health.

7. The thawing of foodstuffs is to be undertaken in such a way as to minimise the risk of growth of pathogenic microorganisms or the formation of toxins in the foods. During thawing, foods are to be subjected to temperatures that would not result in a risk to health. Where run-off liquid from the thawing process may present a risk to health it is to be adequately drained. Following thawing, food is to be handled in such a manner as to minimise the risk of growth of pathogenic microorganisms or the formation of toxins.
8. Hazardous and/or inedible substances, including animal feed, are to be adequately labelled and stored in separate and secure containers.

## CHAPTER X

### PROVISIONS APPLICABLE TO THE WRAPPING AND PACKAGING OF FOODSTUFFS

1. Material used for wrapping and packaging are not to be a source of contamination.
2. Wrapping materials are to be stored in such a manner that they are not exposed to a risk of contamination.
3. Wrapping and packaging operations are to be carried out so as to avoid contamination of the products. Where appropriate and in particular in the case of cans and glass jars, the integrity of the container's construction and its cleanliness is to be assured.
4. Wrapping and packaging material re-used for foodstuffs is to be easy to clean and, where necessary, to disinfect.

## CHAPTER XI

### HEAT TREATMENT

The following requirements apply only to food placed on the market in hermetically sealed containers:

1. any heat treatment process used to process an unprocessed product or to process further a processed product is:
  - (a) to raise every party of the product treated to a given temperature for a given period of time; and
  - (b) to prevent the product from becoming contaminated during the process;
2. to ensure that the process employed achieves the desired objectives, food business operators are to check regularly the main relevant parameters (particularly temperature, pressure, sealing and microbiology), including by the use of automatic devices;
3. the process used should conform to an internationally recognised standard (for example, pasteurisation, ultra high temperature or sterilisation).

## CHAPTER XII

### TRAINING

Food business operators are to ensure:

1. that food handlers are supervised and instructed and/or trained in food hygiene matters commensurate with their work activity;
  2. that those responsible for the development and maintenance of the procedure referred to in Article 5(1) of this Regulation or for the operation of relevant guides have received adequate training in the application of the HACCP principles; and
  3. compliance with any requirements of national law concerning training programmes for persons working in certain food sectors.
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**REGULATION (EC) No 853/2004 OF THE EUROPEAN PARLIAMENT  
AND OF THE COUNCIL  
of 29 April 2004**

**laying down specific hygiene rules for  
on the hygiene of foodstuffs**

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

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

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

Having regard to the Opinion of the European Economic and Social Committee <sup>†</sup>,

Having consulted the Committee of the Regions,

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

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<sup>\*</sup> OJ C 365 E, 19.12.2000, p. 58.

<sup>†</sup> OJ C 155, 29.5.2001, p. 39.

<sup>‡</sup> Opinion of the European Parliament of 15 May 2002 (OJ C 180 E, 31.7.2003, p. 288), Council Common Position of 27 October 2003 (OJ C 48 E, 24.2.2004, p. 23), Position of the European Parliament of 30 March 2004 (not yet published in the Official Journal) and Council Decision of 16 April 2004.

Whereas:

- (1) By Regulation (EC) No /2004<sup>\*</sup>, the European Parliament and the Council laid down general rules for food business operators on the hygiene of foodstuffs.
- (2) Certain foodstuffs may present specific hazards to human health, requiring the setting of specific hygiene rules. This is particularly the case for food of animal origin, in which microbiological and chemical hazards have frequently been reported.
- (3) In the context of the common agricultural policy, many Directives have been adopted to establish specific health rules for the production and placing on the market of the products listed in Annex I to the Treaty. These health rules have reduced trade barriers for the products concerned, contributing to the creation of the internal market while ensuring a high level of protection of public health.
- (4) With regard to public health, these rules contain common principles, in particular in relation to the manufacturers' and competent authorities' responsibilities, structural, operational and hygiene requirements for establishments, procedures for the approval of establishments, requirements for storage and transport and health marks.
- (5) These principles constitute a common basis for the hygienic production of food of animal origin, permitting the simplification of the existing Directives.
- (6) It is desirable to achieve further simplification by applying the same rules wherever appropriate to all products of animal origin.

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\* Page ... of this Official Journal.



- (7) The requirement in Regulation (EC) No /2004 \* whereby food business operators carrying out any stage of production, processing and distribution of food after primary production and associated operations must put in place, implement and maintain procedures based on hazard analysis and critical control point (HACCP) principles also permits simplification.
- (8) Taken together, these elements justify a recasting of the specific hygiene rules contained in existing Directives.
- (9) The principal objectives of the recasting are to secure a high level of consumer protection with regard to food safety, in particular by making food business operators throughout the Community subject to the same rules, and to ensure the proper functioning of the internal market in products of animal origin, thus contributing to the achievement of the objectives of the common agricultural policy.
- (10) It is necessary to maintain and, where required to ensure consumer protection, to tighten detailed hygiene rules for products of animal origin.
- (11) Community rules should not apply either to primary production for private domestic use or to the domestic preparation, handling or storage of food for private domestic consumption. Moreover, where small quantities of primary products or of certain types of meat are supplied directly by the food business operator producing them to the final consumer or to a local retail establishment, it is appropriate to protect public health through national law, in particular because of the close relationship between the producer and the consumer.

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\* Official Publications Office is to insert official number of Regulation on the hygiene of foodstuffs (as in recital 1).

- (12) The requirements of Regulation (EC) No /2004 \* are generally sufficient to ensure food safety in establishments carrying out retail activities involving the direct sale or supply of food of animal origin to the final consumer. This Regulation should generally apply to wholesale activities (that is, when a retail establishment carries out operations with a view to supplying food of animal origin to another establishment). Nevertheless, with the exception of the specific temperature requirements laid down in this Regulation, the requirements of Regulation (EC) No /2004 \* should suffice for wholesale activities consisting only of storage or transport.
- (13) Member States should have some discretion to extend or to limit the application of the requirements of this Regulation to retail under national law. However, they may limit their application only if they consider that the requirements of Regulation (EC) No /2004 \* are sufficient to achieve food hygiene objectives and when the supply of food of animal origin from a retail establishment to another establishment is a marginal, localised and restricted activity. Such supply should therefore be only a small part of the establishment's business; the establishments supplied should be situated in its immediate vicinity; and the supply should concern only certain types of products or establishments.

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\* Official Publications Office is to insert official number of Regulation on the hygiene of foodstuffs (as in recital 1).

- (14) In accordance with Article 10 of the Treaty, Member States are to take all appropriate measures to ensure that food business operators comply with the obligations laid down in this Regulation.
- (15) The traceability of food is an essential element in ensuring food safety. In addition to complying with the general rules of Regulation (EC) No 178/2002<sup>\*</sup>, food business operators responsible for establishments that are subject to approval in accordance with this Regulation should ensure that all products of animal origin that they place on the market bear either a health mark or an identification mark.
- (16) Food imported into the Community is to comply with the general requirements laid down in Regulation (EC) No 178/2002 or to satisfy rules that are equivalent to Community rules. This Regulation defines specific hygiene requirements for food of animal origin imported into the Community.

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\* Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 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 (OJ L 31, 1.2.2002, p. 1). Regulation as amended by Regulation (EC) No 1642/2003 (OJ L 245, 29.9.2003, p.4).

- (17) The adoption of this Regulation should not reduce the level of protection provided by the additional guarantees agreed for Finland and Sweden on their accession to the Community and confirmed by Decisions 94/968/EC <sup>\*</sup>, 95/50/EC <sup>†</sup>, 95/160/EC <sup>‡</sup>, 95/161/EC <sup>§</sup>, 95/168/EC <sup>\*\*</sup>, 95/409/EC <sup>††</sup>, 95/410/EC <sup>‡‡</sup> and 95/411/EC <sup>§§</sup>. It should establish a procedure for the granting, for a transitional period, of guarantees to any Member State that has an approved national control programme which, for the food of animal origin concerned, is equivalent to those approved for Finland and Sweden. Regulation (EC) No 2160/2003 of the European Parliament and of the Council of 17 November 2003 on the control of salmonella and other specified food-borne zoonotic agents <sup>\*\*\*</sup> provides for a similar procedure in respect of live animals and hatching eggs.
- (18) It is appropriate for the structural and hygiene requirements laid down in this Regulation to apply to all types of establishments, including small businesses and mobile slaughterhouses.

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<sup>\*</sup> OJ L 371, 31.12.1994, p. 36.  
<sup>†</sup> OJ L 53, 9.3.1995, p. 31.  
<sup>‡</sup> OJ L 105 9.5.1995, p. 40.  
<sup>§</sup> OJ L 105, 9.5.1995, p. 44.  
<sup>\*\*</sup> OJ L 109, 16.5.1995, p. 44.  
<sup>††</sup> OJ L 243, 11.10.1995, p. 21.  
<sup>‡‡</sup> OJ L 243, 11.10.1995, p. 25.  
<sup>§§</sup> OJ L 243, 11.10.1995, p. 29.  
<sup>\*\*\*</sup> OJ L 325, 12.12.2003, p. 1.

- (19) Flexibility is appropriate to enable the continued use of traditional methods at any of the stages of production, processing or distribution of food and in relation to structural requirements for establishments. Flexibility is particularly important for regions that are subject to special geographical constraints, including the outermost regions referred to in Article 299(2) of the Treaty. However, flexibility should not compromise food hygiene objectives. Moreover, since all food produced in accordance with the hygiene rules will normally be in free circulation throughout the Community, the procedure allowing Member States to exercise flexibility should be fully transparent. It should provide, where necessary to resolve disagreements, for discussion within the Standing Committee on the Food Chain and Animal Health established by Regulation (EC) No 178/2002 and for the Commission to coordinate the process and take appropriate measures.
- (20) The definition of mechanically separated meat (MSM) should be a generic one covering all methods of mechanical separation. Rapid technological developments in this area mean that a flexible definition is appropriate. The technical requirements for MSM should differ, however, depending on a risk assessment of the product resulting from different methods.
- (21) There are interactions between food business operators, including the animal feed sector, and connections between animal health, animal welfare and public health considerations at all stages of production, processing and distribution. This requires adequate communication between the different stakeholders along the food chain from primary production to retail.

(22) In order to ensure proper inspection of hunted wild game placed on the Community market, bodies of hunted animals and their viscera should be presented for official post-mortem inspection at a game-handling establishment. However, to preserve certain hunting traditions without prejudicing food safety, it is appropriate to provide for training for hunters who place wild game on the market for human consumption. This should enable hunters to undertake an initial examination of wild game on the spot. In these circumstances, it is not necessary to require trained hunters to deliver all viscera to the game-handling establishment for post-mortem examination, if they carry out this initial examination and identify no anomalies or hazards. However, Member States should be allowed to establish stricter rules within their territories to take account of specific risks.

(23) This Regulation should establish criteria for raw milk pending the adoption of new requirements for its placing on the market. These criteria should be trigger values, implying that, in the event of any overshooting, food business operators are to take corrective action and to notify the competent authority. The criteria should not be maximum figures beyond which raw milk cannot be placed on the market. This implies that, in certain circumstances, raw milk not fully meeting the criteria can safely be used for human consumption, if appropriate measures are taken. As regards raw milk and raw cream intended for direct human consumption, it is appropriate to enable each Member State to maintain or establish appropriate health measures to ensure the achievement of the objectives of this Regulation on its territory.

- (24) It is appropriate for the criterion for raw milk used to manufacture dairy products to be three times as high as the criterion for raw milk collected from the farm. The criterion for milk used to manufacture processed dairy products is an absolute value, whereas for raw milk collected from the farm it is an average. Compliance with the temperature requirements laid down in this Regulation will not halt all bacterial growth during transport and storage.
- (25) The present recasting means that the existing hygiene rules can be repealed. Directive 2004/.../EC of the European Parliament and of the Council of ..... repealing certain Directives on food hygiene and health conditions for the production and placing on the market of certain products of animal origin intended for human consumption \* achieves this.
- (26) In addition, the rules of this Regulation on eggs replace those of Council Decision 94/371/EC of 20 June 1994 laying down specific public health conditions for the putting on the market of certain types of eggs †, which the repeal of Annex II to Council Directive 92/118/EEC ‡ renders void.
- (27) Scientific advice should underpin Community legislation on food hygiene. To this end, the European Food Safety Authority should be consulted whenever necessary.

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\* Page ... of this Official Journal.

† OJ L 168, 2.7.1994, p. 34.

‡ Council Directive 92/118/EEC of 17 December 1992 laying down animal health and public health requirements governing trade in and imports into the Community of products not subject to the said requirements laid down in specific Community rules referred to in Annex A (I) to Directive 89/662/EEC and, as regards pathogens, to Directive 90/425/EEC (OJ L 62, 15.3.1993, p. 49). Directive as last amended by Commission Regulation (EC) No 445/2004 (OJ L 72, 11.3.2004, p. 60).

- (28) To take account of technical and scientific progress, close and effective cooperation should be ensured between the Commission and the Member States within the Standing Committee on the Food Chain and Animal Health.
- (29) The requirements of this Regulation should not apply until all parts of the new legislation on food hygiene have entered into force. It is also appropriate to provide for at least 18 months to elapse between entry into force and the application of the new rules, to allow the industries affected time to adapt.
- (30) The measures necessary for the implementation of this Regulation should be adopted in accordance with Council Decision 1999/468/EC of 28 June 1999 laying down the procedures for the exercise of implementing powers conferred on the Commission<sup>\*</sup>,

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



HAVE ADOPTED THIS REGULATION:

## CHAPTER I

### GENERAL PROVISIONS

#### Article 1

##### Scope

1. This Regulation lays down specific rules on the hygiene of food of animal origin for food business operators. These rules supplement those laid down by Regulation (EC) No /2004<sup>\*</sup>. They shall apply to unprocessed and processed products of animal origin.
2. Unless expressly indicated to the contrary, this Regulation shall not apply to food containing both products of plant origin and processed products of animal origin. However, processed products of animal origin used to prepare such food shall be obtained and handled in accordance with the requirements of this Regulation.
3. This Regulation shall not apply in relation to:
  - (a) primary production for private domestic use;
  - (b) the domestic preparation, handling or storage of food for private domestic consumption;

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<sup>\*</sup> Official Publications Office is to insert official number of Regulation on the hygiene of foodstuffs.

- (c) the direct supply, by the producer, of small quantities of primary products to the final consumer or to local retail establishments directly supplying the final consumer;
- (d) the direct supply, by the producer, of small quantities of meat from poultry and lagomorphs slaughtered on the farm to the final consumer or to local retail establishments directly supplying such meat to the final consumer as fresh meat;
- (e) hunters who supply small quantities of wild game or wild game meat directly to the final consumer or to local retail establishments directly supplying the final consumer.

4. Member States shall establish, under national law, rules governing the activities and persons referred to in paragraph 3(c), (d) and (e). Such national rules shall ensure the achievement of the objectives of this Regulation.

- 5. (a) Unless expressly indicated to the contrary, this Regulation shall not apply to retail.
- (b) However, this Regulation shall apply to retail when operations are carried out with a view to the supply of food of animal origin to another establishment, unless:
  - (i) the operations consist only of storage or transport, in which case the specific temperature requirements laid down in Annex III shall nevertheless apply; or
  - (ii) the supply of food of animal origin from the retail establishment is to other retail establishments only and, in accordance with national law, is a marginal, localised and restricted activity.

- (c) Member States may adopt national measures to apply the requirements of this Regulation to retail establishments situated on their territory to which it would not apply pursuant to subparagraphs (a) or (b).
6. This Regulation shall apply without prejudice to:
- (a) relevant animal and public health rules, including more stringent rules laid down for the prevention, control and eradication of certain transmissible spongiform encephalopathies;
  - (b) animal welfare requirements; and
  - (c) requirements concerning the identification of animals and the traceability of products of animal origin.

Article 2  
Definitions

The following definitions shall apply for the purposes of this Regulation:

- 1) the definitions laid down in Regulation (EC) No 178/2002;
- 2) the definitions laid down in Regulation (EC) No /2004<sup>\*</sup>;
- 3) the definitions laid down in Annex I; and
- 4) any technical definitions contained in Annexes II and III.

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<sup>\*</sup> Official Publications Office is to insert official number of Regulation on the hygiene of foodstuffs.

## CHAPTER II

### FOOD BUSINESS OPERATORS' OBLIGATIONS

#### Article 3

##### General obligations

1. Food business operators shall comply with the relevant provisions of Annexes II and III.
  
2. Food business operators shall not use any substance other than potable water – or, when Regulation (EC) No /2004 \* or this Regulation permits its use, clean water – to remove surface contamination from products of animal origin, unless use of the substance has been approved in accordance with the procedure referred to in Article 12(2). Food business operators shall also comply with any conditions for use that may be adopted under the same procedure. The use of an approved substance shall not affect the food business operator's duty to comply with the requirements of this Regulation.

#### Article 4

##### Registration and approval of establishments

1. Food business operators shall place products of animal origin manufactured in the Community on the market only if they have been prepared and handled exclusively in establishments:
  - (a) that meet the relevant requirements of Regulation (EC) No /2004 \*, those of Annexes II and III of this Regulation and other relevant requirements of food law; and

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\* Official Publications Office is to insert official number of Regulation on the hygiene of foodstuffs.

(b) that the competent authority has registered or, where required in accordance with paragraph 2, approved.

2. Without prejudice to Article 6(3) of Regulation (EC) No /2004 <sup>\*</sup>, establishments handling those products of animal origin for which Annex III to this Regulation lays down requirements shall not operate unless the competent authority has approved them in accordance with paragraph 3 of this Article, with the exception of establishments carrying out only:

(a) primary production;

(b) transport operations;

(c) the storage of products not requiring temperature-controlled storage conditions; or

(d) retail operations other than those to which this Regulation applies pursuant to Article 1(5)(b).

3. An establishment subject to approval in accordance with paragraph 2 shall not operate unless the competent authority has, in accordance with Regulation (EC) No /2004 of the European Parliament and of the Council of ..... laying down specific rules for the organisation of official controls on products of animal origin intended for human consumption <sup>\*</sup>:

(a) granted the establishment approval to operate following an on-site visit; or

(b) provided the establishment with conditional approval.

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\* Page ... of this Official Journal.

