COUNCIL DIRECTIVE 96/23/EC

of 29 April 1996

on measures to monitor certain substances and residues thereof in live animals and animal products and repealing Directives 85/358/EEC and 86/469/EEC and Decisions 89/187/EEC and 91/664/EEC

THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty establishing the European Community, and in particular Article 43 thereof,

Having regard to the proposal from the Commission [1],

Having regard to the opinion of the European Parliament [2],

Having regard to the opinion of the Economic and Social Committee [3],

(1) Whereas by Directive 96/22/EC [4] the Council decided to maintain the prohibition on the use of certain substances having a hormonal or thyrostatic action, by extending it to beta-agonists having an anabolic effect;

(2) Whereas on 9 March 1995 the European Parliament pointed out, *inter alia,* that the Community urgently needed an effective and uniform monitoring system and asked the Member States to reinforce supervision and monitoring with regard to the use of illegal substances in meat;

(3) Whereas, by Directive 85/358/EEC [5], the Council adopted certain rules on the detection and monitoring of substances having a hormonal or thyrostatic action; whereas those rules should be extended to cover other substances which are used in stockfarming to promote growth and productivity in livestock or for therapeutic purposes and which may prove dangerous to the consumer on account of their residues;

(4) Whereas by Directive 86/469/EEC [6], the Council introduced certain rules on the monitoring of a certain number of residues of pharmacological substances and of environmental contaminants in farm animals and in the fresh meat obtained from such animals; whereas such monitoring should be extended to cover other animal species and all animal products for human consumption;

(5) Whereas 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 [7] laid down in its Annexes limits for certain veterinary medicinal products;

(6) Whereas the Community legislation on monitoring residues in meat lacks clarity, giving rise to varying interpretations in the different Member States;

(7) Whereas there is a need to reinforce the controls carried out by and in the Member States;

(8) Whereas producers and others involved in the stockfarming industry should take greater responsibility in future for the quality and safety of meat for human consumption;

(9) Whereas the specific penalties in respect of stockfarmers not complying with Community legislation in particular prohibiting the use of certain hormonal and anabolic substances in stockfarming are to be incorporated in the separate provisions governing particular product groups;

(10) Whereas Article 4 of Directive 71/118/EEC [8] requires Member States to ensure that checks are conducted to detect residues of substances having a pharmacological action, their derivatives and other substances which may be transmitted to poultrymeat and which may make the consumption of fresh poultrymeat dangerous or harmful to human health;

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[1] OJ No C 302, 9. 11. 1993, p. 12, and OJ No C 222, 10. 8. 1994, p. 17.
[2] OJ No C 128, 9. 5. 1994, p. 100.
[3] OJ No C 52, 19. 2. 1994, p. 30.
[4] See p. 3 of this Official Journal.
[5] OJ No L 191, 23. 7. 1985, p. 46. Directive as last amended by the 1994 Act of Accession.
[6] OJ No L 275, 26. 9. 1986, p. 36. Directive as amended by the 1994 Act of Accession.
[7] OJ No L 224, 18. 8. 1990, p. 1. Regulation as last amended by Commission Regulation (EC) No 282/96 (OJ No L 37, 15. 2. 1996, p. 12).
[8] OJ No L 55, 8. 3. 1971, p. 23. Directive as last amended by the 1994 Act of Accession.

(11) Whereas Directive 91/493/EEC[1] requires a monitoring system to be established by the Member States to detect contaminants present in the aquatic environment;

(12) Whereas Directive 92/46/EEC[2] provides that, by 30 June 1993 at the latest, national measures for the detection of residues in raw milk, heat-treated milk and milk-based products shall have been submitted to the Commission by the Member States, the residues to be detected being those in Part A, group III, and Part B, group II, of Annex I to Directive 86/469/EEC;

(13) Whereas Directive 89/437/EEC[3] requires Member States to ensure that checks are conducted to detect residues of substances having a pharmacological or hormonal action, antibiotics, pesticides, detergents and other substances harmful or likely to alter the organoleptic characteristics of egg products or make the consumption of such products dangerous or harmful to human health;

(14) Whereas Directive 92/45/EEC[4] requires Member States to extend their residue detection plans in order to make wild-game meat subject, where necessary, to sampling checks with a view to detecting the presence of contaminants from the environment and to include rabbits and farmed game in such monitoring;

(15) Whereas, if the illegal use of growth and productivity promoters in stockfarming is to be combated effectively in all Member States, action will have to be organized at Community level;

(16) Whereas systems of self-regulation by producer groups can play an important role in combating the illegal use of growth promoters; whereas it is essential for consumers that these systems adequately guarantee the absence of such promoters and whereas a general European approach is essential to safeguard and support self-regulation systems;

(17) Whereas, to that end, producer groups should be assisted in developing self-regulation systems to ensure that their meat is free of unauthorized substances or products;

(18) Whereas a certain number of provisions of Directives 86/469/EEC and 85/358/EEC and of Decisions 89/187/EEC[5] and 91/664/EEC[6] require clarification in the interests of the effective application of controls and residue detection in the Community; whereas, with a view to immediate and uniform application of the controls provided for, the present rules and amendments to them should be assembled in a single text repealing the aforesaid instruments,

HAS ADOPTED THIS DIRECTIVE:

CHAPTER I

Scope and definitions

Article 1

This Directive lays down measures to monitor the substances and groups of residues listed in Annex I.

Article 2

For the purposes of this Directive, the definitions in Directive 96/22/EC shall apply. In addition:

(a) 'unauthorized substances or products' shall mean substances or products the administering of which to animals is prohibited under Community legislation;

(b) 'illegal treatment' shall mean the use of unauthorized substances or products or the use of substances or products authorized under Community legislation for purposes or under conditions other than those laid down in Community legislation or, where appropriate, in the various national legislations;

(c) 'residue' shall mean a residue of substances having a pharmacological action, of their metabolites and of other substances transmitted to animal products and likely to be harmful to human health;

(d) 'competent authority' shall mean the central authority of a Member State competent in veterinary matters or any authority to which such central authority has delegated such competence;

(e) 'official sample' shall mean a sample taken by the competent authority which bears, for the purposes of examination of the residues or substances listed in

(1) OJ No L 268, 24. 9. 1991, p. 15. Directive as last amended by Directive 95/71/EC (OJ No L 332, 30. 12. 1995, p. 40).
(2) OJ No L 268, 14. 9. 1992, p. 1. Directive as last amended by the 1994 Act of Accession.
(3) OJ No L 212, 22. 7. 1989, p. 87. Directive as last amended by the 1994 Act of Accession.
(4) OJ No L 268, 14. 9. 1992, p. 35. Directive as last amended by the 1994 Act of Accession.
(5) OJ No L 66, 10. 3. 1989, p. 37.
(6) OJ No L 368, 31. 12. 1991, p. 17.

Annex I, a reference to the species, the type, the quantity concerned, the method of collection and particulars identifying the sex of the animal and the origin of the animal or of the animal product;

(f) 'approved laboratory' shall mean a laboratory approved by the competent authorities of a Member State for the purposes of examining an official sample in order to detect the presence of residues;

(g) 'animal' shall mean the species covered by Directive 90/425/EEC(1);

(h) 'batch of animals' shall mean a group of animals of the same species, in the same age range, reared on the same holding, at the same time and under the same conditions of rearing;

(i) 'beta-agonist' shall mean a beta adrenoceptor agonist.

CHAPTER II

Monitoring plans for the detection of residues or substances

Article 3

The production process of animals and primary products of animal origin shall be monitored in accordance with this Chapter for the purpose of detecting the presence of the residues and substances listed in Annex I in live animals, their excrement and body fluids and in tissue, animal products, animal feed and drinking water.

Article 4

1. Member States shall assign the task of coordinating the implementation of the inspections provided for in this Chapter, which are carried out within their national territory, to a central public department or body.

2. The department or body referred to in paragraph 1 shall be responsible for:

(a) drawing up the plan provided for in Article 5 to enable the competent departments to carry out the required inspections;

(b) coordinating the activities of the central and regional departments responsible for monitoring the various residues. Such coordination shall extend to all departments working to prevent the fraudulent use of substances or products on stock farms;

(c) collecting the data needed to evaluate the means used and the results obtained in carrying out the measures provided for in this Chapter;

(d) sending the Commission, by not later than 31 March of each year, the data and results referred to in (c), including the results of any surveys undertaken.

3. This Article shall not affect more specific rules applicable to the monitoring of animal nutrition.

Article 5

1. By 30 June 1997 at the latest, Member States shall submit a plan to the Commission setting out the national measures to be implemented during the initial year of the plan and subsequently any update of plans previously approved in accordance with Article 8 on the basis of the experience of the preceding year, or years by 31 March at the latest of the year of the update.

2. The plan provided for in paragraph 1 shall:

(a) provide for detection of groups of residues or substances according to type of animal, in accordance with Annex II;

(b) specify in particular the measures for detection of the presence of:

(i) the substances referred to in (a) in the animals, in the drinking water of the animals and in all places where the animals are bred or kept;

(ii) residues of the aforementioned substances in live animals, their excrement and body fluids and in animal tissues and products such as meat, milk, eggs and honey;

(c) comply with the sampling rules and levels laid down in Annexes III and IV.

Article 6

1. The plan must conform to the sampling levels and frequencies laid down in Annex IV. However, at the request of a Member State the Commission may, in accordance with the procedure provided for in Article 32, adjust the minimum control requirements laid down in Annex IV provided that it is clearly established that such adjustments increase the overall effectiveness of the plan in respect of the Member State concerned and in no way reduce its ability to identify residues of, or cases of illegal treatment with, substances listed in Annex I.

2. Re-examination of the groups of residues to be checked for in accordance with Annex II and determination of the sampling levels and frequencies covering the animals and products referred to in Article 3 and not already laid down in Annex IV shall take place in accordance with the procedure provided for in Article 33 and on the first occasion within a maximum of 18 months of the adoption of this Directive. In doing so, account shall be taken of experience gained under

(1) OJ No L 224, 18. 8. 1990, p. 29. Directive as last amended by Directive 92/65/EEC (OJ No L 268, 14. 9. 1992, p. 54).

existing national measures and information forwarded to the Commission under existing Community requirements making such specific product groups subject to monitoring for residues.

Article 7

The initial plan shall take into account the specific situation of each Member State and specify in particular:

— legislation on the use of the substances listed in Annex I and, in particular, provisions on their prohibition or authorization, distribution and placing on the market and the rules governing their administration, in so far as such legislation is not harmonized.

— the infrastructure of the relevant departments (in particular, giving details of the type and size of the bodies involved in implementing the plans),

— a list of approved laboratories with details of their capacity for processing samples,

— national tolerances for authorized substances where no maximum Community residue levels have been set under Regulation (EEC) No 2377/90 and Directive 86/363/EEC[1],

— a list of the substances to be detected, methods of analysis, standards for interpreting the findings and, in the case of the substances listed in Annex I, the number of samples to be taken, giving reasons for this number,

— the number of official samples to be taken in relation to the number of animals of the species concerned slaughtered in preceding years in accordance with the sampling levels and frequencies laid down in Annex IV,

— details of the rules governing the collection of official samples, and in particular the rules concerning the particulars to appear on such official samples,

— the type of measures laid down by the competent authorities with regard to animals or products in which residues have been detected.

Article 8

1. The Commission shall examine the initial plans forwarded pursuant to Article 5 (1) to ascertain whether they conform to this Directive. The Commission may ask a Member State to modify or supplement these plans to make them conform.

Once the Commission has established their conformity, it shall submit the plans for approval in accordance with the procedure provided for in Article 33.

In order to take account of changes in the situation in a given Member State or in a region thereof, of the results of national surveys or of investigations carried out in the framework of Articles 16 and 17, the Commission may, at the request of the Member State concerned or on its own initiative, decide, in accordance with the procedure provided for in Article 32, to approve an amendment or addition to a plan previously approved pursuant to paragraph 2.

2. Annual amendments to the initial plans communicated by the Member States, in particular in the light of the results referred to in Article 4 (2) (d), shall be forwarded by the Commission to the other Member States once the Commission has established their conformity with this Directive.

Member States shall have 10 working days from receipt of those amendments in which to inform the Commission of any comments.

If there are no comments from Member States, the amendments to the plans shall be deemed to be approved.

The Commission shall inform the Member States of such approval immediately.

Where there are comments from Member States or where the Commission deems the update not to be in conformity or insufficient, the Commission shall submit the updated plans to the Standing Veterinary Committee, which must act under the procedure laid down in Article 33.

The provisions laid down in paragraph 3 and 4 shall apply to the updated plans.

3. Every six months, Member States shall inform the Commission and the other Member States within the Standing Veterinary Committee of the implementation of plans approved pursuant to paragraph 2 or of the development of the situation. Where necessary, paragraph 4 shall apply. By not later than 31 March each year, Member States shall forward to the Commission the results of their residue and substance detection plans and of their control measures.

Member States shall make public the outcome of the implementation of the plans.

The Commission shall inform Member States, within the Standing Veterinary Committee, of developments in the situation in the various regions of the Community.

4. Each year, or whenever it deems it necessary on public health grounds, the Commission shall report to Member States within the Standing Veterinary Committee on the outcome of the checks and surveys referred to in paragraph 3, in particular on:

[1] OJ No L 221, 7. 8. 1986, p. 43. Directive as last amended by Directive 95/39/EC (OJ No L 197, 22. 8. 1995, p. 29).

— the implementation of national plans,

— developments in the situation in the various regions of the Community.