\* Official Publications Office is to insert official number of Regulation on the hygiene of foodstuffs.

4. Food business operators shall cooperate with the competent authorities in accordance with Regulation (EC) No /2004<sup>\*</sup>. In particular, food business operators shall ensure that an establishment ceases to operate if the competent authority withdraws its approval or, in the case of conditional approval, fails to prolong it or to grant full approval.

5. This Article shall not prevent an establishment from placing food on the market between the date of application of this Regulation and the first subsequent inspection by the competent authority, if the establishment:

- (a) is subject to approval in accordance with paragraph 2 and placed products of animal origin on the market in accordance with Community legislation immediately prior to the application of this Regulation; or
- (b) is of a type in respect of which there was no requirement for approval before the application of this Regulation.

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<sup>\*</sup> Official Publications Office is to insert official number of Regulation on the organisation of official controls (see Article 4(3)).

## Article 5

### Health and identification marking

1. Food business operators shall not place on the market a product of animal origin handled in an establishment subject to approval in accordance with Article 4(2) unless it has either:
  - (a) a health mark applied in accordance with Regulation (EC) No /2004<sup>\*</sup>; or
  - (b) when that Regulation does not provide for the application of a health mark, an identification mark applied in accordance with Annex II, Section I, of this Regulation.
2. Food business operators may apply an identification mark to a product of animal origin only if the product has been manufactured in accordance with this Regulation in establishments meeting the requirements of Article 4.
3. Food business operators may not remove a health mark applied in accordance with Regulation (EC) No /2004<sup>\*</sup> from meat unless they cut or process it or work upon it in another manner.

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\* Official Publications Office is to insert official number of Regulation on the organisation of official controls.

## Article 6

### Products of animal origin from outside the Community

1. Food business operators importing products of animal origin from third countries shall ensure that importation takes place only if:

- (a) the third country of dispatch appears on a list, drawn up in accordance with Article 11 of Regulation (EC) No [\*]/2004, of third countries from which imports of that product are permitted;
- (b)
  - (i) the establishment from which that product was dispatched, and in which it was obtained or prepared, appears on a list, drawn up in accordance with Article 12 of Regulation (EC) No [\*]/2004, of establishments from which imports of that product are permitted, when applicable,
  - (ii) in the case of fresh meat, minced meat, meat preparations, meat products and MSM, the product was manufactured from meat obtained in slaughterhouses and cutting plants appearing on lists drawn up and updated in accordance with Article 12 of Regulation (EC) No [\*]/2004 or in approved Community establishments, and
  - (iii) in the case of live bivalve molluscs, echinoderms, tunicates and marine gastropods, the production area appears on a list drawn up in accordance with Article 13 of that Regulation, when applicable;

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\* Official Publications Office is to insert the official number of the Regulation on the organisation of official controls.



- (c) the product satisfies:
    - (i) the requirements of this Regulation, including the requirements of Article 5 on health and identification marking;
    - (ii) the requirements of Regulation (EC) No [\*/]/2004; and
    - (iii) any import conditions laid down in accordance with Community legislation governing import controls for products of animal origin, and
  - (d) the requirements of Article 14 of Regulation (EC) No [\*\*]/2004 concerning certificates and documents are satisfied, when applicable.
2. By way of derogation from paragraph 1, the importation of fishery products may also take place in accordance with the special provisions laid down in Article 15 of Regulation (EC) No [\*\*]/2004.
3. Food business operators importing products of animal origin shall ensure that:
- (a) products are made available for control upon importation in accordance with Directive 97/78/EC \*;

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\* Official Publications Office is to insert the official number of the Regulation on the hygiene of foodstuffs.

\*\* Official Publications Office is to insert the official number of the Regulation on the organisation of official controls.

\* Directive 97/78/EC of 18 December 1997 laying down the principles governing the organisation of veterinary checks on products entering the Community from third countries (OJ L 24, 30.1.1998, p. 9). Directive amended by the Act of Accession 2003.

- (b) importation complies with the requirements of Directive 2002/99/EC<sup>\*</sup>; and
- (c) operations under their control that take place after importation are carried out in accordance with the requirements of Annex III.

4. Food business operators importing food containing both products of plant origin and processed products of animal origin shall ensure that the processed products of animal origin contained in such food satisfy the requirements of paragraphs 1 to 3. They must be able to demonstrate that they have done so (for example, through appropriate documentation or certification, which need not be in the format specified in paragraph 1(d)).

## CHAPTER III

### TRADE

#### Article 7

#### Documents

1. When required in accordance with Annex II or III, food business operators shall ensure that certificates or other documents accompany consignments of products of animal origin.
2. In accordance with the procedure referred to in Article 12(2):
  - (a) model documents may be established; and
  - (b) provision may be made for the use of electronic documents.

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<sup>\*</sup> 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 (OJ L 18, 23.1.2003, p. 11).

## Article 8

### Special guarantees

1. Food business operators intending to place the following food of animal origin on the market in Sweden or Finland shall comply with the rules set out in paragraph 2 in respect of salmonella:

- (a) meat from bovine and porcine animals, including minced meat but excluding meat preparations and MSM;
- (b) meat from poultry of the following species: domestic fowl, turkeys, guinea-fowl, ducks and geese, including minced meat but excluding meat preparations and MSM; and
- (c) eggs.

2.(a) In the case of meat from bovine and porcine animals and meat from poultry, samples of consignments shall have been taken in the dispatching establishment and been subjected to a microbiological test with negative results in accordance with Community legislation.

(b) In the case of eggs, packing centres shall provide a guarantee that consignments originate from flocks that have been subjected to a microbiological test with negative results in accordance with Community legislation.

- (c) In the case of meat from bovine and porcine animals, the test provided for in subparagraph (a) need not be carried out for consignments intended for an establishment for the purposes of pasteurisation, sterilisation or treatment having a similar effect. In the case of eggs, the test provided for in subparagraph (b) need not be carried out for consignments intended for the manufacture of processed products by a process that guarantees the elimination of salmonella.
- (d) The tests provided for in subparagraphs (a) and (b) need not be carried out for foodstuffs originating in an establishment that is subject to a control programme recognised, in respect of the food of animal origin concerned and in accordance with the procedure referred to in Article 12(2), as equivalent to that approved for Sweden and Finland.
- (e) In the case of meat from bovine and porcine animals and meat from poultry, a trade document or certificate conforming to a model laid down by Community legislation shall accompany the food and state that:
  - (i) the checks referred to in subparagraph (a) have been carried out with negative results; or
  - (ii) the meat is intended for one of the purposes referred to in subparagraph (c); or
  - (iii) the meat comes from an establishment covered by subparagraph (d).
- (f) In the case of eggs, a certificate stating that the tests referred to in subparagraph (b) have been carried out with negative results, or that the eggs are destined to be used in the manner referred to in subparagraph (c), must accompany consignments.

3. In accordance with the procedure referred to in Article 12(2):
- (a) the requirements of paragraphs 1 and 2 may be updated to take account in particular of changes to Member States' control programmes or the adoption of microbiological criteria in accordance with Regulation (EC) No /2004<sup>\*</sup>; and
  - (b) the rules laid down in paragraph 2 in respect of any of the foodstuffs referred to in paragraph 1 may be extended, in whole or in part, to any Member State, or any region of a Member State, that has a control programme recognised as equivalent to that approved for Sweden and Finland in respect of the food of animal origin concerned.
4. For the purposes of this Article, "control programme" means a control programme approved in accordance with Regulation (EC) No 2160/2004 .

#### CHAPTER IV

#### FINAL PROVISIONS

##### Article 9

##### Implementing measures and transitional measures

Implementing measures and transitional arrangements may be laid down in accordance with the procedure referred to in Article 12(2).

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\* Official Publications Office is to insert the official number of the Regulation on the hygiene of foodstuffs.

## Article 10

### Amendment and adaptation of Annexes II and III

1. Annexes II and III may be adapted or updated in accordance with the procedure referred to in Article 12(2), taking into account:

- (a) the development of guides to good practice;
- (b) the experience gained from the implementation of HACCP-based systems pursuant to Article 5 of Regulation (EC) No /2004\*;
- (c) the technological developments and their practical consequences and consumer expectations with regard to food composition;
- (d) scientific advice, particularly new risk assessments;
- (e) microbiological and temperature criteria for foodstuffs;
- (f) changes in patterns of consumption.

2. Exemptions from Annex II and III may be granted in accordance with the procedure referred to in Article 12(2), provided that they do not affect the achievement of the objectives of this Regulation.

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\* Official Publications Office is to insert the official number of the Regulation on the hygiene of foodstuffs.

3. Member States may, without compromising achievement of the objectives of this Regulation, adopt, in accordance with paragraphs 4 to 8, national measures adapting the requirements laid down in Annex III.

4. (a) The national measures referred to in paragraph 3 shall 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 situated in regions that are subject to special geographic constraints.

(b) In other cases, they shall apply only to the construction, layout and equipment of establishments.

5. Any Member State wishing to adopt national measures as referred to in paragraph 3 shall notify the Commission and other Member States. Each 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 foodstuffs and 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.

6. The other Member States shall have three months from the receipt of a notification referred to in paragraph 5 to send written comments to the Commission. In the case of adaptations arising from paragraph 4(b), this period shall, at the request of any Member State, be extended to four months. The Commission may, and when it receives written comments from one or more Member States shall, consult Member States within the committee referred to in Article 12(1). The Commission may decide, in accordance with the procedure referred to in Article 12(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 paragraph 1 or 2 of this Article.

7. A Member State may adopt national measures adapting the requirements of Annex III only:

- (a) in compliance with a decision adopted in accordance with paragraph 6;
- (b) if, one month after the expiry of the period referred to in paragraph 6, the Commission has not informed Member States that it has received written comments or that it intends to propose the adoption of a decision in accordance with paragraph 6; or
- (c) in accordance with paragraph 8.



8. A Member State may, of its own initiative and subject to the general provisions of the Treaty, maintain or establish national rules:

- (a) prohibiting or restricting the placing on the market within its territory of raw milk or raw cream intended for direct human consumption; or
- (b) permitting the use, with the authorisation of the competent authority, of raw milk not meeting the criteria laid down in Annex III, Section IX, as regards plate count and somatic cell count of the manufacture of cheeses with an ageing or ripening period of at least 60 days, and dairy products obtained in connection with the manufacture of such cheeses, provided that this does not prejudice the achievement of the objectives of this Regulation.

#### Article 11

#### Specific decisions

Without prejudice to the generality of Article 9 and Article 10(1), implementing measures may be laid down, or amendments to Annex II or III adopted, in accordance with the procedure referred to in Article 12(2):

- 1) to lay down rules for the transport of meat while it is warm;
- 2) to specify, in respect of MSM, which calcium content is not significantly higher than that of minced meat;

- 3) to lay down other treatments that may be applied in a processing establishment to live bivalve molluscs from class B or C production areas that have not been submitted to purification or relaying;
- 4) to specify recognised testing methods for marine biotoxins;
- 5) to lay down additional health standards for live bivalve molluscs in cooperation with the relevant Community Reference Laboratory, including:
  - (a) limit values and analysis methods for other marine biotoxins;
  - (b) virus testing procedures and virological standards; and
  - (c) sampling plans and the methods and analytical tolerances to be applied to check compliance with the health standards;
- 6) to lay down health standards or checks, where there is scientific evidence indicating that they are necessary to protect public health;
- 7) to extend Annex III, Section VII, Chapter IX, to live bivalve molluscs other than pectinidae;
- 8) to specify criteria for determining when epidemiological data indicate that a fishing ground does not present a health hazard with regard to the presence of parasites and, consequently, for determining when the competent authority may authorise food business operators not to freeze fishery products in accordance with Annex III, Section VIII, Chapter III, Part D;

- 9) to lay down freshness criteria and limits with regard to histamine and total volatile nitrogen for fisheries products;
- 10) to permit the use for the manufacture of certain dairy products of raw milk not meeting the criteria laid down in Annex III, Section IX, as regards its plate count and somatic cell count;
- 11) without prejudice to Directive 96/23/EC<sup>\*</sup>, to fix a maximum permitted value for the combined total of residues of antibiotic substances in raw milk; and
- 12) to approve equivalent processes for the production of gelatine or collagen.

#### Article 12

##### Committee procedure

1. The Commission shall be assisted by the Standing Committee on the Food Chain and Animal Health.
2. Where reference is made to this paragraph, Articles 5 and 7 of Decision 1999/468/EC shall apply, having regard to the provisions of Article 8 thereof.

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

3. The Committee shall adopt its rules of procedure.

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<sup>\*</sup> Council Directive 96/23/EC of 29 April 1996 on measures to monitor certain substances and residues thereof in live animals and animal products (OJ L 125, 23.5.1996, p. 10). Directive as amended by Regulation (EC) No 806/2003 (OJ L 122, 16.5.2003, p. 1).

### Article 13

#### Consultation of the European Food Safety Authority

The Commission shall consult the European Food Safety Authority on any matter falling within the scope of this Regulation that could have a significant impact on public health and, in particular, before proposing to extend Annex III, Section III, to other animal species.

### Article 14

#### Report to the European Parliament and to the Council

1. The Commission shall, not later than ...<sup>\*</sup>, submit a report to the European Parliament and the Council reviewing the experience gained from the implementation of this Regulation.
2. The Commission shall, if appropriate, accompany the report with relevant proposals.

### Article 15

This Regulation shall enter into force twenty days after the date of its publication in the Official Journal of the European Union.

It shall apply 18 months after the date on which all of the following acts have entered into force:

- (a) Regulation (EC) No.../2004<sup>\*\*</sup>;

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\* Five years after the entry into force of this Regulation.

\*\* Official Publications Office is to insert the official number of the Regulation on the hygiene of foodstuffs.

(b) Regulation (EC) No.../2004<sup>\*</sup>; and

(c) Directive 2004/.../EC<sup>\*\*</sup>.

However, it shall apply no earlier than 1 January 2006.

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

Done at Strasbourg, 29.4.2004.

For the European Parliament

The President

P. COX

For the Council

The President

M. McDOWELL

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\* Official Publications Office is to insert here the official number of the Regulation referred to in Article 4(3).

\*\* Official Publications Office is to insert here the official number of the Directive referred to in recital 25.

DEFINITIONS

For the purpose of this Regulation:

1. MEAT

- 1.1. "Meat" means edible parts of the animals referred to in points 1.2 to 1.8, including blood.
- 1.2. "Domestic ungulates" means domestic bovine (including Bubalus and Bison species), porcine, ovine and caprine animals, and domestic solipeds.
- 1.3. "Poultry" means farmed birds, including birds that are not considered as domestic but which are farmed as domestic animals, with the exception of ratites.
- 1.4. "Lagomorphs" means rabbits, hares and rodents.
- 1.5. "Wild game" means:
  - wild ungulates and lagomorphs, as well as other land mammals that are hunted for human consumption and are considered to be wild game under the applicable law in the Member State concerned, including mammals living in enclosed territory under conditions of freedom similar to those of wild game; and
  - wild birds that are hunted for human consumption.

- 1.6. "Farmed game" means farmed ratites and farmed land mammals other than those referred to in point 1.2.
- 1.7. "Small wild game" means wild game birds and lagomorphs living freely in the wild.
- 1.8. "Large wild game" means wild land mammals living freely in the wild that do not fall within the definition of small wild game.
- 1.9. "Carcase" means the body of an animal after slaughter and dressing.
- 1.10. "Fresh meat" means meat that has not undergone any preserving process other than chilling, freezing or quick-freezing, including meat that is vacuum-wrapped or wrapped in a controlled atmosphere.
- 1.11. "Offal" means fresh meat other than that of the carcase, including viscera and blood.
- 1.12. "Viscera" means the organs of the thoracic, abdominal and pelvic cavities, as well as the trachea and oesophagus and, in birds, the crop.
- 1.13. "Minced meat" means boned meat that has been minced into fragments and contains less than 1% salt.
- 1.14. "Mechanically separated meat" or "MSM" means the product obtained by removing meat from flesh-bearing bones after boning or from poultry carcasses, using mechanical means resulting in the loss or modification of the muscle fibre structure.

1.15. "Meat preparations" means fresh meat, including meat that has been reduced to fragments, which has had foodstuffs, seasonings or additives added to it or which has undergone processes insufficient to modify the internal muscle fibre structure of the meat and thus to eliminate the characteristics of fresh meat.

1.16. "Slaughterhouse" means an establishment used for slaughtering and dressing animals, the meat of which is intended for human consumption.

1.17. "Cutting plant" means an establishment used for boning and/or cutting up meat.

1.18. "Game-handling establishment" means any establishment in which game and game meat obtained after hunting are prepared for placing on the market.

## 2. LIVE BIVALVE MOLLUSCS

2.1. "Bivalve molluscs" means filter-feeding lamellibranch molluscs.

2.2. "Marine biotoxins" means poisonous substances accumulated by bivalve molluscs, in particular as a result of feeding on plankton containing toxins.

2.3. "Conditioning" means the storage of live bivalve molluscs coming from class A production areas, purification centres or dispatch centres in tanks or any other installation containing clean seawater, or in natural sites, to remove sand, mud or slime, to preserve or to improve organoleptic qualities and to ensure that they are in a good state of vitality before wrapping or packaging.



- 2.4. "Gatherer" means any natural or legal person who collects live bivalve molluscs by any means from a harvesting area for the purpose of handling and placing on the market.
- 2.5. "Production area" means any sea, estuarine or lagoon area, containing either natural beds of bivalve molluscs or sites used for the cultivation of bivalve molluscs, and from which live bivalve molluscs are taken.
- 2.6. "Relaying area" means any sea, estuarine or lagoon area with boundaries clearly marked and indicated by buoys, posts or any other fixed means, and used exclusively for the natural purification of live bivalve molluscs.
- 2.7. "Dispatch centre" means any on-shore or off-shore establishment for the reception, conditioning, washing, cleaning, grading, wrapping and packaging of live bivalve molluscs fit for human consumption.
- 2.8. "Purification centre" means an establishment with tanks fed by clean seawater in which live bivalve molluscs are placed for the time necessary to reduce contamination to make them fit for human consumption.
- 2.9. "Relaying" means the transfer of live bivalve molluscs to sea, lagoon or estuarine areas for the time necessary to reduce contamination to make them fit for human consumption. This does not include the specific operation of transferring bivalve molluscs to areas more suitable for further growth or fattening.