5. The Commission shall send the European Parliament and the Council a communication each year on the results of action taken at regional, national or Community level, bearing in mind the report and Member States' comments on it.

CHAPTER III

Self-monitoring and co-responsibility on the part of operators

Article 9

A. Member States shall ensure that:

1. any farms which place farm animals on the market and any natural or legal person engaged in trade in such animals register beforehand with the competent authorities and undertake to abide by the relevant Community and national rules, in particular the provisions laid down in Articles 5 and 12 of Directive 90/425/EEC;

2. the owners or persons in charge of the establishment of initial processing of primary products of animal origin take all necessary measures, in particular by carrying out their own checks, to

   (a) accept — whether by direct delivery or through an intermediary — only those animals for which the producer is able to guarantee that withdrawal times have been observed;

   (b) satisfy themselves that the farm animals or products brought into the establishment

      (i) do not contain residue levels which exceed maximum permitted limits;

      (ii) do not contain any trace of prohibited substances or products;

3. (a) the producers or persons in charge referred to in points 1 and 2 place on the market only:

      (i) animals to which no unauthorized substances or products have been administered or which have not undergone illegal treatment within the meaning of this Directive;

      (ii) animals in respect of which, where authorized products or substances have been administered, the withdrawal periods prescribed for these products or substances have been observed;

      (iii) products derived from the animals referred to in (i) and (ii);

   (b) where an animal is presented at a first-stage processing establishment by a natural or legal person other than the producer, the obligations laid down in (a) are incumbent on the latter.

B. For the purposes of applying point A, Member States shall ensure, without prejudice to compliance with the rules laid down in the Directives governing the placing on the market of the various products in question, that:

— the principle of quality monitoring of the production chain by the different parties involved is established in their legislation,

— the self-monitoring measures to be included in the specifications for trade marks or labels are stepped up.

They shall inform the Commission and the other Member States, at their request, of provisions laid down in this regard and in particular of provisions adopted for checks on point A (3) (a) (i) and (ii).

Article 10

Member States shall ensure that the terms of reference and responsibilities of veterinarians monitoring farms are extended to monitoring the rearing conditions and the forms of treatment referred to in this Directive.

Within this framework, the veterinarian shall enter in a register kept on the farm the date and nature of any treatment prescribed or administered, the identification of the animals treated and the corresponding withdrawal periods.

The stockfarmer shall enter in the register, which may be the register provided for in Directive 90/676/EEC[1], the date and nature of the treatment administered. He shall satisfy himself that withdrawal periods have been observed and keep the prescriptions to prove it for five years.

Stockfarmers and veterinarians shall be required to supply any information to the competent authority, at its request, and in particular supply information to the official veterinarian of the slaughterhouse, regarding a given farm's compliance with the requirements of this Directive.

[1] OJ No L 373, 31. 12. 1990, p. 15.

CHAPTER IV

Official control measures

Article 11

1. Without prejudice to the checks carried out in connection with implementation of the surveillance plans referred to in Article 5 or to the checks provided for in specific Directives, Member States may have official random checks conducted:

(a) during the manufacture of the substances included in Group A in Annex I and during their handling, storage, transport, distribution and sale or acquisition;

(b) at any point in the animal feedingstuffs production and distribution chain;

(c) throughout the production chain of animals and raw materials of animal origin covered by this Directive.

2. The checks provided for in paragraph 1 must be conducted with a view in particular to detecting the possession or presence of prohibited substances or products which it is intended to administer to animals for the purposes of fattening or illegal treatment.

3. Where fraud is suspected, and in the case of a positive result from any of the checks referred to in paragraph 1, Articles 16 to 19 and the measures provided for in Chapter V shall apply.

The checks provided for at the slaughterhouse or on the first sale of aquaculture animals and fishery products can be reduced to take account of the fact that the farm of origin or departure belongs to an epidemiological surveillance network or a quality monitoring system as referred to in the first indent of the first subparagraph of Article 9 (B).

Article 12

The checks provided for in this Directive must be carried out by the competent national authorities without prior notice.

The owner, the person empowered to dispose of the animals or their representative shall be obliged to facilitate pre-slaughter inspection operations, and in particular to assist the official veterinarian or the authorized staff in any manipulation judged necessary.

Article 13

The competent authority shall:

(a) where illegal treatment is suspected, ask the owner or person having charge of the animals or the veterinarian in charge of the farm to provide any documentation justifying the nature of the treatment;

(b) where this inquiry confirms illegal treatment or where unauthorized substances or products have been used, or where there are grounds for suspecting their use, conduct or have conducted:

— spot checks on animals on their farms of origin or departure, in particular with a view to detecting such use and in particular any traces of implants; these checks may include official sampling,

— checks to detect substances the use of which is prohibited or of unauthorized substances or products on the farms where the animals are being reared, kept or fattened (including holdings administratively connected with such farms) or on the animals' farms of origin or departure. Official samples of drinking water and feedingstuffs are necessary for that purpose.

— spot checks on animals' feedingstuffs on their farms of origin or departure, and on their drinking water or — for aquaculture animals — from the waters in which they are caught,

— the checks provided for in Article 11 (1) (a),

— any check required to clarify the origin of the unauthorized substances or products or that of the treated animals;

(c) where the maximum levels laid down by Community rules or, pending such legislation, the levels set by national legislation have been exceeded, carry out any measure or investigation which it may deem appropriate in relation to the finding in question.

Article 14

1. Each Member State shall designate at least one national reference laboratory. A given residue or residue group may not be assigned to more than one national reference laboratory.

However, until 31 December 2000, Member States may continue to entrust testing for the same residue or residue group to several national laboratories which they designated prior to the date of adoption of this Directive.

A list of such designated laboratories shall be drawn up in accordance with the procedure laid down in Article 33.

These laboratories shall be responsible for:

— coordinating the work of the other national laboratories responsible for residue analysis, in particular by coordinating the standards and methods of analysis for each residue or residue group concerned,

— assisting the competent authority in organizing the plan for monitoring residues,

— periodically organizing comparative tests for each residue or residue group assigned to them,

— ensuring that national laboratories observe the limits laid down,

— disseminating information supplied by Community reference laboratories,

— ensuring that their staff are able to take part in further training courses organized by the Commission or by Commission reference laboratories.

2. The Community reference laboratories shall be those designated in Chapter 1 of Annex V.

The powers and working conditions of the laboratories shall be as defined in Chapter 2 of Annex V.

Article 15

1. Official samples must be taken in accordance with Annexes III and IV in order to be examined in approved laboratories.

The detailed rules for the taking of official samples and the routine and reference methods to be employed for the analysis of such official samples shall be specified in accordance with the procedure laid down in Article 33.

Whenever an authorization is issued for the placing on the market of a veterinary medicinal product intended for administration to a species the meat or product of which is intended for human consumption, the competent authorities shall forward the routine analysis methods as laid down in Article 5, second subparagraph, point 8 of Directive 81/851/EEC[1] and Article 7 of Regulation (EEC) No 2377/90 to the Community and national reference laboratories for detection of residues.

2. For Group A substances, all positive findings recorded following the application of a routine method instead of a reference method must be confirmed by an approved laboratory using the reference methods laid down in accordance with paragraph 1.

For all substances, if challenged on the basis of a contradictory analysis, those results must be confirmed by the national reference laboratory designated in accordance with Article 14 (1) for the substance or residue in question. Such confirmation must be carried out at the plaintiff's cost in the event of confirmation.

3. Where examination of an official sample reveals illegal treatment, Articles 16 to 19 shall apply, together with the measures laid down in Chapter V.

Where the examination reveals the presence of residues of authorized substances or contaminants exceeding the levels set by Community rules or, pending such legislation, the levels set by national legislation, Articles 18 and 19 shall apply.

Where the examination referred to in this paragraph covers animals or products of animal origin from another Member State, the competent authority of the Member State of origin shall apply Articles 16 (2), 17, 18 and 19 and the measures provided for in Chapter V to the farm or establishment of origin or departure, following the reasoned request of the competent authority having carried out the examination.

Where the examination covers products or animals imported from a third country, the competent authority having carried out that examination shall refer the matter to the Commission, which shall take the measures provided for in Article 30.

Article 16

Member States shall ensure that, where positive results are obtained as described in Article 15:

1. the competent authority shall obtain without delay:

   (a) all the information required to identify the animal and farm of origin or departure;

   (b) full details of the examination and its result. If the controls carried out in a Member State demonstrate the need for an investigation or other action in one or more Member States or third countries, the Member State concerned shall inform the other Member States and the Commission. The Commission shall coordinate the appropriate measures taken in Member States where an investigation or other action proves necessary;

2. the appropriate authority shall carry out:

   (a) an investigation on the farm of origin or departure, as appropriate, to determine the reasons for the presence of residues;

   (b) in the case of illegal treatment, an investigation of the source or sources of the substances or products concerned at the stage of manufacture, handling, storage, transport, administration, distribution or sale, as appropriate;

[1] OJ No L 317, 6. 11. 1981, p. 1. Directive as last amended by Directive 93/40/EEC (OJ No L 214, 24. 8. 1993, p. 31).

(c) any other further investigations which the authority considers necessary;

3. animals from which samples have been taken are clearly identified. They may not in any circumstances leave the farm until the results of the checks are available.

Article 17

Where illegal treatment is established, the competent authority must ensure that the livestock concerned in the investigations referred to in point (b) of Article 13 is immediately placed under official control. It must furthermore ensure that all the animals concerned bear an official mark or identification and that, as a first step, an official sample is taken from a statistically representative sample, on internationally recognized scientific bases.

Article 18

1. Where there is evidence of residues of authorized substances or products of a level exceeding the maximum limit for residues, the competent authority shall carry out an investigation in the farm of origin or departure, as applicable, to determine why the above limit was exceeded.

In accordance with the results of that investigation, the competent authority shall take all necessary measures to safeguard public health which may include prohibiting animals from leaving the farm concerned or products from leaving the farm or establishment concerned for a set period.

2. In the event of repeated infringements of maximum residue limits when animals are placed on the market by a farmer or products are placed on the market by a farmer or a processing establishment, intensified checks on the animals and products from the farm and/or establishment in question must be carried out by the competent authorities for a period of at least six months, products or carcases being impounded pending the results of analysis of the samples.

Any results showing that the maximum residue limit has been exceeded must lead to the carcases or products concerned being declared unfit for human consumption.

Article 19

1. The costs of the investigations and checks referred to in Article 16 shall be borne by the owner or person having charge of the animals.

Where the investigation confirms that suspicion was justified, the costs of analyses carried out under Articles 17 and 18 shall be borne by the owner or person having charge of the animals.

2. Without prejudice to criminal or administrative penalties, the cost of destroying animals which have given a positive result or animals which have been deemed positive in accordance with Article 23 shall be borne by the owner of the animals without indemnity or compensation.

Article 20

1. Council Directive 89/608/EEC of 21 November 1989 on mutual assistance between the administrative authorities of the Member States and cooperation between the latter and the Commission to ensure the correct application of legislation on veterinary and zootechnical matters [1] shall apply for the purposes of this Directive.

2. Where a Member State considers that, in another Member State, the controls provided for in this Directive are not being, or have ceased to be, carried out, it shall inform the competent central authority of that State accordingly. Following an investigation carried out in accordance with point 2 of Article 16, that authority shall take all necessary measures and shall, at the earliest opportunity notify the competent central authority, of the first Member State of the decisions taken and the reasons for those decisions.

If the first Member State fears that such measures are not being taken or are inadequate, it shall, together with the Member State which has been challenged, seek ways and means of remedying the situation; if appropriate, this may involve an on-the-spot inspection.

Member States shall inform the Commission of disputes and of solutions arrived at.

If the Member States involved in a dispute are unable to reach agreement, one of them shall bring the matter to the notice of the Commission within a reasonable period of time, and the latter shall instruct one or more experts to deliver an opinion.

Pending that opinion, the Member State of destination may carry out checks on products coming from the establishment(s) or holding(s) to which the dispute relates and, if the result is positive, take measures similar to those provided for in Article 7 (1) (b) of Directive 89/662/EEC [2].

In the light of the experts' opinion, appropriate measures may be taken in accordance with the procedure provided for in Article 32.

(1) OJ No L 351, 2. 12. 1989, p. 34.
(2) OJ No L 395, 30. 12. 1989, p. 13. Directive as last amended by Directive 92/67/EEC (OJ No L 268, 14. 9. 1992, p. 73).

Those measures may be reviewed in accordance with the same procedure, in the light of a new expert opinion delivered within 15 days.

Article 21

1. To the extent necessary to ensure uniform application of this Directive, and in cooperation with the competent authorities of the Member States, the Commission's veterinary experts may verify on the spot that the plans and the system for checking the plans by the competent authorities have been uniformly implemented. A Member State within whose territory a verification is being carried out shall give all necessary assistance to the experts in carrying out their duties. The Commission shall inform the Member State concerned of the results of the verifications carried out.

The Member State concerned shall take the measures necessary to take account of the results of these verifications and shall notify the Commission of the measures taken. Where the Commission considers that the measures taken are insufficient, it shall, after consultation with the Member State in question and having regard to the measures necessary to safeguard public health, take appropriate measures in accordance with the procedure laid down in Article 32.

2. The general rules for implementing this Article, especially as regards the frequency and method of carrying out the verifications referred to in the first subparagraph of paragraph 1 (including cooperation with the competent authorities), shall be determined in accordance with the procedure laid down in Article 33.