### 3. FISHERY PRODUCTS

- 3.1. "Fishery products" means all seawater or freshwater animals (except for live bivalve molluscs, live echinoderms, live tunicates and live marine gastropods, and all mammals, reptiles and frogs) whether wild or farmed and including all edible forms, parts and products of such animals.
- 3.2. "Factory vessel" means any vessel on board which fishery products undergo one or more of the following operations followed by wrapping or packaging and, if necessary, chilling or freezing: filleting, slicing, skinning, shelling, shucking, mincing or processing.
- 3.3. "Freezer vessel" means any vessel on board which freezing of fishery products is carried out, where appropriate after preparatory work such as bleeding, heading, gutting and removal of fins and, where necessary, followed by wrapping or packaging.
- 3.4. "Mechanically separated fishery product" means any product obtained by removing flesh from fishery products using mechanical means resulting in the loss or modification of the flesh structure.
- 3.5. "Fresh fishery products" means unprocessed fishery products, whether whole or prepared, including products packaged under vacuum or in a modified atmosphere, that have not undergone any treatment to ensure preservation other than chilling.
- 3.6. "Prepared fishery products" means unprocessed fishery products that have undergone an operation affecting their anatomical wholeness, such as gutting, heading, slicing, filleting, and chopping.

#### 4. MILK

- 4.1. "Raw milk" means milk produced by the secretion of the mammary gland of farmed animals that has not been heated to more than 40°C or undergone any treatment that has an equivalent effect.
- 4.2. "Milk production holding" means an establishment where one or more farmed animals are kept to produce milk with a view to placing it on the market as food.

#### 5. EGGS

- 5.1. "Eggs" means eggs in shell – other than broken, incubated or cooked eggs – that are produced by farmed birds and are fit for direct human consumption or for the preparation of egg products.
- 5.2. "Liquid egg" means unprocessed egg contents after removal of the shell.
- 5.3. "Cracked eggs" means eggs with damaged shell and intact membranes.
- 5.4. "Packing centre" means an establishment where eggs are graded by quality and weight.

#### 6. FROGS' LEGS AND SNAILS

- 6.1. "Frogs' legs" means the posterior part of the body divided by a transverse cut behind the front limbs, eviscerated and skinned, of the species *Rana* (family Ranidae).

6.2. "Snails" means terrestrial gastropods of the species *Helix pomatia* Linné, *Helix aspersa* Muller, *Helix lucorum* and species of the family Achatinidae.

## 7. PROCESSED PRODUCTS

7.1. "Meat products" means processed products resulting from the processing of meat or from the further processing of such processed products, so that the cut surface shows that the product no longer has the characteristics of fresh meat.

7.2. "Dairy products" means processed products resulting from the processing of raw milk or from the further processing of such processed products.

7.3. "Egg products" means processed products resulting from the processing of eggs, or of various components or mixtures of eggs, or from the further processing of such processed products.

7.4. "Processed fishery products" means processed products resulting from the processing of fishery products or from the further processing of such processed products.

7.5. "Rendered animal fat" means fat derived from rendering meat, including bones, and intended for human consumption.

7.6. "Greaves" means the protein-containing residue of rendering, after partial separation of fat and water.

7.7. "Gelatine" means natural, soluble protein, gelling or non-gelling, obtained by the partial hydrolysis of collagen produced from bones, hides and skins, tendons and sinews of animals.

- 7.8. "Collagen" means the protein-based product derived from animal bones, hides, skins and tendons manufactured in accordance with the relevant requirements of this Regulation.
- 7.9. "Treated stomachs, bladders and intestines" means stomachs, bladders and intestines that have been submitted to a treatment such as salting, heating or drying after they have been obtained and after cleaning.

## 8. OTHER DEFINITIONS

8.1. "Products of animal origin" means:

- food of animal origin, including honey and blood;
- live bivalve molluscs, live echinoderms, live tunicates and live marine gastropods intended for human consumption; and
- other animals destined to be prepared with a view to being supplied live to the final consumer.

8.2. "Wholesale market" means a food business that includes several separate units which share common installations and sections where foodstuffs are sold to food business operators.

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REQUIREMENTS CONCERNING SEVERAL PRODUCTS OF ANIMAL ORIGIN

SECTION I: IDENTIFICATION MARKING

When required in accordance with Article 5 or 6, and subject to the provisions of Annex III, food business operators must ensure that products of animal origin have an identification mark applied in compliance with the following provisions.

A. APPLICATION OF THE IDENTIFICATION MARK

1. The identification mark must be applied before the product leaves the establishment.
2. However, a new mark need not be applied to a product unless its packaging and/or wrapping is removed or it is further processed in another establishment, in which case the new mark must indicate the approval number of the establishment where these operations take place.
3. An identification mark is not necessary for eggs in respect of which Regulation (EC) No 1907/90 \* lays down requirements concerning labelling or marking.
4. Food business operators must, in accordance with Article 18 of Regulation (EC) No 178/2002, have in place systems and procedures to identify food business operators from whom they have received, and to whom they have delivered, products of animal origin.

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\* Council Regulation (EEC) No 1907/90 of 26 June 1990 on certain marketing standards for eggs (OJ L 173, 6.7.1990, p. 5). Regulation as last amended by Regulation (EC) No 2052/2003 (OJ L 305, 22.11.2003, p.1).

B. FORM OF THE IDENTIFICATION MARK

5. The mark must be legible and indelible, and the characters easily decipherable. It must be clearly displayed for the competent authorities.
6. The mark must indicate the name of the country in which the establishment is located, which may be written out in full or shown as a two-letter code in accordance with the relevant ISO standard.

In the case of Member States, however, these codes are AT, BE, DE, DK, ES, FI, FR, GR, IE, IT, LU, NL, PT, SE and UK.

Food business operators may continue to use stocks and equipment that they ordered before the entry into force of this Regulation until they are exhausted or require replacement.

7. The mark must indicate the approval number of the establishment. If an establishment manufactures both food to which this Regulation applies and food to which it does not, the food business operator may apply the same identification mark to both types of food.
8. When applied in an establishment located within the Community, the mark must be oval in shape and include the abbreviation CE, EC, EF, EG, EK or EY.

C. METHOD OF MARKING

9. The mark may, depending on the presentation of different products of animal origin, be applied directly to the product, the wrapping or the packaging, or be printed on a label affixed to the product, the wrapping or the packaging. The mark may also be an irremovable tag made of a resistant material.
10. In the case of packaging containing cut meat or offal, 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. This is not necessary, however, if the process of opening destroys the packaging. When wrapping provides the same protection as packaging, the label may be affixed to the wrapping.
11. For products of animal origin that are placed in transport containers or large packages and are intended for further handling, processing, wrapping or packaging in another establishment, the mark may be applied to the external surface of the container or packaging.
12. In the case of liquid, granulate and powdered products of animal origin carried in bulk, and fishery products carried in bulk, an identification mark is not necessary if accompanying documentation contains the information specified in paragraphs 6, 7 and, where appropriate, 8.
13. When products of animal origin are placed in a package destined for direct supply to the final consumer, it is sufficient to apply the mark to the exterior of that package only.



14. When the mark is applied directly to products of animal origin, the colours used must be authorised in accordance with Community rules on the use of colouring substances in foodstuffs.

## SECTION II: OBJECTIVES OF HACCP-BASED PROCEDURES

1. Food business operators operating slaughterhouses must ensure that the procedures that they have put in place in accordance with the general requirements of Article 5 of Regulation (EC) No .../2004 \* meet the requirements that the hazard analysis shows to be necessary and the specific requirements listed in paragraph 2.
2. The procedures must guarantee that each animal or, where appropriate, each lot of animals accepted onto the slaughterhouse premises:
  - (a) is properly identified;
  - (b) is accompanied by the relevant information from the holding of provenance referred to in Section III;
  - (c) does not come from a holding or an area subject to a movement prohibition or other restriction for reasons of animal or public health, except when the competent authority so permits;
  - (d) is clean;

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\* Official Publications Office is to insert the official number of Regulation on the hygiene of foodstuffs.

- (e) is healthy, as far as the food business operator can judge; and
  - (f) is in a satisfactory state as regards welfare on arrival at the slaughterhouse.
3. In the event of failure to comply with any of the requirements listed under paragraph 2, the food business operator must notify the official veterinarian and take appropriate measures.

### SECTION III: FOOD CHAIN INFORMATION

Food business operators operating slaughterhouses must, as appropriate, request, receive, check and act upon food chain information as set out in this Section in respect of all animals, other than wild game, sent or intended to be sent to the slaughterhouse.

1. Slaughterhouse operators must not accept animals onto the slaughterhouse premises unless they have requested and been provided with relevant food safety information contained in the records kept at the holding of provenance in accordance with Regulation (EC) No .../2004\*.
2. Slaughterhouse operators must be provided with the information no less than 24 hours before the arrival of animals at the slaughterhouse, except in the circumstances mentioned in point 7.
3. The relevant food safety information referred to in point 1 is to cover, in particular:
  - (a) the status of the holding of provenance or the regional animal health status;
  - (b) the animals' health status;

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\* Official Publications Office is to insert the official number of Regulation on the hygiene of foodstuffs.

- (c) veterinary medicinal products or other treatments administered to the animals within a relevant period and with a withdrawal period greater than zero, together with their dates of administration and withdrawal periods;
- (d) the occurrence of diseases that may affect the safety of meat;
- (e) the results, if they are relevant to the protection of public health, of any analysis carried out on samples taken from the animals or other samples taken to diagnose diseases that may affect the safety of meat, including samples taken in the framework of the monitoring and control of zoonoses and residues;
- (f) relevant reports about previous ante- and post-mortem inspections of animals from the same holding of provenance including, in particular, reports from the official veterinarian;
- (g) production data, when this might indicate the presence of disease; and
- (h) the name and address of the private veterinarian normally attending the holding of provenance.

4. (a) However, it is not necessary for the slaughterhouse operator to be provided with:
  - (i) the information referred to in point 3(a), (b), (f) and (h), if the operator is already aware of this information (for example, through a standing arrangement or a quality assurance scheme); or
  - (ii) the information referred to in point 3(a), (b), (f) and (g), if the producer declares that there is no relevant information to report.
- (b) The information need not be provided as a verbatim extract from the records of the holding of provenance. It may be provided through electronic data exchange or in the form of a standardised declaration signed by the producer.
5. Food business operators deciding to accept animals onto the slaughterhouse premises after evaluating the relevant food chain information must make it available to the official veterinarian without delay and, except in the circumstances mentioned in point 7, no less than 24 hours before the arrival of the animal or lot. The food business operator must notify the official veterinarian of any information that gives rise to health concerns before ante-mortem inspection of the animal concerned.
6. If any animal arrives at the slaughterhouse without food chain information, the operator must immediately notify the official veterinarian. Slaughter of the animal may not take place until the official veterinarian so permits.

7. If the competent authority so permits, food chain information may accompany the animals to which it relates to the slaughterhouse, rather than arriving at least 24 hours in advance, in the case of:
- (a) porcine animals, poultry or farmed game that have undergone ante-mortem inspection at the holding of provenance, if a certificate that the veterinarian has signed stating that he or she examined the animals at the holding and found them to be healthy accompanies them;
  - (b) domestic solipeds;
  - (c) animals that have undergone emergency slaughter, if a declaration, that the veterinarian has signed recording the favourable outcome of the ante-mortem inspection accompanies them; and
  - (d) animals that are not delivered directly from the holding of provenance to the slaughterhouse.

Slaughterhouse operators must evaluate the relevant information. If they accept the animals for slaughter, they must give the documents mentioned in subparagraphs (a) and (c) to the official veterinarian. Slaughter or dressing of the animals may not take place until the official veterinarian so permits.

8. Food business operators must check passports accompanying domestic solipeds to ensure that the animal is intended for slaughter for human consumption. If they accept the animal for slaughter, they must give the passport to the official veterinarian."

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**SPECIFIC REQUIREMENTS**

**SECTION I: MEAT OF DOMESTIC UNGULATES**

**CHAPTER I: TRANSPORT OF LIVE ANIMALS TO THE SLAUGHTERHOUSE**

Food business operators transporting live animals to slaughterhouses must ensure compliance with the following requirements.

1. During collection and transport, animals must be handled carefully without causing unnecessary distress.
2. Animals showing symptoms of disease or originating in herds known to be contaminated with agents of public health importance may only be transported to the slaughterhouse when the competent authority so permits.

**CHAPTER II: REQUIREMENTS FOR SLAUGHTERHOUSES**

Food business operators must ensure that the construction, layout and equipment of slaughterhouses in which domestic ungulates are slaughtered meet the following requirements.

1. (a) Slaughterhouses must have adequate and hygienic lairage facilities or, climate permitting, waiting pens that are easy to clean and disinfect. These facilities must be equipped for watering the animals and, if necessary, feeding them. The drainage of the wastewater must not compromise food safety.

- (b) They must also have separate lockable facilities or, climate permitting, pens for sick or suspect animals with separate draining and sited in such a way as to avoid contamination of other animals, unless the competent authority considers that such facilities are unnecessary.
- (c) The size of the lairage facilities must ensure that the welfare of the animals is respected. Their layout must facilitate ante-mortem inspections, including the identification of the animals or groups of animals.

2. To avoid contaminating meat, they must:

- (a) have a sufficient number of rooms, appropriate to the operations being carried out;
- (b) have a separate room for the emptying and cleaning of stomachs and intestines, unless the competent authority authorises the separation in time of these operations within a specific slaughterhouse on a case-by-case basis;
- (c) ensure separation in space or time of the following operations:
  - (i) stunning and bleeding;
  - (ii) in the case of porcine animals, scalding, depilation, scraping and singeing;
  - (iii) evisceration and further dressing;
  - (iv) handling clean guts and tripe;



- (v) preparation and cleaning of other offal, particularly the handling of skinned heads if it does not take place at the slaughter line;
  - (vi) packaging offal; and
  - (vii) dispatching meat;
- (d) have installations that prevent contact between the meat and the floors, walls and fixtures; and
- (e) have slaughter lines (where operated) that are designed to allow constant progress of the slaughter process and to avoid cross-contamination between the different parts of the slaughter line. Where more than one slaughter line is operated in the same premises, there must be adequate separation of the lines to prevent cross-contamination.
3. They must have facilities for disinfecting tools with hot water supplied at not less than 82°C, or an alternative system having an equivalent effect.
  4. The equipment for washing hands used by the staff engaged in handling exposed meat must have taps designed to prevent the spread of contamination.
  5. There must be lockable facilities for the refrigerated storage of detained meat and separate lockable facilities for the storage of meat declared unfit for human consumption.

6. There must be a separate place with appropriate facilities for the cleaning, washing and disinfection of means of transport for livestock. However, slaughterhouses need not have these places and facilities if the competent authority so permits and official authorised places and facilities exist nearby.
7. They must have lockable facilities reserved for the slaughter of sick and suspect animals. This is not essential if this slaughter takes place in other establishments authorised by the competent authority for this purpose, or at the end of the normal slaughter period.
8. If manure or digestive tract content is stored in the slaughterhouse, there must be a special area or place for that purpose.
9. They must have an adequately equipped lockable facility or, where needed, room for the exclusive use of the veterinary service.

### CHAPTER III: REQUIREMENTS FOR CUTTING PLANTS

Food business operators must ensure that cutting plants handling meat of domestic ungulates:

- 1) are constructed so as to avoid contamination of meat, in particular by:
  - (a) allowing constant progress of the operations; or
  - (b) ensuring separation between the different production batches;

- 2) have rooms for the separate storage of packaged and exposed meat, unless stored at different times or in such a way that the packaging material and the manner of storage cannot be a source of contamination for the meat;
- 3) have cutting rooms equipped to ensure compliance with the requirements laid down in Chapter V;
- 4) have equipment for washing hands with taps designed to prevent the spread of contamination, for use by staff engaged in handling exposed meat; and
- 5) have facilities for disinfecting tools with hot water supplied at not less than 82°C, or an alternative system having an equivalent effect.

#### CHAPTER IV: SLAUGHTER HYGIENE

Food business operators operating slaughterhouses in which domestic ungulates are slaughtered must ensure compliance with the following requirements.

1. After arrival in the slaughterhouse, the slaughter of the animals must not be unduly delayed. However, where required for welfare reasons, animals must be given a resting period before slaughter.
2. (a) Meat from animals other than those referred to in subparagraphs (b) and (c) must not be used for human consumption if they die otherwise than by being slaughtered in the slaughterhouse.

- (b) Only live animals intended for slaughter may be brought into the slaughter premises, with the exception of:
    - (i) animals that have undergone emergency slaughter outside the slaughterhouse in accordance with Chapter VI;
    - (ii) animals slaughtered at the place of production in accordance with Section III; and
    - (iii) wild game, in compliance with Section IV, Chapter II.
  - (c) Meat from animals that undergo slaughter following an accident in a slaughterhouse may be used for human consumption if, on inspection, no serious lesions other than those due to the accident are found.
3. The animals or, where appropriate, each batch of animals sent for slaughter must be identified so that their origin can be traced.
  4. Animals must be clean.
  5. Slaughterhouse operators must follow the instructions of the veterinarian appointed by the competent authority in accordance with Regulation (EC) No.../2004 \* to ensure that ante-mortem inspection of every animal to be slaughtered is carried out under suitable conditions.

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6. Animals brought into the slaughter hall must be slaughtered without undue delay.
7. Stunning, bleeding, skinning, evisceration and other dressing must be carried out without undue delay and in a manner that avoids contaminating the meat. In particular:
  - (a) the trachea and oesophagus must remain intact during bleeding, except in the case of slaughter according to a religious custom;
  - (b) during the removal of hides and fleece:
    - (i) contact between the outside of the skin and the carcass must be prevented; and
    - (ii) operators and equipment coming into contact with the outer surface of hides and fleece must not touch the meat;
  - (c) measures must be taken to prevent the spillage of digestive tract content during and after evisceration and to ensure that evisceration is completed as soon as possible after stunning; and
  - (d) removal of the udder must not result in contamination of the carcass with milk or colostrum.

8. Complete skinning of the carcass and other parts of the body intended for human consumption must be carried out, except for porcine animals and the heads and feet of ovine and caprine animals and calves. Heads and feet must be handled so as to avoid contamination of other meat.
9. When not skinned, porcine animals must have their bristles removed immediately. The risk of contamination of the meat with scalding water must be minimised. Only approved additives may be used for this operation. Porcine animals must be thoroughly rinsed afterwards with potable water.
10. The carcasses must not contain visible faecal contamination. Any visible contamination must be removed without delay by trimming or alternative means having an equivalent effect.
11. Carcasses and offal must not come into contact with floors, walls or work stands.
12. Slaughterhouse operators must follow the instructions of the competent authority to ensure that post-mortem inspection of all slaughtered animals is carried out under suitable conditions in accordance with Regulation (EC) No.../2004 \*.
13. Until post-mortem inspection is completed, parts of a slaughtered animal subject to such inspection must:
  - (a) remain identifiable as belonging to a given carcass; and

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\* Official Publications Office is to insert the official number of Regulation on the organisation of official controls.

- (b) come into contact with no other carcass, offal or viscera, including those that have already undergone post-mortem inspection.

However, provided that it shows no pathological lesion, the penis may be discarded immediately.

14. Both kidneys must be removed from their fatty covering. In the case of bovine and porcine animals, and solipeds, the peri-renal capsule must also be removed.
15. If the blood or other offal of several animals is collected in the same container before completion of post-mortem inspection, the entire contents must be declared unfit for human consumption if the carcass of one or more of the animals concerned has been declared unfit for human consumption.
16. After post-mortem inspection:
  - (a) the tonsils of bovine animals and solipeds must be removed hygienically;
  - (b) parts unfit for human consumption must be removed as soon as possible from the clean sector of the establishment;
  - (c) meat detained or declared unfit for human consumption and inedible by-products must not come into contact with meat declared fit for human consumption; and

- (d) viscera or parts of viscera remaining in the carcase, except for the kidneys, must be removed entirely and as soon as possible, unless the competent authority authorises otherwise.
17. After completion of slaughter and post-mortem inspection, the meat must be stored in accordance with the requirements laid down in Chapter VII.
  18. When destined for further handling:
    - (a) stomachs must be scalded or cleaned;
    - (b) intestines must be emptied and cleaned; and
    - (c) heads and feet must be skinned or scalded and depilated.
  19. Where establishments are approved for the slaughter of different animal species or for the handling of carcasses of farmed game and wild game, precautions must be taken to prevent cross-contamination by separation either in time or in space of operations carried out on the different species. Separate facilities for the reception and storage of unskinned carcasses of farmed game slaughtered at the farm and for wild game must be available.
  20. If the slaughterhouse does not have lockable facilities reserved for the slaughter of sick or suspect animals, the facilities used to slaughter such animals must be cleaned, washed and disinfected under official supervision before the slaughter of other animals is resumed.



## CHAPTER V: HYGIENE DURING CUTTING AND BONING

Food business operators must ensure that cutting and boning of meat of domestic ungulates takes place in accordance with the following requirements.

1. Carcasses of domestic ungulates may be cut into half-carcasses or quarters, and half carcasses into no more than three wholesale cuts, in slaughterhouses. Further cutting and boning must be carried out in a cutting plant.
2. The work on meat must be organised in such a way as to prevent or minimise contamination. To this end, food business operators must ensure in particular that:
  - (a) meat intended for cutting is brought into the workrooms progressively as needed;
  - (b) during cutting, boning, trimming, slicing, dicing, wrapping and packaging, the meat is maintained at not more than 3°C for offal and 7°C for other meat, by means of an ambient temperature of not more than 12°C or an alternative system having an equivalent effect; and
  - (c) where the premises are approved for the cutting of meat of different animal species, precautions are taken to avoid cross-contamination, where necessary by separation of the operations on the different species in either space or time.
3. However, meat may be boned and cut before it reaches the temperature referred to in point 2(b) in accordance with Chapter VII, point 3.

4. Meat may also be boned and cut prior to reaching the temperature referred to in point 2(b) when the cutting room is on the same site as the slaughter premises. In this case, the meat must be transferred to the cutting room either directly from the slaughter premises or after a waiting period in a chilling or refrigerating room. As soon as it is cut and, where appropriate, packaged, the meat must be chilled to the temperature referred to in point 2(b).

## CHAPTER VI: EMERGENCY SLAUGHTER OUTSIDE THE SLAUGHTERHOUSE

Food business operators must ensure that meat from domestic ungulates that have undergone emergency slaughter outside the slaughterhouse may be used for human consumption only if it complies with all the following requirements.

1. An otherwise healthy animal must have suffered an accident that prevented its transport to the slaughterhouse for welfare reasons.
2. A veterinarian must carry out an ante-mortem inspection of the animal.
3. The slaughtered and bled animal must be transported to the slaughterhouse hygienically and without undue delay. Removal of the stomach and intestines, but no other dressing, may take place on the spot, under the supervision of the veterinarian. Any viscera removed must accompany the slaughtered animal to the slaughterhouse and be identified as belonging to that animal.
4. If more than two hours elapse between slaughter and arrival at the slaughterhouse, the animal must be refrigerated. Where climatic conditions so permit, active chilling is not necessary.

5. A declaration by the food business operator who reared the animal, stating the identity of the animal and indicating any veterinary products or other treatments administered to the animal, dates of administration and withdrawal periods, must accompany the slaughtered animal to the slaughterhouse.
6. A declaration issued by the veterinarian recording the favourable outcome of the ante-mortem inspection, the date and time of, and reason for, emergency slaughter, and the nature of any treatment administered by the veterinarian to the animal, must accompany the slaughtered animal to the slaughterhouse.
7. The slaughtered animal must be fit for human consumption following post-mortem inspection carried out in the slaughterhouse in accordance with Regulation (EC) No.../2004 \*, including any additional tests required in the case of emergency slaughter.
8. Food business operators must follow any instructions that the official veterinarian may give after post-mortem inspection concerning the use of the meat.
9. Food business operators may not place meat from animals having undergone emergency slaughter on the market unless it bears a special health mark which cannot be confused either with the health mark provided for in Regulation (EC) No.../2004 \* or with the identification mark provided for in Annex II, Section I to this Regulation. Such meat may be placed on the market only in the Member State where slaughter takes place and in accordance with national law.

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## CHAPTER VII: STORAGE AND TRANSPORT

Food business operators must ensure that the storage and transport of meat of domestic ungulates takes place in accordance with the following requirements.

1. (a) Unless other specific provisions provide otherwise, post-mortem inspection must be followed immediately by chilling in the slaughterhouse to ensure a temperature throughout the meat of not more than 3°C for offal and 7°C for other meat along a chilling curve that ensures a continuous decrease of the temperature. However, meat may be cut and boned during chilling in accordance with Chapter V, point 4.
- (b) During the chilling operations, there must be adequate ventilation to prevent condensation on the surface of the meat.
2. Meat must attain the temperature specified in point 1 and remain at that temperature during storage.
3. Meat must attain the temperature specified in point 1 before transport, and remain at that temperature during transport. However, transport may also take place if the competent authority so authorises to enable the production of specific products, provided that:
  - (a) such transport takes place in accordance with the requirements that the competent authority specifies in respect of transport from one given establishment to another; and
  - (b) the meat leaves the slaughterhouse, or a cutting room on the same site as the slaughter premises, immediately and transport takes no more than two hours.

4. Meat intended for freezing must be frozen without undue delay, taking into account where necessary a stabilisation period before freezing.
5. Exposed meat must be stored and transported separately from packaged meat, unless stored or transported at different times or in such a way that the packaging material and the manner of storage or transport cannot be a source of contamination for the meat.

## SECTION II: MEAT FROM POULTRY AND LAGOMORPHS

### CHAPTER I: TRANSPORT OF LIVE ANIMALS TO THE SLAUGHTERHOUSE

Food business operators transporting live animals to slaughterhouses must ensure compliance with the following requirements.

1. During collection and transport, animals must be handled carefully without causing unnecessary distress.
2. Animals showing symptoms of disease or originating in flocks known to be contaminated with agents of public-health importance may only be transported to the slaughterhouse when permitted by the competent authority.
3. Crates for delivering animals to the slaughterhouse and modules, where used, must be made of non-corrodible material and be easy to clean and disinfect. Immediately after emptying and, if necessary, before re-use, all equipment used for collecting and delivering live animals must be cleaned, washed and disinfected.

## CHAPTER II: REQUIREMENTS FOR SLAUGHTERHOUSES

Food business operators must ensure that the construction, layout and equipment of slaughterhouses in which poultry or lagomorphs are slaughtered meet the following requirements.

1. They must have a room or covered space for the reception of the animals and for their inspection before slaughter.
2. To avoid contaminating meat, they must:
  - (a) have a sufficient number of rooms, appropriate to the operations being carried out;
  - (b) have a separate room for evisceration and further dressing, including the addition of seasonings to whole poultry carcasses, unless the competent authority authorises separation in time of these operations within a specific slaughterhouse on a case-by-case basis;
  - (c) ensure separation in space or time of the following operations:
    - (i) stunning and bleeding;
    - (ii) plucking or skinning, and any scalding; and
    - (iii) dispatching meat;

- (d) have installations that prevent contact between the meat and the floors, walls and fixtures; and
  - (e) have slaughter lines (where operated) that are designed to allow a constant progress of the slaughter process and to avoid cross-contamination between the different parts of the slaughter line. Where more than one slaughter line is operated in the same premises, there must be adequate separation of the lines to prevent cross-contamination.
3. They must have facilities for disinfecting tools with hot water supplied at not less than 82°C, or an alternative system having an equivalent effect.
  4. The equipment for washing hands used by the staff engaged in handling exposed meat must have taps designed to prevent the spread of contamination.
  5. There must be lockable facilities for the refrigerated storage of detained meat and separate lockable facilities for the storage of meat declared unfit for human consumption.
  6. There must be a separate place with appropriate facilities for the cleaning, washing and disinfection of:
    - (a) transport equipment such as crates; and
    - (b) means of transport.

These places and facilities are not compulsory for (b) if officially authorised places and facilities exist nearby.

7. They must have an adequately equipped lockable facility or, where needed, room for the exclusive use of the veterinary service.

### CHAPTER III: REQUIREMENTS FOR CUTTING PLANTS

1. Food business operators must ensure that cutting plants handling meat from poultry or lagomorphs:
  - (a) are constructed so as to avoid contamination of meat, in particular by:
    - (i) allowing constant progress of the operations; or
    - (ii) ensuring separation between the different production batches;
  - (b) have rooms for the separate storage of packaged and exposed meat, unless stored at different times or in such a way that the packaging material and the manner of storage cannot be a source of contamination for the meat;
  - (c) have cutting rooms equipped to ensure compliance with the requirements laid down in Chapter V;
  - (d) have equipment for washing hands used by staff handling exposed meat with taps designed to prevent the spread of contamination; and
  - (e) have facilities for disinfecting tools with hot water supplied at not less than 82°C, or an alternative system having an equivalent effect.



2. If the following operations are undertaken in a cutting plant:
    - (a) the evisceration of geese and ducks reared for the production of "foie gras", which have been stunned, bled and plucked on the fattening farm; or
    - (b) the evisceration of delayed eviscerated poultry,
- food business operators must ensure that separate rooms are available for that purpose.

#### CHAPTER IV: SLAUGHTER HYGIENE

Food business operators operating slaughterhouses in which poultry or lagomorphs are slaughtered must ensure compliance with the following requirements.

1.
  - (a) Meat from animals other than those referred to in (b) must not be used for human consumption if they die otherwise than by being slaughtered in the slaughterhouse.
  - (b) Only live animals intended for slaughter may be brought into the slaughter premises, with the exception of:
    - (i) delayed eviscerated poultry, geese and ducks reared for the production of "foie gras" and birds that are not considered as domestic but which are farmed as domestic animals, if slaughtered at the farm in accordance with Chapter VI;

(ii) farmed game slaughtered at the place of production in accordance with Section III; and

(iii) small wild game in accordance with Section IV, Chapter III.

2. Slaughterhouse operators must follow the instructions of the competent authority to ensure that ante-mortem inspection is carried out under suitable conditions.
3. Where establishments are approved for the slaughter of different animal species or for the handling of farmed raptines and small wild game, precautions must be taken to prevent cross contamination by separation either in time or in space of the operations carried out on the different species. Separate facilities for the reception and storage of carcasses of farmed raptines slaughtered at the farm and for small wild game must be available.
4. Animals brought into the slaughter room must be slaughtered without undue delay.
5. Stunning, bleeding, skinning or plucking, evisceration and other dressing must be carried out without undue delay in such a way that contamination of the meat is avoided. In particular, measures must be taken to prevent the spillage of digestive tract contents during evisceration.
6. Slaughterhouse operators must follow the instructions of the competent authority to ensure that the post-mortem inspection is carried out under suitable conditions, and in particular that slaughtered animals can be inspected properly.

7. After post-mortem inspection:
  - (a) parts unfit for human consumption must be removed as soon as possible from the clean sector of the establishment;
  - (b) meat detained or declared unfit for human consumption and inedible by-products must not come into contact with meat declared fit for human consumption; and
  - (c) viscera or parts of viscera remaining in the carcass, except for the kidneys, must be removed entirely, if possible, and as soon as possible, unless otherwise authorised by the competent authority.
8. After inspection and evisceration, slaughtered animals must be cleaned and chilled to not more than 4°C as soon as possible, unless the meat is cut while warm.
9. When carcasses are subjected to an immersion chilling process, account must be taken of the following.
  - (a) Every precaution must be taken to avoid contamination of carcasses, taking into account parameters such as carcass weight, water temperature, volume and direction of water flow and chilling time.
  - (b) Equipment must be entirely emptied, cleaned and disinfected whenever this is necessary and at least once a day.

10. Sick or suspect animals, and animals slaughtered in application of disease eradication or control programmes, must not be slaughtered in the establishment except when permitted by the competent authority. In that event, slaughter must be performed under official supervision and steps taken to prevent contamination; the premises must be cleaned and disinfected before being used again.

## CHAPTER V: HYGIENE DURING AND AFTER CUTTING AND BONING

Food business operators must ensure that cutting and boning of meat of poultry and lagomorphs takes place in accordance with the following requirements.

1. The work on meat must be organised in such a way as to prevent or minimise contamination. To this end, food business operators must ensure in particular that:
  - (a) meat intended for cutting is brought into the workrooms progressively as needed;
  - (b) during cutting, boning, trimming, slicing, dicing, wrapping and packaging, the temperature of the meat is maintained at not more than 4°C by means of an ambient temperature of 12°C or an alternative system having an equivalent effect; and
  - (c) where the premises are approved for the cutting of meat of different animal species, precautions are taken to avoid cross-contamination, where necessary by separation of the operations on the different species in either space or time.

2. However, meat may be boned and cut prior to reaching the temperature referred to in point 1(b) when the cutting room is on the same site as the slaughter premises, provided that it is transferred to the cutting room either:
  - (a) directly from the slaughter premises; or
  - (b) after a waiting period in a chilling or refrigerating room.
3. As soon as it is cut and, where appropriate, packaged, the meat must be chilled to the temperature referred to in point 1(b).
4. Exposed meat must be stored and transported separately from packaged meat, unless stored or transported at different times or in such a way that the packaging material and the manner of storage or transport cannot be a source of contamination for the meat.

#### CHAPTER VI: SLAUGHTER ON THE FARM

Food business operators may slaughter poultry referred to in Chapter IV, point 1(b)(i), on the farm only with the authorisation of the competent authority and in compliance with the following requirements.

1. The farm must undergo regular veterinary inspection.
2. The food business operator must inform the competent authority in advance of the date and time of slaughter.

3. The holding must have facilities for concentrating the birds to allow an ante-mortem inspection of the group to be made.
4. The holding must have premises suitable for the hygienic slaughter and further handling of the birds.
5. Animal welfare requirements must be complied with.
6. The slaughtered birds must be accompanied to the slaughterhouse by a declaration by the food business operator who reared the animal indicating any veterinary products or other treatments administered to the animal, dates of administration and withdrawal periods, and the date and time of slaughter.
7. The slaughtered animal must be accompanied to the slaughterhouse by a certificate issued by the official veterinarian or approved veterinarian in accordance with Regulation (EC) No .../2004 \*.
8. In the case of poultry reared for the production of "foie gras", the uneviscerated birds must be transported immediately and, if necessary, refrigerated to a slaughterhouse or cutting plant. They must be eviscerated within 24 hours of slaughter under the supervision of the competent authority.
9. Delayed eviscerated poultry obtained at the farm of production may be kept for up to 15 days at a temperature of not more than 4°C. It must then be eviscerated in a slaughterhouse or in a cutting plant located in the same Member State as the farm of production.

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### SECTION III: MEAT OF FARMED GAME

1. The provisions of Section I apply to the production and placing on the market of meat from even-toed farmed game mammals (Crevice and Suede), unless the competent authority considers them inappropriate.
2. The provisions of Section II apply to the production and placing on the market of meat from ratites. However, those of Section I apply where the competent authority considers them appropriate. Appropriate facilities must be provided, adapted to the size of the animals.
3. Notwithstanding points 1 and 2, food business operators may slaughter farmed ratites and farmed ungulates referred to in point 1 at the place of origin with the authorisation of the competent authority if:
  - (a) the animals cannot be transported, to avoid any risk for the handler or to protect the welfare of the animals;
  - (b) the herd undergoes regular veterinary inspection;
  - (c) the owner of the animals submits a request;
  - (d) the competent authority is informed in advance of the date and time of slaughter of the animals;
  - (e) the holding has procedures for concentrating the animals to allow an ante-mortem inspection of the group to be made;

- (f) the holding has facilities suitable for the slaughter, bleeding and, where raptures are to be plucked, plucking of the animals;
  - (g) animal welfare requirements are complied with;
  - (h) slaughtered and bled animals are transported to the slaughterhouse hygienically and without undue delay. If transport takes more than two hours, the animals are, if necessary, refrigerated. Evisceration may take place on the spot, under the supervision of the veterinarian;
  - (i) a declaration by the food business operator who reared the animals, stating their identity and indicating any veterinary products or other treatments administered, dates of administration and withdrawal periods, accompanies the slaughtered animals to the slaughterhouse; and
  - (j) during transport to the approved establishment, a certificate issued and signed by the official veterinarian or approved veterinarian, attesting to a favourable result of the ante-mortem inspection, correct slaughter and bleeding and the date and time of slaughter, accompanies the slaughtered animals.
4. Food business operators may also slaughter bison on the farm in accordance with paragraph 3 in exceptional circumstances.