CHAPTER V

Measures to be taken in the event of infringement

Article 22

Where unauthorized substances or products or substances listed in Group A and Group B (1) and (2) of Annex I are discovered in the possession of non-authorized persons, those unauthorized substances or products must be placed under official control until appropriate measures are taken by the competent authority, without prejudice to the possible imposition of penalties on the offender(s).

Article 23

1. During the period in which animals are impounded as provided for in Article 17, animals from the farm in question may not leave the farm of origin or be handed over to any other person except under official control. The competent authority shall take appropriate precautionary measures in accordance with the nature of the substance or substances identified.

2. After sampling has been carried out in accordance with Article 17, if there is confirmation of a case of illegal treatment, the animal or animals found to be positive shall be slaughtered immediately on the spot or taken immediately to the designated slaughterhouse or to the knacker's yard under cover of an official veterinary certificate in order to be slaughtered there. Animals so slaughtered shall be sent to a high-risk processing plant as defined by Directive 90/667/EEC [1].

In addition, samples must be taken at the farm's expense from the entire batch of animals belonging to the farm at which checks were carried out and which may be suspect.

3. However, if half or more of the samples taken by representative sampling in accordance with Article 17 are positive, the farmer may be left a choice between a check on all the animals present on the farm which may be suspect, or slaughter of these animals.

4. For a further period of at least 12 months, the farm(s) belonging to the same owner shall be subject to more stringent checks for the residues in question. Where an organized system of self-monitoring has been set up, this facility shall be withdrawn from the farmer for that period.

5. In view of the infringement recorded, the farms or establishments supplying the holding concerned shall be subject to checks in addition to those provided for in Article 11 (1) to determine the origin of the substance in question. The same shall apply to all farms and establishments in the same supply chain of animals and animal feed as the farm of origin or departure.

Article 24

The official veterinarian of a slaughterhouse must:

1. if he suspects or has evidence that the animals concerned have been subjected to illegal treatment or that unauthorized substances or products have been administered to them:

   (a) arrange for the animals to be slaughtered separately from other batches of animals arriving at the slaughterhouse;

   (b) impound the carcases and offal and carry out all sampling procedures necessary to detect the substances in question;

[1] OJ No L 363, 27. 12. 1990, p. 51. Directive as last amended by the 1994 Act of Accession.

(c) if positive results are obtained, send the meat and offal to a high-risk processing plant as defined by Directive 90/667/EEC, without indemnity or compensation.

In that event, Articles 20 to 23 shall apply;

2. if the suspects or has evidence that the animals concerned have been subjected to an authorized treatment but that the withdrawal periods have not been complied with, postpone slaughter of the animals until he can be satisfied that the quantity of residues does not exceed the permitted levels.

This period may in no circumstances be less than the withdrawal period laid down in point (b) of Article 6 (2) of Directive 96/22/EC for the substances in question, or than the withdrawal periods provided for in the marketing authorization.

However, in an emergency or where required for the well-being of the animals, or if the infrastructure or equipment of the slaughterhouse is such that slaughter cannot be deferred, the animals may be slaughtered before the end of the ban or postponement period. The meat and offal shall be impounded pending the outcome of the official checks carried out by the slaughterhouse's official veterinarian. Only meat and offal containing a quantity of residues not exceeding the permitted levels shall be used for human consumption;

3. declare unfit for human consumption carcases and products in which the residue level exceeds the levels authorized by Community or national regulations.

Article 25

Without prejudice to criminal penalties, where the holding, use or manufacture of unauthorized substances or products in a manufacturing establishment is confirmed, any authorizations or official approval arrangements enjoyed by the establishment concerned shall be suspended for a period during which the establishment shall be subjected to more stringent checks.

In the case of a repeated offence, such authorizations or approval arrangements shall be permanently withdrawn.

Article 26

Rights of appeal allowed by national legislation in force in the Member States against decisions taken by the competent authorities under Articles 23 and 24 shall not be affected by this Directive.

Article 27

Without prejudice to criminal penalties, or penalties imposed by professional bodies, appropriate administrative measures must be taken against any person where he is responsible, as the case may be, for the transfer or administering of prohibited substances or products or for the administering of authorized substances or products for purposes other than those laid down in the current legislation.

Article 28

Any failure to cooperate with the competent authority and any obstruction by slaughterhouse personnel or the slaughterhouse supervisor or, in the case of a private enterprise, by the slaughterhouse owner or owners, or by the owner of the animals or person having charge of them, during inspection and sampling as required for the implementation of national plans for monitoring residues and during the investigations and checks provided for in this Regulation, shall result in appropriate criminal and/or administrative penalties being imposed by the competent national authorities.

If it is proven that a slaughterhouse owner or supervisor is helping to conceal the illegal use of prohibited substances, the Member State shall deny the guilty party any opportunity of receiving or applying for Community aid for a period of 12 months.

CHAPTER VI

Imports from third countries

Article 29

1. Inclusion and retention on the lists of third countries provided for in Community legislation from which Member States are authorized to import animals and animal products covered by this Directive shall be subject to submission by the third country concerned of a plan setting out the guarantees which it offers as regards the monitoring of the groups of residues and substances referred to in Annex I. This plan must be updated at the request of the Commission, particularly when the checks referred to in paragraph 3 render it necessary.

The provisions of Article 8 concerning time limits for submission and updating of plans shall apply for plans to be submitted by third countries.

The guarantees must have an effect at least equivalent to those provided for in this Directive and must, in particular, meet the requirements of Article 4 and specify the particulars laid down in Article 7 of this Directive and meet the requirements of Article 11 (2) of Directive 96/22/EC.

The Commission shall approve the plan in accordance with the procedure laid down in Article 33. Under the same procedure, guarantees alternative to those resulting from the implementation of this Regulation may be accepted.

2. Where the requirements of paragraph 1 are not complied with, inclusion of a third country on the lists of third countries laid down by Community legislation or as a result of the benefit of pre-listing may be suspended in accordance with the procedure laid down in Article 33, at the request of a Member State or by the Commission on its own initiative.

3. Compliance with the requirements of and adherence to the guarantees offered by the plans submitted by third countries shall be verified by means of the checks referred to in Article 5 of Directive 72/462/EEC(1) and the checks provided for in Directives 90/675/EEC(2) and 91/496/EEC(3).

4. Member States shall inform the Commission each year of the results of residue checks carried out on animals and animal products imported from third countries, in accordance with Directives 90/675/EEC and 91/496/EEC.

Article 30

1. Where the checks provided by Directives 90/675/EEC and 91/496/EEC reveal the use of unauthorized products or substances for the treatment of the animals in a given batch — batch within the meaning of Article 2 (2) (e) of Directive 91/496/EEC — or the presence of such products or substances in all or part of a batch originating in the same establishment, the competent authority shall take the following measures in respect of the animals and products involved in such use:

— it shall inform the Commission of the nature of the products used and the batch concerned; the Commission shall forthwith inform all frontier posts,

— the Member States shall carry out more stringent checks on all batches of animals or products from the same source. In particular, the next 10 batches from the same source must be impounded — and a deposit lodged against inspection costs — at the frontier inspection post for a check on residues by taking a representative sample of each batch or of the part of the batch.