## SECTION IV: WILD GAME MEAT

### CHAPTER I: TRAINING OF HUNTERS IN HEALTH AND HYGIENE

1. Persons who hunt wild game with a view to placing it on the market for human consumption must have sufficient knowledge of the pathology of wild game, and of the production and handling of wild game and wild game meat after hunting, to undertake an initial examination of wild game on the spot.
2. It is however enough if at least one person of a hunting team has the knowledge referred to in paragraph 1. References in this Section to a "trained person" are references to that person.
3. The trained person could also be the gamekeeper or the game manager if he or she is part of the hunting team or located in the immediate vicinity of where hunting is taking place. In the latter case, the hunter must present the wild game to the gamekeeper or game manager and inform them of any abnormal behaviour observed before killing.
4. Training must be provided to the satisfaction of the competent authority to enable hunters to become trained persons. It should cover at least the following subjects:
  - (a) the normal anatomy, physiology and behaviour of wild game;
  - (b) abnormal behaviour and pathological changes in wild game due to diseases, environmental contamination or other factors which may affect human health after consumption;

- (c) the hygiene rules and proper techniques for the handling, transportation, evisceration etc. of wild game animals after killing; and
  - (d) legislation and administrative provisions on the animal and public health and hygiene conditions governing the placing on the market of wild game.
5. The competent authority should encourage hunters' organisations to provide such training.

## CHAPTER II: HANDLING OF LARGE WILD GAME

1. After killing, large wild game must have their stomachs and intestines removed as soon as possible and, if necessary, be bled.
2. The trained person must carry out an examination of the body, and of any viscera removed, to identify any characteristics that may indicate that the meat presents a health risk.  
The examination must take place as soon as possible after killing.
3. Meat of large wild game may be placed on the market only if the body is transported to a game-handling establishment as soon as possible after the examination referred to in point 2.  
The viscera must accompany the body as specified in point 4. The viscera must be identifiable as belonging to a given animal.

4. (a) If no abnormal characteristics are found during the examination referred to in paragraph 2, no abnormal behaviour was observed before killing, and there is no suspicion of environmental contamination, the trained person must attach to the animal body a numbered declaration stating this. This declaration must also indicate the date, time and place of killing. In this case, the head and the viscera need not accompany the body, except in the case of species susceptible to Trichinosis (porcine animals, solipeds and others), whose head (except for tusks) and diaphragm must accompany the body. However, hunters must comply with any additional requirements imposed in the Member State where hunting takes place, in particular to permit the monitoring of certain residues and substances in accordance with Directive 96/23/EC;
- (b) In other circumstances, the head (except for tusks, antlers and horns) and all the viscera except for the stomach and intestines must accompany the body. The trained person who carried out the examination must inform the competent authority of the abnormal characteristics, abnormal behaviour or suspicion of environmental contamination that prevented him or her from making a declaration in accordance with (a);
- (c) If no trained person is available to carry out the examination referred to in paragraph 2 in a particular case, the head (except for tusks, antlers and horns) and all the viscera except for the stomach and the intestines must accompany the body.

5. Chilling must begin within a reasonable period of time after killing and achieve a temperature throughout the meat of not more than 7°C. Where climatic conditions so permit, active chilling is not necessary.
6. During transport to the game-handling establishment, heaping must be avoided.
7. Large wild game delivered to a game-handling establishment must be presented to the competent authority for inspection.
8. In addition, unskinned large wild game may be skinned and placed on the market only if:
  - (a) before skinning, it is stored and handled separately from other food and not frozen; and
  - (b) after skinning, it undergoes a final inspection in accordance with Regulation (EC) No .../2004\*.
9. The rules laid down in Section I, Chapter V, apply to the cutting and boning of large wild game.

### CHAPTER III: HANDLING OF SMALL WILD GAME

1. The trained person must carry out an examination to identify any characteristics that may indicate that the meat presents a health risk. The examination must take place as soon as possible after killing.

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2. If abnormal characteristics are found during the examination, abnormal behaviour was observed before killing, or environmental contamination is suspected, the trained person must inform the competent authority.
3. Meat of small wild game may be placed on the market only if the body is transported to a game-handling establishment as soon as possible after the examination referred to in point 1.
4. Chilling must begin within a reasonable period of time of killing and achieve a temperature throughout the meat of not more than 4°C. Where climatic conditions so permit, active chilling is not necessary.
5. Evisceration must be carried out, or completed, without undue delay upon arrival at the game-handling establishment, unless the competent authority permits otherwise.
6. Small wild game delivered to a game-handling establishment must be presented to the competent authority for inspection.
7. The rules laid down in Section II, Chapter V, apply to the cutting and boning of small wild game.

SECTION V: MINCED MEAT, MEAT PREPARATIONS AND  
MECHANICALLY SEPARATED MEAT (MSM)

CHAPTER I: REQUIREMENTS FOR PRODUCTION ESTABLISHMENTS

Food business operators operating establishments producing minced meat, meat preparations or MSM must ensure that they:

- 1) are constructed so as to avoid contamination of meat and products, in particular by:
  - (a) allowing constant progress of the operations; or
  - (b) ensuring separation between the different production batches;
- 2) have rooms for the separate storage of packaged and exposed meat and products, unless stored at different times or in such a way that the packaging material and the manner of storage cannot be a source of contamination for the meat or products;
- 3) have rooms equipped to ensure compliance with the temperature requirements laid down in Chapter III;
- 4) have equipment for washing hands used by staff handling exposed meat and products with taps designed to prevent the spread of contamination; and
- 5) have facilities for disinfecting tools with hot water supplied at not less than 82°C, or an alternative system having an equivalent effect.

## CHAPTER II: REQUIREMENTS FOR RAW MATERIAL

Food business operators producing minced meat, meat preparations or MSM must ensure that the raw materials used satisfy the following requirements.

1. The raw material used to prepare minced meat must meet the following requirements.
  - (a) It must comply with the requirements for fresh meat;
  - (b) It must derive from skeletal muscle, including adherent fatty tissues;
  - (c) It must not derive from:
    - (i) scrap cuttings and scrap trimmings (other than whole muscle cuttings);
    - (ii) MSM;
    - (iii) meat containing bone fragments or skin; or
    - (iv) meat of the head with the exception of the masseters, the non-muscular part of the linea alba, the region of the carpus and the tarsus, bone scrapings and the muscles of the diaphragm (unless the serosa has been removed).
2. The following raw material may be used to prepare meat preparations:
  - (a) fresh meat;

- (b) meat meeting the requirements of point 1; and
  - (c) if the meat preparation is clearly not intended to be consumed without first undergoing heat treatment:
    - (i) meat derived from the mincing or fragmentation of meat meeting the requirements of point 1 other than point 1(c)(i); and
    - (ii) MSM meeting the requirements of Chapter III, point 3(d).
3. The raw material used to produce MSM must meet the following requirements.
- (a) It must comply with the requirements for fresh meat;
  - (b) The following material must not be used to produce MSM:
    - (i) for poultry, the feet, neckskin and head; and
    - (ii) for other animals, the bones of the head, feet, tails, femur, tibia, fibula, humerus, radius and ulna.



### CHAPTER III: HYGIENE DURING AND AFTER PRODUCTION

Food business operators producing minced meat, meat preparations or MSM must ensure compliance with the following requirements.

1. The work on meat must be organised in such a way as to prevent or minimise contamination. To this end, food business operators must ensure in particular that the meat used is:
  - (a) at a temperature of not more than 4°C for poultry, 3°C for offal and 7°C for other meat; and
  - (b) brought into the preparation room progressively as needed.
2. The following requirements apply to the production of minced meat and meat preparations.
  - (a) Unless the competent authority authorises boning immediately before mincing, frozen or deep-frozen meat used for the preparation of minced meat or meat preparations must be boned before freezing. It may be stored only for a limited period.
  - (b) When prepared from chilled meat, minced meat must be prepared:
    - (i) in the case of poultry, within no more than 3 days of their slaughter;
    - (ii) in the case of animal other than poultry, within no more than 6 days of their slaughter; or

- (iii) within no more than 15 days from the slaughter of the animals in the case of boned, vacuum-packed beef and veal.
- (c) Immediately after production, minced meat and meat preparations must be wrapped or packaged and be:
  - (i) chilled to an internal temperature of not more than 2°C for minced meat and 4°C for meat preparations; or
  - (ii) frozen to an internal temperature of not more than -18°C.

These temperature conditions must be maintained during storage and transport.

3. The following requirements apply to the production and use of MSM produced using techniques that do not alter the structure of the bones used in the production of MSM and the calcium content of which is not significantly higher than that of minced meat.
  - (a) Raw material for deboning from an on-site slaughterhouse must be no more than 7 days old; otherwise, raw material for deboning must be no more than 5 days old. However, poultry carcasses must be no more than 3 days old.
  - (b) Mechanical separation must take place immediately after deboning.
  - (c) If not used immediately after being obtained, MSM must be wrapped or packaged and then chilled to a temperature of not more than 2°C or frozen to an internal temperature of not more than -18°C. These temperature requirements must be maintained during storage and transport.

- (d) If the food business operator has carried out analyses demonstrating that MSM complies with the microbiological criteria for minced meat adopted in accordance with Regulation (EC) No.../2004 \* it may be used in meat preparations that are clearly not intended to be consumed without first undergoing heat treatment and in meat products.
  - (e) MSM not shown to comply with the criteria referred to in (d) may be used only to manufacture heat-treated meat products in establishments approved in accordance with this Regulation.
4. The following requirements apply to the production and use of MSM produced using techniques other than those mentioned in point 3.
- (a) Raw material for deboning from an on-site slaughterhouse must be no more than 7 days old; otherwise, raw material for deboning must be no more than 5 days old. However, poultry carcasses must be no more than 3 days old.
  - (b) If mechanical separation does not take place immediately after deboning the flesh-bearing bones must be stored and transported at a temperature of not more than 2°C or, if frozen, at a temperature of not more than -18°C.
  - (c) Flesh-bearing bones obtained from frozen carcasses must not be refrozen.
  - (d) If not used within one hour of being obtained, MSM must be chilled immediately to a temperature of not more than 2°C.

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- (e) If, after chilling, MSM is not processed within 24 hours, it must be frozen within 12 hours of production and reach an internal temperature of not more than -18°C within six hours.
  - (f) Frozen MSM must be wrapped or packaged before storage or transport, must not be stored for more than three months and must be maintained at a temperature of not more than -18°C during storage and transport.
  - (g) MSM may be used only to manufacture heat-treated meat products in establishments approved in accordance with this Regulation.
5. Minced meat, meat preparations and MSM must not be re-frozen after thawing.

#### CHAPTER IV: LABELLING

1. In addition to the requirements of Directive 2000/13/EC<sup>\*</sup>, food business operators must ensure compliance with the requirement of point 2 if, and to the extent that, national rules in the Member State in the territory of which the product is placed on the market so require.
2. Packages intended for supply to the final consumer containing minced meat from poultry or solipeds or meat preparations containing MSM must bear a notice indicating that such products should be cooked before consumption.

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<sup>\*</sup> Directive 2000/13/EC of the European Parliament and of the Council of 20 March 2000 on the approximation of the laws of the Member States relating to the labelling, presentation and advertising of foodstuffs (OJ L 109, 6.5.2000, p. 29). Directive as last amended by Directive 2003/89/EC (OJ L 308, 25.11.2001, p. 15).

## SECTION VI: MEAT PRODUCTS

1. Food business operators must ensure that the following items are not used in the preparation of meat products:
  - (a) genital organs of either female or male animals, except testicles;
  - (b) urinary organs, except the kidneys and the bladder;
  - (c) the cartilage of the larynx, the trachea and the extra-lobular bronchi;
  - (d) eyes and eyelids;
  - (e) the external auditory meatus;
  - (f) horn tissue; and
  - (g) in poultry, the head – except the comb and the ears, the wattles and caruncles – the oesophagus, the crop, the intestines and the genital organs.
2. All meat, including minced meat and meat preparations, used to produce meat product must meet the requirements for fresh meat. However, minced meat and meat preparations used to produce meat products need not satisfy other specific requirements of Section V.

## SECTION VII: LIVE BIVALVE MOLLUSCS

1. This Section applies to live bivalve molluscs. With the exception of the provisions on purification, it also applies to live echinoderms, tunicates and marine gastropods.
2. Chapters I to VIII apply to animals harvested from production areas that the competent authority has classified in accordance with Regulation (EC) No .../2004 \*. Chapter IX applies to pectinidae harvested outside those areas.
3. Chapters V, VI, VIII and IX, and paragraph 3 of Chapter VII, apply to retail.
4. The requirements of this Section supplement those laid down in Regulation (EC) No .../2004 \*\*.ol style="list-style-type: none;">- (a) In the case of operations that take place before live bivalve molluscs arrive at a dispatch or purification centre, they supplement the requirements of Annex I to that Regulation.
- (b) In the case of other operations, they supplement the requirements of Annex II to that Regulation.

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\* Official Publications Office is to insert the official number of Regulation on the organisation of official controls.

\*\* Official Publications Office is to insert the official number of Regulation on the hygiene of foodstuffs.

## CHAPTER I: GENERAL REQUIREMENTS FOR THE PLACING ON THE MARKET OF LIVE BIVALVE MOLLUSCS

1. Live bivalve molluscs may not be placed on the market for retail sale otherwise than via a dispatch centre, where an identification mark must be applied in accordance with Chapter VII.
2. Food business operators may accept batches of live bivalve molluscs only if the documentary requirements set out in paragraphs 3 to 7 have been complied with.
3. Whenever a food business operator moves a batch of live bivalve molluscs between establishments, up to and including the arrival of the batch at a dispatch centre or processing establishment, a registration document must accompany the batch.
4. The registration document must be in at least one official language of the Member State in which the receiving establishment is located and contain at least the information specified below.
  - (a) In the case of a batch of live bivalve molluscs sent from a production area, the registration document must contain at least the following information:
    - (i) the gatherer's identity and address;
    - (ii) the date of harvesting;

- (iii) the location of the production area described in as precise detail as is practicable or by a code number;
  - (iv) the health status of the production area;
  - (v) the shellfish species and quantity; and
  - (vi) the destination of the batch.
- (b) In the case of a batch of live bivalve molluscs sent from a relaying area, the registration document must contain at least the information referred to in (a) and the following information:
  - (i) the location of the relaying area; and
  - (ii) the duration of relaying.
- (c) In the case of a batch of live bivalve molluscs sent from a purification centre, the registration document must contain at least the information referred to in (a) and the following information:
  - (i) the address of the purification centre;



(ii) the duration of purification; and

(iii) the dates on which the batch entered and left the purification centre.

5. Food business operators sending batches of live bivalve molluscs must complete the relevant sections of the registration document so that they are easy to read and cannot be altered. Food business operators receiving batches must date-stamp the document on receipt of the batch or record the date of receipt in another manner.

6. Food business operators must keep a copy of the registration document relating to each batch sent and received for at least twelve months after its dispatch or receipt (or such longer period as the competent authority may specify).

7. However, if:

(a) the staff gathering live bivalve molluscs also operate the dispatch centre, purification centre, relaying area or processing establishment receiving the live bivalve molluscs; and

(b) a single competent authority supervises all the establishments concerned,

registration documents are not necessary if that competent authority so permits.

## CHAPTER II: HYGIENE REQUIREMENTS FOR THE PRODUCTION AND HARVESTING OF LIVE BIVALVE MOLLUSCS

### A. REQUIREMENTS FOR PRODUCTION AREAS

1. Gatherers may only harvest live bivalve molluscs from production areas with fixed locations and boundaries that the competent authority has classified – where appropriate, in cooperation with food business operators – as being of class A, B or C in accordance with Regulation (EC) No .../2004 \*.
2. Food business operators may place live bivalve molluscs collected from class A production areas on the market for direct human consumption only if they meet the requirements of Chapter V.
3. Food business operators may place live bivalve molluscs collected from class B production areas on the market for human consumption only after treatment in a purification centre or after relaying.
4. Food business operators may place live bivalve molluscs collected from class C production areas on the market for human consumption only after relaying over a long period in accordance with Part C of this Chapter.

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5. After purification or relaying, live bivalve molluscs from class B or C production areas must meet all of the requirements of Chapter V. However, live bivalve molluscs from such areas that have not been submitted for purification or relaying may be sent to a processing establishment, where they must undergo treatment to eliminate pathogenic microorganisms (where appropriate, after removal of sand, mud or slime in the same or another establishment). The permitted treatment methods are:
- (a) sterilisation in hermetically sealed containers; and
  - (b) heat treatments involving:
    - (i) immersion in boiling water for the period required to raise the internal temperature of the mollusc flesh to not less than 90°C and maintenance of this minimum temperature for a period of not less than 90 seconds;
    - (ii) cooking for three to five minutes in an enclosed space where the temperature is between 120 and 160°C and the pressure is between 2 and 5 kg/cm<sup>2</sup>, followed by shelling and freezing of the flesh to a core temperature of -20°C; and
    - (iii) steaming under pressure in an enclosed space satisfying the requirements relating to cooking time and the internal temperature of the mollusc flesh mentioned under (i). A validated methodology must be used. Procedures based on the HACCP principles must be in place to verify the uniform distribution of heat.

6. Food business operators must not produce live bivalve molluscs in, or harvest them from, areas that the competent authority has not classified, or which are unsuitable for health reasons. Food business operators must take account of any relevant information concerning areas' suitability for production and harvesting, including information obtained from own-checks and the competent authority. They must use this information, particularly information on environmental and weather conditions, to determine the appropriate treatment to apply to harvested batches.

#### B. REQUIREMENTS FOR HARVESTING AND HANDLING FOLLOWING HARVESTING

Food business operators harvesting live bivalve molluscs, or handling them immediately after harvesting, must ensure compliance with the following requirements.