Where such additional checks demonstrate the presence of unauthorized substances or products or of residues of such substances or products:

(i) the batch or the part of the batch concerned must be returned to the country of origin at the expense of the consignor or his agent with a clear indication on the certificate of the reasons for rejecting the batch;

(ii) depending on the nature of the infringement found and the risk associated with such an infringement, it must be left to the consignor to decide whether to send back the batch or part of the batch concerned, to destroy it or to use it for other purposes authorized by Community legislation, without indemnity or compensation;

— the Commission shall be informed of the outcome of the more stringent checks and on the basis of this information shall make all necessary investigations, to identify the reasons for and origins of the infringements found.

2. Where the checks provided for by Directive 90/675/EEC reveal that the maximum residue limits have been exceeded, use shall be made of the checks referred to in the second indent of paragraph 1.

3. If, in cases involving third countries which have concluded equivalence agreements with the Community, the Commission, after making enquiries of the competent authorities of the third countries concerned, concludes that they have failed to fulfil their obligations and the guarantees given by the plans referred to in Article 29 (1), it shall cease to allow that country, under the procedure laid down in Article 32, to benefit from the said agreements for the animals and products in question until the third country in question has made good its shortcomings. The suspension shall be revoked under the same procedure.

If necessary, in order to re-establish the benefit afforded by the said agreements, a Community deputation including experts from the Member States shall visit the country concerned, at that country's expense, in order to verify that such measures have been taken.

(1) OJ No L 302, 31. 12. 1972, p. 28. Directive as last amended by the 1994 Act of Accession.
(2) OJ No L 373, 31. 12. 1990, p. 1. Directive as last amended by Directive 92/52/EC (OJ No L 265, 8. 11. 1995, p. 16).
(3) OJ No L 268, 24. 9. 1991, p. 56. Directive as last amended by the 1994 Act of Accession.

CHAPTER VII

General provisions

Article 31

The Council, acting on a proposal from the Commission, shall amend Directive 85/73/EEC[1] before 1 July 1997 in order to provide for the charging of a fee to cover monitoring carried out pursuant to this Directive.

Pending that decision by the Council, Member States shall be authorized to charge national fees to cover the actual costs of such monitoring.

Article 32

1. Where the procedure laid down in this Article is to be followed, matters shall be referred without delay to the Standing Veterinary Committee set up by Decision 68/361/EEC[2], by its Chairman, either on his own initiative or at the request of a Member State.

2. The Commission representative shall submit a draft of the measures to be taken. The Committee shall deliver its opinion on those matters within a time limit which the Chairman may set according to the urgency of the matter submitted. Opinions shall be delivered by a majority of 62 votes.

3. (a) The Commission shall adopt the measures and implement them immediately where they are in accordance with the opinion of the Committee.

(b) Where they are not in accordance with the opinion of the Committee, or if no opinion is delivered, the Commission shall forthwith submit to the Council a proposal concerning the measures to be taken. The Council shall adopt the measures by a qualified majority.

If, 15 days after the proposals were submitted to it, the Council has not adopted any measures, the Commission shall adopt the measures proposed and implement them immediately unless the Council has rejected those measures by a simple majority.

Article 33

1. Where the procedure laid down in this Article is to be followed, matters shall be referred without delay to the Standing Veterinary Committee, by its Chairman, either on his own initiative or at the request of a Member State.

2. The Commission representative shall submit a draft of the measures to be taken. The Committee shall deliver its opinion on those matters within a time limit which the Chairman may set according to the urgency of the matter submitted. Opinions shall be delivered by a majority of 62 votes.

3. (a) The Commission shall adopt the measures and implement them immediately where they are in accordance with the opinion of the Committee.

(b) Where they are not in accordance with the opinion of the Committee, or if no opinion is delivered, the Commission shall forthwith submit to the Council a proposal concerning the measures to be taken. The Council shall adopt the measures by a qualified majority.

If, three months after the proposals were submitted to it, the Council has not adopted any measures, the Commission shall adopt the measures proposed and implement them immediately unless the Council has rejected those measures by a simple majority.

Article 34

Without prejudice to Article 6 (2), Annexes I, III, IV and V may be amended or supplemented by the Council acting by a qualified majority on a proposal from the Commission.

In particular, the aforementioned Annexes may be amended within three years of the date of adoption of this Directive, with a view to risk assessment of the following factors:

— potential toxicity of residues in foodstuffs of animal origin,

— likelihood of residues occurring in foodstuffs of animal origin.

Article 35

The Council, acting by a qualified majority on a proposal from the Commission, may adopt transitional measures required for the implementation of the arrangements laid down by this Directive.

Article 36

1. Directives 85/358/EEC and 86/469/EEC and Decisions 89/187/EEC and 91/664/EEC are hereby repealed as from 1 July 1997.

2. The following are also repealed as from the said date:

(a) Article 4 (3) of Directive 71/118/EEC;

(b) Article 5 (3) and (4) of Directive 89/437/EEC;

(1) OJ No L 32, 5. 2. 1985, p. 14. Directive as last amended by Directive 95/24/EC (OJ No L 243, 11. 10. 1995, p. 14).
(2) OJ No L 255, 18. 10. 1968, p. 23.

(c) the last subparagraph of point II.3.B of Chapter V of the Annex to Directive 91/493/EEC;

(d) Article 11 (1) of Directive 92/45/EEC;

(e) Article 15 (1) of Directive 92/46/EEC.

3. References to Directives and Decisions which have been repealed shall be deemed to be references to this Directive and shall be read in accordance with the correlation table in Annex VI.

Article 37

1. Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with this Directive before 1 July 1997.

When Member States adopt these measures, they shall contain a reference to this Directive or shall be accompanied by such reference on the occasion of their official publication. The methods of making such reference shall be laid down by Member States.

2. Member States shall communicate to the Commission the texts of the main provisions of national law which they adopt in the field governed by this Directive.

Article 38

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

Article 39

This Directive is addressed to the Member States.

Done at Luxembourg, 29 April 1996.

For the Council
The President
W. LUCHETTI

ANNEX I

GROUP A — **Substances having anabolic effect and unauthorized substances**

(1) Stilbenes, stilbene derivatives, and their salts and esters

(2) Antithyroid agents

(3) Steroids

(4) Resorcylic acid lactones including zeranol

(5) Beta-agonists

(6) Compounds included in Annex IV to Council Regulation (EEC) No 2377/90 of 26 June 1990

GROUP B — **Veterinary drugs**[1] **and contaminants**

(1) Antibacterial substances, including sulphonomides, quinolones

(2) Other veterinary drugs

- (a) Anthelmintics
- (b) Anticoccidials, including nitroimidazoles
- (c) Carbamates and pyrethroids
- (d) Sedatives
- (e) Non-steroidal anti-inflammatory drugs (NSAIDs)
- (f) Other pharmacologically active substances

(3) Other substances and environmental contaminants

- (a) Organochlorine compounds including PcBs
- (b) Organophosphorus compounds
- (d) Chemical elements
- (d) Mycotoxins
- (e) Dyes
- (f) Others

[1] Including unlicensed substances which could be used for veterinary purposes.