1. Harvesting techniques and further handling must not cause additional contamination or excessive damage to the shells or tissues of the live bivalve molluscs or result in changes significantly affecting their suitability for treatment by purification, processing or relaying. Food business operators must in particular:
  - (a) adequately protect live bivalve molluscs from crushing, abrasion or vibration;
  - (b) not expose live bivalve molluscs to extreme temperatures;
  - (c) not re-immerses live bivalve molluscs in water that could cause additional contamination;  
and
  - (d) if carrying out conditioning in natural sites, use only areas that the competent authority has classified as being of class A.

2. Means of transport must permit adequate drainage, be equipped to ensure the best survival conditions possible and provide efficient protection against contamination.

#### C. REQUIREMENTS FOR RELAYING LIVE BIVALVE MOLLUSCS

Food business operators relaying live bivalve molluscs must ensure compliance with the following requirements.

1. Food business operators may use only those areas that the competent authority has approved for relaying live bivalve molluscs. Buoys, poles or other fixed means must clearly identify the boundaries of the sites. There must be a minimum distance between relaying areas, and also between relaying areas and production areas, so as to minimise any risk of the spread of contamination.
2. Conditions for relaying must ensure optimal conditions for purification. In particular, food business operators must:
  - (a) use techniques for handling live bivalve molluscs intended for relaying that permit the resumption of filter-feeding activity after immersion in natural waters;
  - (b) not relay live bivalve molluscs at a density that prevents purification;
  - (c) immerse live bivalve molluscs in seawater at the relaying area for an appropriate period, fixed depending on the water temperature, which period must be of at least two months' duration unless the competent authority agrees to a shorter period on the basis of the food business operator's risk analysis; and

- (d) ensure sufficient separation of sites within a relaying area to prevent mixing of batches; the "all in, all out" system must be used, so that a new batch cannot be brought in before the whole of the previous batch has been removed.
3. Food business operators managing relaying areas must keep permanent records of the source of live bivalve molluscs, relaying periods, relaying areas used and the subsequent destination of the batch after relaying, for inspection by the competent authority.

### CHAPTER III: STRUCTURAL REQUIREMENTS FOR DISPATCH AND PURIFICATION CENTRES

1. The location of premises on land must not be subject to flooding by ordinary high tides or run-off from surrounding areas.
2. Tanks and water storage containers must meet the following requirements:
  - (a) Internal surfaces must be smooth, durable, impermeable and easy to clean.
  - (b) They must be constructed so as to allow complete draining of water.
  - (c) Any water intake must be situated in a position that avoids contamination of the water supply.
3. In addition, in purification centres, purification tanks must be suitable for the volume and type of products to be purified.

## CHAPTER IV: HYGIENE REQUIREMENTS FOR PURIFICATION AND DISPATCH CENTRES

### A. REQUIREMENTS FOR PURIFICATION CENTRES

Food business operators purifying live bivalve molluscs must ensure compliance with the following requirements.

1. Before purification commences, live bivalve molluscs must be washed free of mud and accumulated debris using clean water.
2. Operation of the purification system must allow live bivalve molluscs rapidly to resume and to maintain filter-feeding activity, to eliminate sewage contamination, not to become re-contaminated and to be able to remain alive in a suitable condition after purification for wrapping, storage and transport before being placed on the market.
3. The quantity of live bivalve molluscs to be purified must not exceed the capacity of the purification centre. The live bivalve molluscs must be continuously purified for a period sufficient to achieve compliance with allow the health standards of Chapter V and microbiological criteria adopted in accordance with Regulation (EC) No .../2004 \*.
4. Should a purification tank contain several batches of live bivalve molluscs, they must be of the same species and the length of the treatment must be based on the time required by the batch needing the longest period of purification.

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\* Official Publications Office is to insert the official number of Regulation on the hygiene of foodstuffs.

5. Containers used to hold live bivalve molluscs in purification systems must have a construction that allows clean seawater to flow through. The depth of layers of live bivalve molluscs must not impede the opening of shells during purification.
6. No crustaceans, fish or other marine species may be kept in a purification tank in which live bivalve molluscs are undergoing purification.
7. Every package containing purified live bivalve molluscs sent to a dispatch centre must be provided with a label certifying that all molluscs have been purified.

## B. REQUIREMENTS FOR DISPATCH CENTRES

Food business operators operating dispatch centres must ensure compliance with the following requirements.

1. Handling of live bivalve molluscs, particularly conditioning, calibration, wrapping and packing, must not cause contamination of the product or affect the viability of the molluscs.
2. Before dispatch, the shells of live bivalve molluscs must be washed thoroughly with clean water.
3. Live bivalve molluscs must come from:
  - (a) a class A production area;
  - (b) a relaying area;



- (c) a purification centre; or
  - (d) another dispatch centre.
4. The requirements laid down in points 1 and 2 also apply to dispatch centres situated on board vessels. Molluscs handled in such centres must come from a class A production area or a relaying area.

## CHAPTER V: HEALTH STANDARDS FOR LIVE BIVALVE MOLLUSCS

In addition to ensuring compliance with microbiological criteria adopted in accordance with Regulation (EC) No .../2004<sup>\*</sup>, food business operators must ensure that live bivalve molluscs placed on the market for human consumption meet the standards laid down in this Chapter.

1. They must have organoleptic characteristics associated with freshness and viability, including shells free of dirt, an adequate response to percussion and normal amounts of intravalvular liquid.
2. They must not contain marine biotoxins in total quantities (measured in the whole body or any part edible separately) that exceed the following limits:
  - (a) for Paralytic Shellfish Poison (PSP), 800 micrograms per kilogram;
  - (b) for Amnesic Shellfish Poison (ASP), 20 milligrams of domoic acid per kilogram;

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<sup>\*</sup> Official Publications Office is to insert the official number of Regulation on the hygiene of foodstuffs.

- (c) for okadaic acid, dinophysistoxins and pectenotoxins together, 160 micrograms of okadaic acid equivalents per kilogram;
- (d) for yessotoxins, 1 milligram of yessotoxin equivalent per kilogram; and
- (e) for azaspiracids, 160 micrograms of azaspiracid equivalents per kilogram.

#### CHAPTER VI: WRAPPING AND PACKAGING OF LIVE BIVALVE MOLLUSCS

1. Oysters must be wrapped or packaged with the concave shell downwards.
2. Individual consumer-size packages of live bivalve molluscs must be closed and remain closed after leaving the dispatch centre and until presented for sale to the final consumer.

#### CHAPTER VII: IDENTIFICATION MARKING AND LABELLING

1. The label, including the identification mark, must be waterproof.
2. In addition to the general requirements for identification marks contained in Annex II, Section I, the following information must be present on the label:
  - (a) the species of bivalve mollusc (common name and scientific name); and
  - (b) the date of packaging, comprising at least the day and the month.

By way of derogation from Directive 2000/13/EC, the date of minimum durability may be replaced by the entry "these animals must be alive when sold".

3. The retailer must keep the label attached to the packaging of live bivalve molluscs that are not in individual consumer-size packages for at least 60 days after splitting up the contents.

#### CHAPTER VIII: OTHER REQUIREMENTS

1. Food business operators storing and transporting live bivalve molluscs must ensure that they are kept at a temperature that does not adversely affect food safety or their viability.
2. Live bivalve molluscs must not be re-immersed in, or sprayed with, water after they have been packaged for retail sale and left the dispatch centre.

#### CHAPTER IX: SPECIFIC REQUIREMENTS FOR PECTINIDAE HARVESTED OUTSIDE CLASSIFIED PRODUCTION AREAS

Food business operators harvesting pectinidae outside classified production areas or handling such pectinidae must comply with the following requirements.

1. Pectinidae may not be placed on the market unless they are harvested and handled in accordance with Chapter II, Part B, and meet the standards laid down in Chapter V, as proved by a system of own-checks.
2. In addition, where data from official monitoring programmes enable the competent authority to classify fishing grounds – where appropriate, in cooperation with food business operators – the provisions of Chapter II, Part A, apply by analogy to pectinidae.

3. Pectinidae may not be placed on the market for human consumption otherwise than via a fish auction, a dispatch centre or a processing establishment. When they handle pectinidae, food business operators operating such establishments must inform the competent authority and, as regards dispatch centres, comply with the relevant requirements of Chapters III and IV.
4. Food business operators handling pectinidae must comply:
  - (a) with the documentary requirements of Chapter I, points 3 to 7, where applicable. In this case, the registration document must clearly indicate the location of the area where the pectinidae were harvested; or
  - (b) as regards packaged pectinidae, and wrapped pectinidae if the wrapping provides protection equivalent to that of packaging, with the requirements of Chapter VII concerning identification marking and labelling.

#### SECTION VIII: FISHERY PRODUCTS

1. This Section does not apply to bivalve molluscs, echinoderms, tunicates and marine gastropods when placed on the market live. With the exception of Chapters I and II, it applies to such animals when not placed on the market live, in which case they must have been obtained in accordance with Section VII.
2. Chapter III, Parts A, C and D, Chapter IV and Chapter V apply to retail.

3. The requirements of this Section supplement those laid down in Regulation (EC) No .../2004 \*.
  - (a) In the case of establishments, including vessels, engaged in primary production and associated operations they supplement the requirements of Annex I to that Regulation.
  - (b) In the case of other establishments, including vessels, they supplement the requirements of Annex II to that Regulation.
  
4. In relation to fishery products:
  - (a) primary production covers the farming, fishing and collection of live fishery products with a view to their being placed on the market; and
  - (b) associated operations cover any of the following operations, if carried out on board fishing vessels: slaughter, bleeding, heading, gutting, removing fins, refrigeration and wrapping; they also include:
    - (1) the transport and storage of fishery products the nature of which has not been substantially altered, including live fishery products, within fish farms on land and,
    - (2) the transport of fishery products the nature of which has not been substantially altered, including live fishery products, from the place of production to the first establishment of destination.

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\* Official Publications Office is to insert the official number of Regulation on the hygiene of foodstuffs.

## CHAPTER I: REQUIREMENTS FOR VESSELS

Food business operators must ensure that:

1. vessels used to harvest fishery products from their natural environment, or to handle or process them after harvesting, comply with the structural and equipment requirements laid down in Part I; and
2. operations carried out on board vessels take place in accordance with the rules laid down in Part II.

### I. STRUCTURAL AND EQUIPMENT REQUIREMENTS

#### A. Requirements for all vessels

1. Vessels must be designed and constructed so as not to cause contamination of the products with bilge-water, sewage, smoke, fuel, oil, grease or other objectionable substances.
2. Surfaces with which fishery products come into contact must be of suitable corrosion-resistant material that is smooth and easy to clean. Surface coatings must be durable and non-toxic.
3. Equipment and material used for working on fishery products must be made of corrosion-resistant material that is easy to clean and disinfect.
4. When vessels have a water intake for water used with fishery products, it must be situated in a position that avoids contamination of the water supply.

B. Requirements for vessels designed and equipped to preserve fresh fishery products for more than twenty-four hours

1. Vessels designed and equipped to preserve fishery products for more than twenty-four hours must be equipped with holds, tanks or containers for the storage of fishery products at the temperatures laid down in Chapter VII.
2. Holds must be separated from the engine compartments and from the crew quarters by partitions which are sufficient to prevent any contamination of the stored fishery products. Holds and containers used for the storage of fishery products must ensure their preservation under satisfactory conditions of hygiene and, where necessary, ensure that melt water does not remain in contact with the products.
3. In vessels equipped for chilling fishery products in cooled clean seawater, tanks must incorporate devices for achieving a uniform temperature throughout the tanks. Such devices must achieve a chilling rate that ensures that the mix of fish and clean seawater reaches not more than 3°C 6 hours after loading and not more than 0 °C after 16 hours and allow the monitoring and, where necessary, recording of temperatures.

C. Requirements for freezer vessels

Freezer vessels must:

1. have freezing equipment with sufficient capacity to lower the temperature rapidly so as to achieve a core temperature of not more than -18°C;

2. have refrigeration equipment with sufficient capacity to maintain fishery products in the storage holds at not more than  $-18^{\circ}\text{C}$ . Storage holds must be equipped with a temperature-recording device in a place where it can be easily read. The temperature sensor of the reader must be situated in the area where the temperature in the hold is the highest; and
3. meet the requirements for vessels designed and equipped to preserve fishery products for more than 24 hours laid down in Part B, paragraph 2.

D. Requirements for factory vessels

1. Factory vessels must have at least:
  - (a) a receiving area reserved for taking fishery products on board, designed to allow each successive catch to be separated. This area must be easy to clean and designed so as to protect the products from the sun or the elements and from any source of contamination;
  - (b) a hygienic system for conveying fishery products from the receiving area to the work area;
  - (c) work areas that are large enough for the hygienic preparation and processing of fishery products, easy to clean and disinfect and designed and arranged in such a way as to prevent any contamination of the products;
  - (d) storage areas for the finished products that are large enough and designed so that they are easy to clean. If a waste-processing unit operates on board, a separate hold must be designated for the storage of such waste;



- (e) a place for storing packaging materials that is separate from the product preparation and processing areas;
  - (f) special equipment for disposing waste or fishery products that are unfit for human consumption directly into the sea or, where circumstances so require, into a watertight tank reserved for that purpose. If waste is stored and processed on board with a view to its sanitation, separate areas must be allocated for that purpose;
  - (g) a water intake situated in a position that avoids contamination of the water supply; and
  - (h) hand-washing equipment for use by the staff engaged in handling exposed fishery products with taps designed to prevent the spread of contamination.
2. However, factory vessels on board which crustaceans and molluscs are cooked, chilled and wrapped, need not meet the requirements of paragraph 1 if no other form of handling or processing takes place on board such vessels.
  3. Factory vessels that freeze fishery products must have equipment meeting the requirements for freezer vessels laid down in Part C, points 1 and 2.

## II. HYGIENE REQUIREMENTS

1. When in use, the parts of vessels or containers set aside for the storage of fishery products must be kept clean and maintained in good repair and condition. In particular, they must not be contaminated by fuel or bilge water.

2. As soon as possible after they are taken on board, fishery products must be protected from contamination and from the effects of the sun or any other source of heat. When they are washed, the water used must be either potable water or, where appropriate, clean water.
3. Fishery products must be handled and stored so as to prevent bruising. Handlers may use spiked instruments to move large fish or fish which might injure them, provided that the flesh of the products suffers no damage.
4. Fishery products other than those kept alive must undergo chilling as soon as possible after loading. However, when chilling is not possible, fishery products must be landed as soon as possible.
5. Ice used to chill fishery products must be made from potable water or clean water.
6. Where fish are headed and/or gutted on board, such operations must be carried out hygienically as soon as possible after capture, and the products must be washed immediately and thoroughly with potable water or clean water. In that event, the viscera and parts that may constitute a danger to public health must be removed as soon as possible and kept apart from products intended for human consumption. Livers and roes intended for human consumption must be preserved under ice, at a temperature approaching that of melting ice, or be frozen.
7. Where freezing in brine of whole fish intended for canning is practised, a temperature of not more than  $-9^{\circ}\text{C}$  must be achieved for the product. The brine must not be a source of contamination for the fish.

## CHAPTER II: REQUIREMENTS DURING AND AFTER LANDING

1. Food business operators responsible for the unloading and landing of fishery products must:
  - (a) ensure that unloading and landing equipment that comes into contact with fishery products is constructed of material that is easy to clean and disinfect and maintained in a good state of repair and cleanliness; and
  - (b) avoid contamination of fishery products during unloading and landing, in particular by:
    - (i) carrying out unloading and landing operations rapidly;
    - (ii) placing fishery products without delay in a protected environment at the temperature specified in Chapter VII; and
    - (iii) not using equipment and practices that cause unnecessary damage to the edible parts of the fishery products.
2. Food business operators responsible for auction and wholesale markets or parts thereof where fishery products are displayed for sale must ensure compliance with the following requirements.
  - (a) (i) There must be lockable facilities for the refrigerated storage of detained fishery products and separate lockable facilities for the storage of fishery products declared unfit for human consumption.

- (ii) If the competent authority so requires, there must be an adequately equipped lockable facility or, where needed, room for the exclusive use of the competent authority.
- (b) At the time of display or storage of fishery products:
  - (i) the premises must not be used for other purposes;
  - (ii) vehicles emitting exhaust fumes likely to impair the quality of fishery products must not have access to the premises;
  - (iii) persons having access to the premises must not introduce other animals; and
  - (iv) the premises must be well lit to facilitate official controls.
- 3. When chilling was not possible on board the vessel, fresh fishery products, other than those kept alive, must undergo chilling as soon as possible after landing and be stored at a temperature approaching that of melting ice.
- 4. Food business operators must cooperate with relevant competent authorities so as to permit them to carry out official controls in accordance with Regulation (EC) No.../2004 \*, in particular as regards any notification procedures for the landing of fishery products that the competent authority of the Member State the flag of which the vessel is flying or the competent authority of the Member State where the fishery products are landed might consider necessary.

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\* Official Publications Office is to insert the official number of Regulation on the organisation of official controls.

## CHAPTER III: REQUIREMENTS FOR ESTABLISHMENTS, INCLUDING VESSELS, HANDLING FISHERY PRODUCTS

Food business operators must ensure compliance with the following requirements, where relevant, in establishments handling fishery products.

### A. REQUIREMENTS FOR FRESH FISHERY PRODUCTS

1. Where chilled, unpackaged products are not distributed, dispatched, prepared or processed immediately after reaching an establishment on land, they must be stored under ice in appropriate facilities. Re-icing must be carried out as often as necessary. Packaged fresh fishery products must be chilled to a temperature approaching that of melting ice.
2. Operations such as heading and gutting must be carried out hygienically. Where gutting is possible from a technical and commercial viewpoint, it must be carried out as quickly as possible after the products have been caught or landed. The products must be washed thoroughly with potable water or, on board vessels, clean water immediately after these operations.
3. Operations such as filleting and cutting must be carried out so as to avoid contamination or spoilage of fillets and slices. Fillets and slices must not remain on the worktables beyond the time necessary for their preparation. Fillets and slices must be wrapped and, where necessary, packaged and must be chilled as quickly as possible after their preparation.

4. Containers used for the dispatch or storage of unpackaged prepared fresh fishery products stored under ice must ensure that melt water does not remain in contact with the products.
5. Whole and gutted fresh fishery products may be transported and stored in cooled water on board vessels. They may also continue to be transported in cooled water after landing, and be transported from aquaculture establishments, until they arrive at the first establishment on land carrying out any activity other than transport or sorting.

#### B. REQUIREMENTS FOR FROZEN PRODUCTS

Establishments on land that freeze fishery products must have equipment that satisfies the requirements laid down for freezer vessels in Chapter I, Part I.C, points 1 and 2.

#### C. REQUIREMENTS FOR MECHANICALLY SEPARATED FISHERY PRODUCTS

Food business operators manufacturing mechanically separated fishery products must ensure compliance with the following requirements.

1. The raw materials used must satisfy the following requirements.
  - (a) Only whole fish and bones after filleting may be used to produce mechanically separated fishery products;
  - (b) All raw materials must be free from guts.

2. The manufacturing process must satisfy the following requirements:
  - (a) Mechanical separation must take place without undue delay after filleting;
  - (b) If whole fish are used, they must be gutted and washed beforehand;
  - (c) After production, mechanically separated fishery products must be frozen as quickly as possible or incorporated in a product intended for freezing or a stabilising treatment.

#### D. REQUIREMENTS CONCERNING PARASITES

1. The following fishery products must be frozen at a temperature of not more than  $-20^{\circ}\text{C}$  in all parts of the product for not less than 24 hours; this treatment must be applied to the raw product or the finished product:
  - (a) fishery products to be consumed raw or almost raw;
  - (b) fishery products from the following species, if they are to undergo a cold smoking process in which the internal temperature of the fishery product is not more than  $60^{\circ}\text{C}$ :
    - (i) herring;
    - (ii) mackerel;
    - (iii) sprat;
    - (iv) (wild) Atlantic and Pacific salmon; and

- (c) marinated and/or salted fishery products, if the processing is insufficient to destroy nematode larvae.
2. Food business operators need not carry out the treatment required under paragraph 1 if:
    - (a) epidemiological data are available indicating that the fishing grounds of origin do not present a health hazard with regard to the presence of parasites; and
    - (b) the competent authority so authorises.
  3. A document from the manufacturer, stating the type of process they have undergone, must accompany fishery products referred to in paragraph 1 when placed on the market, except when supplied to the final consumer.

#### CHAPTER IV: REQUIREMENTS FOR PROCESSED FISHERY PRODUCTS

Food business operators cooking crustaceans and molluscs must ensure compliance with the following requirements.

1. Rapid cooling must follow cooking. Water used for this purpose must be potable water or, on board vessels, clean water. If no other method of preservation is used, cooling must continue until a temperature approaching that of melting ice is reached.



2. Shelling or shucking must be carried out hygienically, avoiding contamination of the product. Where such operations are done by hand, workers must pay particular attention to washing their hands.
3. After shelling or shucking, cooked products must be frozen immediately, or be chilled as soon as possible to the temperature laid down in Chapter VII.

## CHAPTER V: HEALTH STANDARDS FOR FISHERY PRODUCTS

In addition to ensuring compliance with microbiological criteria adopted in accordance with Regulation (EC) No .../2004 \*, food business operators must ensure, depending on the nature of the product or the species, that fishery products placed on the market for human consumption meet the standards laid down in this Chapter.

### A. ORGANOLEPTIC PROPERTIES OF FISHERY PRODUCTS

Food business operators must carry out an organoleptic examination of fishery products. In particular, this examination must ensure that fishery products comply with any freshness criteria.

### B. HISTAMINE

Food business operators must ensure that the limits with regard to histamine are not exceeded.

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\* Official Publications Office is to insert the official number of Regulation on the hygiene of foodstuffs.

### C. TOTAL VOLATILE NITROGEN

Unprocessed fishery products must not be placed on the market if chemical tests reveal that the limits with regard to TVB-N or TMA-N have been exceeded.

### D. PARASITES

Food business operators must ensure that fishery products have been subjected to a visual examination for the purpose of detecting visible parasites before being placed on the market. They must not place fishery products that are obviously contaminated with parasites on the market for human consumption.

### E. TOXINS HARMFUL TO HUMAN HEALTH

1. Fishery products derived from poisonous fish of the following families must not be placed on the market: Tetraodontidae, Molidae, Diodontidae and Canthigasteridae.
2. Fishery products containing biotoxins such as ciguatoxin or muscle-paralysing toxins must not be placed on the market. However, fishery products derived from bivalve molluscs, echinoderms, tunicates and marine gastropods may be placed on the market if they have been produced in accordance with Section VII and comply with the standards laid down in Chapter V, point 2, of that Section.

## CHAPTER VI: WRAPPING AND PACKAGING OF FISHERY PRODUCTS

1. Receptacles in which fresh fishery products are kept under ice must be water-resistant and ensure that melt water does not remain in contact with the products.
2. Frozen blocks prepared on board vessels must be adequately wrapped before landing.
3. When fishery products are wrapped on board fishing vessels, food business operators must ensure that wrapping material:
  - (a) is not a source of contamination;
  - (b) is stored in such a manner that it is not exposed to a risk of contamination;
  - (c) intended for re-use is easy to clean and, where necessary, to disinfect.

## CHAPTER VII: STORAGE OF FISHERY PRODUCTS

Food business operators storing fishery products must ensure compliance with the following requirements.

1. Fresh fishery products, thawed unprocessed fishery products, and cooked and chilled products from crustaceans and molluscs, must be maintained at a temperature approaching that of melting ice.

2. Frozen fishery products must be kept at a temperature of not more than  $-18^{\circ}\text{C}$  in all parts of the product; however, whole frozen fish in brine intended for the manufacture of canned food may be kept at a temperature of not more than  $-9^{\circ}\text{C}$ .
3. Fishery products kept alive must be kept at a temperature and in a manner that does not adversely affect food safety or their viability.

## CHAPTER VIII: TRANSPORT OF FISHERY PRODUCTS

Food business operators transporting fishery products must ensure compliance with the following requirements.

1. During transport, fishery products must be maintained at the required temperature.  
In particular:
  - (a) fresh fishery products, thawed unprocessed fishery products, and cooked and chilled products from crustaceans and molluscs, must be maintained at a temperature approaching that of melting ice;

- (b) frozen fishery products, with the exception of frozen fish in brine intended for the manufacture of canned food, must be maintained during transport at an even temperature of not more than  $-18^{\circ}\text{C}$  in all parts of the product, possibly with short upward fluctuations of not more than  $3^{\circ}\text{C}$ .
- 2. Food business operators need not comply with point 1(b) when frozen fishery products are transported from a cold store to an approved establishment to be thawed on arrival for the purposes of preparation and/or processing, if the journey is short and the competent authority so permits.
- 3. If fishery products are kept under ice, melt water must not remain in contact with the products.
- 4. Fishery products to be placed on the market live must be transported in such a way as not adversely to affect food safety or their viability.

## SECTION IX: RAW MILK AND DAIRY PRODUCTS

### CHAPTER I: RAW MILK – PRIMARY PRODUCTION

Food business operators producing or, as appropriate, collecting raw milk must ensure compliance with the requirements laid down in this Chapter.

## I. HEALTH REQUIREMENTS FOR RAW MILK PRODUCTION

### 1. Raw milk must come from animals:

- (a) that do not show any symptoms of infectious diseases communicable to humans through milk;
- (b) that are in a good general state of health, present no sign of disease that might result in the contamination of milk and, in particular, are not suffering from any infection of the genital tract with discharge, enteritis with diarrhoea and fever, or a recognisable inflammation of the udder;
- (c) that do not have any udder wound likely to affect the milk;
- (d) to which no unauthorised substances or products have been administered and that have not undergone illegal treatment within the meaning of Directive 96/23/EC; and
- (e) in respect of which, where authorised products or substances have been administered, the withdrawal periods prescribed for these products or substances have been observed.

2. (a) In particular, as regards brucellosis, raw milk must come from:
- (i) cows or buffaloes belonging to a herd which, within the meaning of Directive 64/432/EEC <sup>\*</sup>, is free or officially free of brucellosis;
  - (ii) sheep or goats belonging to a holding officially free or free of brucellosis within the meaning of Directive 91/68/EEC <sup>†</sup>; or
  - (iii) females of other species belonging, for species susceptible to brucellosis, to herds regularly checked for that disease under a control plan that the competent authority has approved.
- (b) As regards tuberculosis, raw milk must come from:
- (i) cows or buffaloes belonging to a herd which, within the meaning of Directive 64/432/EEC, is officially free of tuberculosis; or
  - (ii) females of other species belonging, for species susceptible to tuberculosis, to herds regularly checked for this disease under a control plan that the competent authority has approved.

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<sup>\*</sup> Council Directive 64/432/EEC of 26 June 1964 on animal health problems affecting intra-Community trade in bovine animals and swine (OJ L 121, 29.7.1964, p. 1977/64). Directive as last amended by the 2003 Act of Accession.

<sup>†</sup> Council Directive 91/68/EEC of 28 January 1991 on animal health conditions governing intra-Community trade in ovine and caprine animals (OJ L 46, 19.2.1991, p. 19). Directive as last amended by Regulation (EC) No 806/2003 (OJ L 122, 16.5.2003, p.1).

- (c) If goats are kept together with cows, such goats must be inspected and tested for tuberculosis.
3. However, raw milk from animals that do not meet the requirements of point 2 may be used with the authorisation of the competent authority:
- (a) in the case of cows or buffaloes that do not show a positive reaction to tests for tuberculosis or brucellosis, nor any symptoms of these diseases, after having undergone a heat treatment such as to show a negative reaction to the phosphatase test;
  - (b) in the case of sheep or goats that do not show a positive reaction to tests for brucellosis, or which have been vaccinated against brucellosis as part of an approved eradication programme, and which do not show any symptom of that disease, either:
    - (i) for the manufacture of cheese with a maturation period of at least two months; or
    - (ii) after having undergone heat treatment such as to show a negative reaction to the phosphatase test; and
  - (c) in the case of females of other species that do not show a positive reaction to tests for tuberculosis or brucellosis, nor any symptoms of these diseases, but belong to a herd where brucellosis or tuberculosis has been detected after the checks referred to in point 2(a)(iii) or 2(b)(ii), if treated to ensure its safety.



4. Raw milk from any animal not complying with the requirements of points 1 to 3 – in particular, any animal showing individually a positive reaction to the prophylactic tests vis-à-vis tuberculosis or brucellosis as laid down in Directive 64/432/EEC and Directive 91/68/EEC – must not be used for human consumption.
5. The isolation of animals that are infected, or suspected of being infected, with any of the diseases referred to in point 1 or 2 must be effective to avoid any adverse effect on other animals' milk.

## II. HYGIENE ON MILK PRODUCTION HOLDINGS

### A. Requirements for premises and equipment

1. Milking equipment, and premises where milk is stored, handled or cooled must be located and constructed so as to limit the risk of contamination of milk.
2. Premises for the storage of milk must be protected against vermin, have adequate separation from premises where animals are housed and, where necessary to meet the requirements laid down in Part B, have suitable refrigeration equipment.
3. Surfaces of equipment that are intended to come into contact with milk (utensils, containers, tanks, etc. intended for milking, collection or transport) must be easy to clean and, where necessary, disinfect and be maintained in a sound condition. This requires the use of smooth, washable and non-toxic materials.

4. After use, such surfaces must be cleaned and, where necessary, disinfected. After each journey, or after each series of journeys when the period of time between unloading and the following loading is very short, but in all cases at least once a day, containers and tanks used for the transport of raw milk must be cleaned and disinfected in an appropriate manner before re-use.

B. Hygiene during milking, collection and transport

1. Milking must be carried out hygienically, ensuring in particular:

- (a) that, before milking starts, the teats, udder and adjacent parts are clean;
- (b) that milk from each animal is checked for organoleptic or physico-chemical abnormalities by the milker or a method achieving similar results and that milk presenting such abnormalities is not used for human consumption;
- (c) that milk from animals showing clinical signs of udder disease is not used for human consumption otherwise than in accordance with the instructions of a veterinarian;
- (d) the identification of animals undergoing medical treatment likely to transfer residues to the milk, and that milk obtained from such animals before the end of the prescribed withdrawal period is not used for human consumption; and

- (e) that teat dips or sprays are used only if the competent authority has approved them and in a manner that does not produce unacceptable residue levels in the milk.
2. Immediately after milking, milk must be held in a clean place designed and equipped to avoid contamination. It must be cooled immediately to not more than 8 °C in the case of daily collection, or not more than 6 °C if collection is not daily.
  3. During transport the cold chain must be maintained and, on arrival at the establishment of destination, the temperature of the milk must not be more than 10°C.
  4. Food business operators need not comply with the temperature requirements laid down in points 2 and 3 if the milk meets the criteria provided for in Part III and either:
    - (a) the milk is processed within 2 hours of milking; or
    - (b) a higher temperature is necessary for technological reasons related to the manufacture of certain dairy products and the competent authority so authorises.

C. Staff hygiene

1. Persons performing milking and/or handling raw milk must wear suitable clean clothes.

2. Persons performing milking must maintain a high degree of personal cleanliness.  
Suitable facilities must be available near the place of milking to enable persons performing milking and handling raw milk to wash their hands and arms.

### III. CRITERIA FOR RAW MILK

1. The following criteria for raw milk apply pending the establishment of standards in the context of more specific legislation on the quality of milk and dairy products.
2. A representative number of samples of raw milk collected from milk production holdings taken by random sampling must be checked for compliance with points 3 and 4.

The checks may be carried out by, or on behalf of:

- (a) the food business operator producing the milk;
- (b) the food business operator collecting or processing the milk;
- (c) a group of food business operators; or
- (d) in the context of a national or regional control scheme.

3. (a) Food business operators must initiate procedures to ensure that raw milk meets the following criteria:

(i) for raw cows' milk:

Plate count at 30 °C (per ml)	$\leq 100\,000^{(*)}$
Somatic cell count (per ml)	$\leq 400\,000^{(**)}$

(ii) for raw milk from other species:

Plate count at 30 °C (per ml)	$\leq 1\,500\,000^{(*)}$
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(b) However, if raw milk from species other than cows is intended for the manufacture of products made with raw milk by a process that does not involve any heat treatment, food business operators must take steps to ensure that the raw milk used meets the following criterion.

Plate count at 30 °C (per ml)	$\leq 500\,000^{(*)}$
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(\*) Rolling geometric average over a two-month period, with at least two samples per month.

(\*\*) Rolling geometric average over a three-month period, with at least one sample per month, unless the competent authority specifies another methodology to take account of seasonal variations in production levels.

4. Without prejudice to Directive 96/23/EC, food business operators must initiate procedures to ensure that raw milk is not placed on the market if either:
  - (a) it contains antibiotic residues in a quantity that, in respect of any one of the substances referred to in Annexes I and III to Regulation (EEC) No 2377/90<sup>\*</sup>, exceeds the levels authorised under that Regulation; or
  - (b) the combined total of residues of antibiotic substances exceeds any maximum permitted value.
5. When raw milk fails to comply with point 3 or 4, the food business operator must inform the competent authority and take measures to correct the situation.

## CHAPTER II: REQUIREMENTS CONCERNING DAIRY PRODUCTS

### I. TEMPERATURE REQUIREMENTS

1. Food business operators must ensure that, upon acceptance at a processing establishment, milk is quickly cooled to not more than 6 °C and kept at that temperature until processed.
2. However, food business operators may keep milk at a higher temperature if:
  - (a) processing begins immediately after milking, or within 4 hours of acceptance at the processing establishment; or

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<sup>\*</sup> Council Regulation (EEC) No 2377/90 of 26 June 1990 laying down a Community procedure for the establishment of maximum residue limits of veterinary medicinal products in foodstuffs of animal origin (OJ L 224, 18.8.1990, p. 1). Regulation as last amended by Commission Regulation (EC) No 324/2004 (OJ L 58, 26.2.2004, p. 16).

- (b) the competent authority authorises a higher temperature for technological reasons concerning the manufacture of certain dairy products.

## II. REQUIREMENTS FOR HEAT TREATMENT

1. When raw milk or dairy products undergo heat treatment, food business operators must ensure that this satisfies the requirements of Regulation (EC) No .../2004 \*, Annex II, Chapter XI.
2. When considering whether to subject raw milk to heat treatment, food business operators must:
  - (a) have regard to the procedures developed in accordance with the HACCP principles pursuant to Regulation (EC) No ..../2004 \*; and
  - (b) comply with any requirements that the competent authority may impose in this regard when approving establishments or carrying out checks in accordance with Regulation (EC) No .../2004 \*\*.

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\* Official Publications Office is to insert official number of Regulation on the hygiene of foodstuffs.

\*\* Official Publications Office is to insert official number of Regulation on the organisation of official controls.

### III. CRITERIA FOR RAW COWS' MILK

1. Food business operators manufacturing dairy products must initiate procedures to ensure that, immediately before processing:
  - (a) raw cows' milk used to prepare dairy products has a plate count at 30°C of less than 300 000 per ml; and
  - (b) processed cows' milk used to prepare dairy products has a plate count at 30°C of less than 100 000 per ml.
2. When milk fails to meet the criteria laid down in paragraph 1, the food business operator must inform the competent authority and take measures to correct the situation.

### CHAPTER III: WRAPPING AND PACKAGING

Sealing of consumer packages must be carried out immediately after filling in the establishment where the last heat treatment of liquid dairy products takes place, by means of sealing devices that prevent contamination. The sealing system must be designed in such a way that, after opening, the evidence of its opening remains clear and easy to check.



## CHAPTER IV: LABELLING

1. In addition to the requirements of Directive 2000/13/EC, except in the cases envisaged in Article 13(4) and (5) of that Directive, labelling must clearly show:
  - (a) in the case of raw milk intended for direct human consumption, the words "raw milk";
  - (b) in the case of products made with raw milk, the manufacturing process for which does not include any heat treatment or any physical or chemical treatment, the words "made with raw milk".
2. The requirements of paragraph 1 apply to products destined for retail trade. The term "labelling" includes any packaging, document, notice, label, ring or collar accompanying or referring to such products.