ANNEX II

RESIDUE OR SUBSTANCE GROUP TO BE DETECTED BY TYPE OF ANIMAL, THEIR FEEDINGSTUFFS, INCLUDING DRINKING WATER, AND PRIMARY ANIMAL PRODUCTS

Type of animal, feedingstuffs or animal products Substance groups	Bovine, ovine, caprine, porcine, equine animals	Poultry	Aquaculture animals	Milk	Eggs	Rabbit meat and the meat of wild(*) game and farmed game	Honey
A 1	X	X	X			X	
2	X	X				X	
3	X	X	X			X	
4	X	X				X	
5	X	X				X	
6	X	X	X	X	X	X	
B 1	X	X	X	X	X	X	X
2a	X	X	X	X		X	
b	X	X			X	X	
c	X	X				X	X
d	X						
e	X	X		X		X	
f							
3a	X	X	X	X	X	X	X
b	X			X			X
c	X	X	X	X		X	X
d	X	X	X	X			
e			X				
f							

(*) Only chemical elements are relevant where wild game is concerned.

ANNEX III

SAMPLING STRATEGY

1. The residue control plan is aimed at surveying and revealing the reasons for residue hazards in foods of animal origin on farms, slaughterhouses, dairies, fish processing plants, and egg collecting and packing stations.

   Official samples are to be taken in accordance with the relevant chapter of Annex IV.

   Wherever official samples are taken, sampling must be unforeseen, unexpected and effected at no fixed time and on no particular day of the week. The Member States must take all the precautions necessary to ensure that the element of surprise in the checks is constantly maintained.

2. For Group A substances, surveillance should be aimed at detecting the illegal administration of prohibited substances and the abusive administration of approved substances, respectively. The emphasis of such sampling must be concentrated according to the relevant chapter of Annex IV.

   The samples must be targeted taking account of the following minimum criteria: sex, age, species, fattening system, all available background information, and all evidence of misuse or abuse of substances of this group.

   The details of these criteria will be laid down in the Commission Decision provided for in Article 15 (1).

3. For Group B substances, surveillance should be aimed particularly at controlling the compliance with MRLs for residues of veterinary medicinal products fixed in Annexes I and III to Regulation (EEC) No 2377/90, and the maximum levels of pesticides fixed in Annex III to Directive 86/363/EEC, and monitoring the concentration of environmental contaminants.

   Unless random sampling can be justified by Member States when presenting their national plans to the Commission, all the samples shall be targeted according to criteria laid down in the Commission Decision provided for in Article 15 (1).

ANNEX IV

SAMPLING LEVELS AND FREQUENCY

The purpose of this Annex is to define the minimum number of animals from which the samples must be taken.

Each sample can be analysed for detecting the presence of one or more substances.

CHAPTER 1

Bovine, porcine, ovine, caprine and equine animals

1. **Bovine animals**

The minimum number of animals to be controlled each year for all kinds of residues and substances must at least equal 0,4 % of bovine animals slaughtered the previous year, with the following breakdown:

Group A: 0,25 % divided as follows:

— one half of the samples are to be taken from live animals on the holding;

(by derogation, 25 % of samples analysed for the research of Group A 5 substances can be taken from appropriate material (feedingstuffs, drinking water, etc.))

— one half of the samples are to be taken at the slaughterhouse.

Each sub-group in Group A must be checked each year using a minimum of 5 % of the total number of samples to be collected for Group A.

The balance must be allocated according to the experience and background information of the Member State.

Group B: 0,15 %

30 % of the samples must be checked for Group B 1 substances.

30 % of the samples must be checked for Group B 2 substances.

10 % of the samples must be checked for Group B 3 substances.

The balance must be allocated according to the situation of the Member State.

2. **Porcine animals**

The minimum number of animals to be checked each year for all kinds of residues and substances must at least equal 0,05 % of the pigs slaughtered the previous year, with the following breakdown:

Group A: 0,02 %

In those Member States which carry out their sampling of animals at the slaughterhouse, in addition analysis of drinking water, feedingstuffs, faeces, or all other appropriate parameters must be undertaken at farm level. In that case, the minimum number of farms to be visited annually must represent at least one farm per 100 000 pigs slaughtered the previous year.

Each sub-group in Group A must be checked each year using a minimum of 5 % of the total number of samples to be collected for Group A.

The balance will be allocated according to the experience and background information of the Member State.

Group B: 0,03 %

The same breakdown per sub-group as for bovine animals has to be respected. The balance will be allocated according to the situation of the Member State.

3. **Sheep and goats**

The minimum number of animals to be checked for all kind of residues and substances must at least equal 0,05 % of sheep and goats over three months of age slaughtered the previous year, with the following breakdown:

Group A: 0,01 %

Each sub-group of Group A must be checked each year using a minimum of 5 % of the total number of samples to be collected for Group A.

The balance will be allocated according to the experience and background information of the Member State.

Group B: 0,04 %

The same breakdown per sub-group as for bovine animals has to be respected. The balance will be allocated according to the experience of the Member State.

4. **Equine animals**

The number of samples is to be determined by each Member State in relation to the problems identified.

CHAPTER 2

Broiler chickens, spent hens, turkeys, other poultry

A sample consists of one or more animals depending on the requirements of the analytical methods.

For each category of poultry considered (broiler chickens, spent hens, turkeys, and other poultry), the minimum number of samples to be taken each year must at least equal one per 200 tonnes of annual production (deadweight), with a minimum of 100 samples for each group of substances if the annual production of the category of birds considered is over 5 000 tonnes.

The following breakdown must be respected:

Group A: 50 % of the total samples

The equivalent of one fifth of these samples must be taken at farm level.

Each sub-group of Group A must be checked each year using a minimum of 5 % of the total number of samples to be collected for Group A.

The balance will be allocated according to the experience and background information of the Member State.

Group B: 50 % of the total samples,

30 % must be checked for Group B 1 substances,

30 % must be checked for Group B 2 substances,

10 % must be checked for Group B 3 substances.

The balance will be allocated according to the situation of the Member State.

CHAPTER 3

Aquaculture products

1. **Finfish farming products**

A sample is one or more fish, according to the size of the fish in question and of the requirements of the analytical method.

Member States must respect the minimum sampling levels and frequencies given below, depending on the production of farmed fish (expressed in tonnes).