## CHAPTER V: IDENTIFICATION MARKING

By way of derogation from the requirements of Annex II, Section I:

1. rather than indicating the approval number of the establishment, the identification mark may include a reference to where on the wrapping or packaging the approval number of the establishment is indicated;
2. in the case of the reusable bottles, the identification mark may indicate only the initials of the consigning country and the approval number of the establishment.

## SECTION X: EGGS AND EGG PRODUCTS

### CHAPTER I: EGGS

1. At the producer's premises, and until sale to the consumer, eggs must be kept clean, dry, free of extraneous odour, effectively protected from shocks and out of direct sunshine.
2. Eggs must be stored and transported at a temperature, preferably constant, that is best suited to assure optimal conservation of their hygiene properties.
3. Eggs must be delivered to the consumer within a maximum time limit of 21 days of laying.

### CHAPTER II: EGG PRODUCTS

#### I. REQUIREMENTS FOR ESTABLISHMENTS

Food business operators must ensure that establishments for the manufacture of egg products are constructed, laid out and equipped so as to ensure separation of the following operations:

- 1) washing, drying and disinfecting dirty eggs, where carried out;
- 2) breaking eggs, collecting their contents and removing parts of shells and membranes; and
- 3) operations other than those referred to in points 1 and 2.

## II. RAW MATERIALS FOR THE MANUFACTURE OF EGG PRODUCTS

Food business operators must ensure that raw materials used to manufacture egg products comply with the following requirements.

1. The shells of eggs used in the manufacture of egg products must be fully developed and contain no breaks. However, cracked eggs may be used for the manufacture of egg products if the establishment of production or a packing centre delivers them directly to a processing establishment, where they must be broken as soon as possible.
2. Liquid egg obtained in an establishment approved for that purpose may be used as raw material. Liquid egg must be obtained in accordance with the requirements of points 1, 2, 3, 4 and 7 of Part III.

## III. SPECIAL HYGIENE REQUIREMENTS FOR THE MANUFACTURE OF EGG PRODUCTS

Food business operators must ensure that all operations are carried out in such a way as to avoid any contamination during production, handling and storage of egg products, in particular by ensuring compliance with the following requirements.

1. Eggs must not be broken unless they are clean and dry.

2. Eggs must be broken in a manner that minimises contamination, in particular by ensuring adequate separation from other operations. Cracked eggs must be processed as soon as possible.
3. Eggs other than those of hens, turkeys or guinea fowl must be handled and processed separately. All equipment must be cleaned and disinfected before processing of hens', turkeys' and guinea fowls' eggs is resumed.
4. Egg contents may not be obtained by the centrifuging or crushing of eggs, nor may centrifuging be used to obtain the remains of egg whites from empty shells for human consumption.
5. After breaking, each particle of the egg product must undergo processing as quickly as possible to eliminate microbiological hazards or to reduce them to an acceptable level. A batch that has been insufficiently processed may immediately undergo processing again in the same establishment, if this processing renders it fit for human consumption. When a batch is found to be unfit for human consumption, it must be denatured so as to ensure that it is not used for human consumption.
6. Processing is not required for egg white intended for the manufacture of dried or crystallised albumin destined subsequently to undergo heat treatment.

7. If processing is not carried out immediately after breaking, liquid egg must be stored either frozen or at a temperature of not more than 4 °C. The storage period before processing at 4 °C must not exceed 48 hours. However, these requirements do not apply to products to be de-sugared, if de-sugaring process is performed as soon as possible.
8. Products that have not been stabilised so as to be kept at room temperature must be cooled to not more than 4 °C. Products for freezing must be frozen immediately after processing.

#### IV. ANALYTICAL SPECIFICATIONS

1. The concentration of 3-OH-butyric acid must not exceed 10 mg/kg in the dry matter of the unmodified egg product.
2. The lactic acid content of raw material used to manufacture egg products must not exceed 1 g/kg of dry matter. However, for fermented products, this value must be the one recorded before the fermentation process.
3. The quantity of eggshell remains, egg membranes and any other particles in the processed egg product must not exceed 100 mg/kg of egg product.

#### V. LABELLING AND IDENTIFICATION MARKING

1. In addition to the general requirements for identification marking laid down in Annex II, Section I, consignments of egg products, destined not for retail but for use as an ingredient in the manufacture of another product, must have a label giving the temperature at which the egg products must be maintained and the period during which conservation may thus be assured.

2. In the case of liquid eggs, the label referred to in paragraph 1 must also bear the words: "non-pasteurised egg products - to be treated at place of destination" and indicate the date and hour of breaking.

## SECTION XI: FROGS' LEGS AND SNAILS

Food business operators preparing frogs' legs or snails for human consumption must ensure compliance with the following requirements.

1. Frogs and snails must be killed in an establishment constructed, laid out and equipped for that purpose.
2. Establishment in which frogs' legs are prepared must have a room reserved for the storage and washing of live frogs, and for their slaughter and bleeding. This room must be physically separate from the preparation room.
3. Frogs and snails that die otherwise than by being killed in the establishment must not be prepared for human consumption.
4. Frogs and snails must be subjected to an organoleptic examination carried out by sampling. If that examination indicates that they might present a hazard, they must not be used for human consumption.

5. Immediately following preparation, frogs' legs must be washed fully with running potable water and immediately chilled to a temperature approaching that of melting ice, frozen or processed.
6. After killing, snails' hepato-pancreas must, if it might present a hazard, be removed and not be used for human consumption.

## SECTION XII: RENDERED ANIMAL FATS AND GREAVES

### CHAPTER I: REQUIREMENTS APPLICABLE TO ESTABLISHMENTS COLLECTING OR PROCESSING RAW MATERIALS

Food business operators must ensure that establishments collecting or processing raw materials for the production of rendered animal fats and greaves comply with the following requirements.

1. Centres for the collection of raw materials and further transport to processing establishments must be equipped with facilities for the storage of raw materials at a temperature of not more than 7°C.
2. Each processing establishment must have:
  - (a) refrigeration facilities;

- (b) a dispatch room, unless the establishment dispatches rendered animal fat only in tankers; and
  - (c) if appropriate, suitable equipment for the preparation of products consisting of rendered animal fats mixed with other foodstuffs and/or seasonings.
3. However, the refrigeration facilities required under points 1 and 2(a) are not necessary if the arrangements for the supply of raw materials ensure that they are never stored or transported without active refrigeration otherwise than as provided for in Chapter II, point 1(d).

## CHAPTER II: HYGIENE REQUIREMENTS FOR THE PREPARATION OF RENDERED ANIMAL FAT AND GREAVES

Food business operators preparing rendered animal fats and greaves must ensure compliance with the following requirements.

1. Raw materials must:
  - (a) derive from animals which have been slaughtered in a slaughterhouse, and which have been found fit for human consumption following ante-mortem and post-mortem inspection;
  - (b) consist of adipose tissues or bones, which are reasonably free from blood and impurities;



- (c) come from establishments registered or approved under Regulation (EC) No .../2003 \* or under this Regulation; and
  - (d) be transported, and stored until rendering, in hygienic conditions and at an internal temperature of not more than 7 °C. However, raw materials may be stored and transported without active refrigeration if rendered within 12 hours after the day on which they were obtained.
2. During rendering the use of solvents is prohibited.
  3. When the fat for refining meets the standards laid down in point 4, rendered animal fat prepared in accordance with points 1 and 2 may be refined in the same establishment or in another establishment with a view to improving its physico-chemical quality.

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\* Official Publications Office is to insert official number of Regulation on the hygiene of foodstuffs.

4. Rendered animal fat, depending on type, must meet the following standards:

	Ruminants			Porcine animals			Other animal fat	
	Edible tallow		Tallow for refining	Edible fat		Lard and other fat for refining	Edible	For refining
	Premier jus <sup>(1)</sup>	Other		Lard <sup>(2)</sup>	Other			
FFA (m/m% oleic acid) maximum	0.75	1.25	3.0	0.75	1.25	2.0	1.25	3.0
Peroxide maximum	4 meq/kg	4 meq/kg	6 meq/kg	4 meq/kg	4 meq/kg	6 meq/kg	4 meq/kg	10 meq/kg
Total insoluble impurities	Maximum 0.15%			Maximum 0.5%				
Odour, taste, colour	Normal							
(1) Rendered animal fat obtained by low-temperature rendering of fresh fat from the heart, caul, kidneys and mesentery of bovine animals, and fat from cutting rooms.								
(2) Rendered animal fat obtained from the adipose tissues of porcine animals.								

5. Greaves intended for human consumption must be stored in accordance with the following temperature requirements.

(a) When greaves are rendered at a temperature of not more than 70°C, they must be stored:

(i) at a temperature of not more than 7°C for a period not exceeding 24 hours; or

(ii) at a temperature of not more than -18°C.

- (b) When greaves are rendered at a temperature of more than 70°C and have a moisture content of 10% (m/m) or more, they must be stored:
  - (i) at a temperature of not more than 7°C for a period not exceeding 48 hours or a time/temperature ratio giving an equivalent guarantee; or
  - (ii) at a temperature of not more than -18°C.
- (c) When greaves are rendered at a temperature of more than 70°C and have a moisture content of less than 10% (m/m), there are no specific requirements.

### SECTION XIII: TREATED STOMACHS, BLADDERS AND INTESTINES

Food business operators treating stomachs, bladders and intestines must ensure compliance with the following requirements.

1. Animal intestines, bladders and stomachs may be placed on the market only if:
  - (a) they derive from animals which have been slaughtered in a slaughterhouse, and which have been found fit for human consumption following ante-mortem and post-mortem inspection;
  - (b) they are salted, heated or dried; and
  - (c) after the treatment referred to in (b), effective measures are taken to prevent re-contamination.

2. Treated stomachs, bladders and intestines that cannot be kept at ambient temperature must be stored chilled using facilities intended for that purpose until their dispatch. In particular, products that are not salted or dried must be kept at a temperature of not more than 3°C.

#### SECTION XIV: GELATINE

1. Food business operators manufacturing gelatine must ensure compliance with the requirements of this Section.
2. For the purpose of this Section, "tanning" means the hardening of hides, using vegetable tanning agents, chromium salts or other substances such as aluminium salts, ferric salts, silicic salts, aldehydes and quinones, or other synthetic hardening agents.

#### CHAPTER I: REQUIREMENTS FOR RAW MATERIALS

1. For the production of gelatine intended for use in food, the following raw materials may be used:
  - (a) bones;
  - (b) hides and skins of farmed ruminant animals;
  - (c) pig skins;
  - (d) poultry skin;

- (e) tendons and sinews;
  - (f) wild game hides and skins; and
  - (g) fish skin and bones.
2. The use of hides and skins is prohibited if they have undergone any tanning process, regardless of whether this process was completed.
  3. Raw materials listed in point 1(a) to (e) must derive from animals which have been slaughtered in a slaughterhouse and whose carcasses have been found fit for human consumption following ante-mortem and post-mortem inspection or, in the case of hides and skins from wild game, found fit for human consumption.
  4. Raw materials must come from establishments registered or approved under Regulation (EC) No .../2004 \* or under this Regulation.
  5. Collection centres and tanneries may also supply raw material for the production of gelatine intended for human consumption if the competent authority specifically authorises them for this purpose and they fulfil the following requirements.
    - (a) They must have storage rooms with hard floors and smooth walls that are easy to clean and disinfect and, where appropriate, provided with refrigeration facilities.

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\* Official Publications Office is to insert official number of Regulation on the hygiene of foodstuffs.

- (b) The storage rooms must be kept in a satisfactory state of cleanliness and repair, so that they do not constitute a source of contamination for the raw materials.
- (c) If raw material not in conformity with this Chapter is stored and/or processed in these premises, it must be segregated from raw material in conformity with this Chapter throughout the period of receipt, storage, processing and dispatch.

## CHAPTER II: TRANSPORT AND STORAGE OF RAW MATERIALS

1. In place of the identification mark provided for in Annex II, Section I, a document indicating the establishment of origin and containing the information set out in the Appendix to this Annex must accompany raw materials during transport, when delivered to a collection centre or tannery and when delivered to the gelatine-processing establishment.
2. Raw materials must be transported and stored chilled or frozen unless they are processed within 24 hours after their departure. However, degreased and dried bones or ossein, salted, dried and limed hides, and hides and skins treated with alkali or acid may be transported and stored at ambient temperature.

### CHAPTER III: REQUIREMENTS FOR THE MANUFACTURE OF GELATINE

1. The production process for gelatine must ensure that:
  - (a) all ruminant bone material derived from animals born, reared or slaughtered in countries or regions classified as having a low incidence of BSE in accordance with Community legislation is subjected to a process which ensures that all bone material is finely crushed and degreased with hot water and treated with dilute hydrochloric acid (at minimum concentration of 4% and  $\text{pH} < 1.5$ ) over a period of at least two days, followed by an alkaline treatment of saturated lime solution ( $\text{pH} > 12.5$ ) for a period of at least 20 days with a sterilisation step of 138-140 °C during four seconds or by any approved equivalent process; and
  - (b) other raw material is subjected to a treatment with acid or alkali, followed by one or more rinses. The pH must be adjusted subsequently. Gelatine must be extracted by heating one or several times in succession, followed by purification by means of filtration and sterilisation.
2. If a food business operator manufacturing gelatine complies with the requirements applying to gelatine intended for human consumption in respect of all the gelatine that it produces, it may produce and store gelatine not intended for human consumption in the same establishment.

## CHAPTER IV: REQUIREMENTS FOR FINISHED PRODUCTS

Food business operators must ensure that gelatine complies with the residue limits set out in the following table.

Residue	Limit
As	1 ppm
Pb	5 ppm
Cd	0.5 ppm
Hg	0.15 ppm
Cr	10 ppm
Cu	30 ppm
Zn	50 ppm
SO <sub>2</sub> ( Reith Williams)	50 ppm
H <sub>2</sub> O <sub>2</sub> (European Pharmacopoeia 1986 (V <sub>2</sub> O <sub>2</sub> ))	10 ppm

### SECTION XV: COLLAGEN

1. Food business operators manufacturing collagen must ensure compliance with the requirements of this Section.
2. For the purpose of this Section, "tanning" means the hardening of hides, using vegetable tanning agents, chromium salts or other substances such as aluminium salts, ferric salts, silicic salts, aldehydes and quinones, or other synthetic hardening agents.



## CHAPTER I: REQUIREMENTS FOR RAW MATERIALS

1. For the production of collagen intended for use in food, the following raw materials may be used:
  - (a) hides and skins of farmed ruminant animals;
  - (b) pig skins and bones;
  - (c) poultry skin and bones;
  - (d) tendons;
  - (e) wild game hides and skins; and
  - (f) fish skin and bones.
2. The use of hides and skins is prohibited if they have undergone any tanning process, regardless of whether this process was completed.
3. Raw materials listed in point 1(a) to (d) must derive from animals which have been slaughtered in a slaughterhouse and whose carcasses have been found fit for human consumption following ante-and post-mortem inspection or, in the case of hides and skins from wild game, found fit for human consumption.

4. Raw materials must come from establishments registered or approved under Regulation (EC) No .../2004<sup>\*</sup> or under this Regulation.
5. Collection centres and tanneries may also supply raw material for the production of collagen intended for human consumption if the competent authority specifically authorises them for this purpose and they fulfil the following requirements.
  - (a) They must have storage rooms with hard floors and smooth walls that are easy to clean and disinfect and, where appropriate, provided with refrigeration facilities.
  - (b) The storage rooms must be kept in a satisfactory state of cleanliness and repair, so that they do not constitute a source of contamination for the raw materials.
  - (c) If raw material not in conformity with this Chapter is stored and/or processed in these premises, it must be segregated from raw material in conformity with this Chapter throughout the period of receipt, storage, processing and dispatch.

## CHAPTER II: TRANSPORT AND STORAGE OF RAW MATERIALS

1. In place of the identification mark provided for in Annex II, Section I, a document indicating the establishment of origin and containing the information set out in the Appendix to this Annex must accompany raw materials during transport, when delivered to a collection centre or tannery and when delivered to the collagen-processing establishment.

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<sup>\*</sup> Official Publications Office is to insert official number of Regulation on the hygiene of foodstuffs.

2. Raw materials must be transported and stored chilled or frozen unless they are processed within 24 hours after their departure. However, degreased and dried bones or ossein, salted, dried and limed hides, and hides and skins treated with alkali or acid may be transported and stored at ambient temperature.

### CHAPTER III: REQUIREMENTS FOR THE MANUFACTURE OF COLLAGEN

1. Collagen must be produced by a process that ensures that the raw material is subjected to a treatment involving washing, pH adjustment using acid or alkali followed by one or more rinses, filtration and extrusion or by an approved equivalent process.
2. After having been subjected to the process referred to in paragraph 1 above, collagen may undergo a drying process.
3. If a food business operator manufacturing collagen complies with the requirements applying to collagen intended for human consumption in respect of all the collagen that it produces, it may produce and store collagen not intended for human consumption in the same establishment.

## CHAPTER IV: REQUIREMENTS FOR FINISHED PRODUCTS

Food business operators must ensure that collagen complies with the residue limits set out in the following table.

Residue	Limit
As	1 ppm
Pb	5 ppm
Cd	0,5 ppm
Hg	0,15 ppm
Cr	10 ppm
Cu	30 ppm
Zn	50 ppm
SO <sub>2</sub> ( Reith Williams)	50 ppm
H <sub>2</sub> O <sub>2</sub> (European Pharmacopoeia 1986 (V <sub>2</sub> O <sub>2</sub> ))	10 ppm

## CHAPTER V: LABELLING

Wrapping and packaging containing collagen must bear the words "collagen fit for human consumption" and indicate the date of preparation.

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MODEL DOCUMENT TO ACCOMPANY RAW MATERIAL  
DESTINED FOR THE PRODUCTION OF GELATINE OR COLLAGEN

I. Identification of raw material

Type of products: .....

Date of manufacture: .....

Type of packaging: .....

Number of packages: .....

Guaranteed storage period: .....

Net weight (kg): .....

II. Origin of raw material

Address(es) and registration number(s) of the approved production establishment(s): .....

.....

III. Destination of raw material

The raw material will be sent:

from: .....

(place of loading)

to: .....

(country and place of destination)

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

Name and address of consignor: .....

Name and address of consignee: .....

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