The minimum number of samples to be collected each year must be at least 1 per 100 tonnes of annual production.

The compounds sought and the samples selected for analysis should be selected according to the likely use of these substances.

The following breakdown must be respected:

Group A: one third of the total samples:

all the samples must be taken at farm level, on fish at all stages of farming(1), including fish which is ready to be placed on the market for consumption.

Group B: two thirds of the total samples:

the sampling should be carried out:

(a) preferably at the farm, on fish ready to be placed on the market for consumption;

(b) either at the processing plant, or at wholesale level, on fresh fish, on condition that tracing-back to the farm of origin, in the event of positive results, can be done.

In all cases, samples taken at farm level should be taken from a minimum of 10 % of registered sites of production.

2. **Other aquaculture products**

When Member States have reason to believe that veterinary medicine or chemicals are being applied to the other aquaculture products, or when environmental contamination is suspected, then these species must be included in the sampling plan in proportion to their production as additional samples to those taken for finfish farming products.

(1) For sea-farming, in which sampling conditions may be especially difficult, samples may be taken from feed in place of samples from fish.

ANNEX V

Chapter 1

The following laboratories shall be designated Community reference laboratories for the detection of residues of certain substances:

(a) For the residues listed in Annex I, Group A 1, 2, 3, 4, Group B 2 (d) and Group B 3 (d)

Rijksinstituut voor Volksgezondheid en Milieuhygiëne (RIVM)
A. van Leeuwenhoeklaan, 9
NL-3720 BA Bilthoven

(b) For the residues listed in Annex I, Group B 1 and B 3 (e) and carbadox residues and olaquindox residues

Laboratories des médicaments vétérinaires (CNEVA-LMV)
La Haute Marche, Javene
F-35135-Fougères

(c) For the residues listed in Annex I, Group A 5 and Group B 2 (a), (b), (e)

Bundesinstitut für Gesundheitlichen Verbraucherschutz und Veterinärmedizin (BGVV)
Diedersdorfer Weg, 1
D-12277-Berlin

(d) For the residues listed in Annex I, Group B 2 (c) and Group B 3 (a), (b), (c):

Istituto Superiore di Sanità
Viale Regina Elena, 299
I-00161-Roma

The compounds included in Group A 6, B 2 (f) and B 3 (f) are allocated to the designated Community reference laboratories, according to their pharmacological action.

Chapter 2

The powers and operating conditions of the Community reference laboratories for the detection of residues in live animals, their excrement and body fluids and in tissue, animal products, animal feed and drinking water shall be as follows:

1. The functions of Community reference laboratories shall be:

(a) to promote and coordinate research into new analytical methods and to inform national reference laboratories of advances in analytical methods and equipment;

(b) to help the national reference laboratories (NRLs) for residues to implement an appropriate quality assurance scheme system based on good laboratory practice (GLP) principles and EN 45 000 criteria;

(c) to approve validated methods as reference methods, to be integrated into a collection of methods;

(d) to provide the national reference laboratories with the routine analytical methods accepted during the MRL procedure;

(e) to provide national reference laboratories with details of analytical methods and the comparative tests to be conducted, and to inform them of the results of the tests;

(f) to provide national reference laboratories, at their request, with technical advice on the analysis of the substances for which they have been designated the Community reference laboratory;

(g) to organize comparative tests for the benefit of the national reference laboratories, the frequency of which shall be determined in agreement with the Commission. Consequently, the Community reference laboratories shall distribute blank samples and samples containing known amounts of analyte to be analysed;

(h) to identify residues and determine their concentration in cases where the results of an analysis give rise to a disagreement between Member States;

(i) to conduct initial and further training courses for the benefit of analysts from national laboratories;

(j) to provide the Commission services, including the standards, measurements and testing programme, with technical and scientific assistance;

(k) to compile a report on each year's work and transmit it to the Commission;

(l) to liaise, in the field of analytical methods and equipment, with the national reference laboratories designated by third countries in the plans to be submitted in accordance with Article 11 of this Directive.

2. In order to perform the functions specified in paragraph 1, Community reference laboratories must satisfy the following minimum requirements:

(a) have been designated as a national reference laboratory in a Member State;

(b) have suitable qualified staff who are adequately trained in analytical methods used for the residues for which they have been designated the Community reference laboratory;

(c) possess the equipment and substances needed to carry out the analysis for which they are responsible;

(d) have an adequate administrative infrastructure;

(e) have sufficient data-processing capacity to produce statistics based on their findings and to enable rapid communication of those statistics and other information to national reference laboratories and the Commission;

(f) ensure that their staff respect the confidential nature of certain issues, results or communications;

(g) have sufficient knowledge of international standards and practices;

(h) have available an up-to-date list of certified reference material and reference material held by the Institute for Reference Material and Methods, and an up-to-date list of manufacturers and vendors of that material.

ANNEX VI

Correlation table

This Directive	Directives 85/358/EEC and 86/469/EEC and Decisions 89/187/EEC and 91/664/EEC	
Article 1	—	
Article 2	Article 2	86/469/EEC
Article 3	Article 1	86/469/EEC
	Article 2	85/358/EEC
Article 4	Article 3	86/469/EEC
Article 5	Article 4 (1) first and second indents	86/469/EEC
Article 6	—	
Article 7	Article 4 (1) except first and second indents	86/469/EEC
Article 8	Article 4 (2) to 4 (5)	86/469/EEC
	Article 12	86/469/EEC
	Article 9	85/358/EEC
Article 9	—	
Article 10	—	
Article 11	Article 1	85/358/EEC
Article 12	—	
Article 13	Article 3	85/358/EEC
	Article 10	86/469/EEC
Article 14 (1)	Article 8 (1) (b)	86/469/EEC
Article 14 (2)	Article 8 (2)	86/469/EEC
	Decision 91/664/EEC	
	Decision 89/187/EEC	
Article 15 (1)	Article 8 (3)	86/469/EEC
	Article 5 (2)	85/358/EEC
Article 15 (2)	Article 8 (3)	86/469/EEC
	Article 5 (3)	85/358/EEC
Article 15 (3)	Article 9	86/469/EEC
Article 16	Article 9 (1) and Article 9 (2)	86/469/EEC
	Article 6 (1) and Article 6 (2)	85/358/EEC
Article 17	Article 9 (3) (a)	86/469/EEC
	Article 6 (3) (a)	85/358/EEC
Article 18	Article 9 (3) (c) and (d)	86/469/EEC
Article 19	—	
Article 20 (1)	—	
Article 20 (2)	Article 11	86/469/EEC
Article 21	Article 5	86/469/EEC
Article 22	Article 7	85/358/EEC
Article 23	Articles 9 (3) (b) (c) (d) and 9 (4), 9 (5)	86/469/EEC
	Articles 6 (3) (b) (c) (d) and 6 (4)	85/358/EEC
Article 24	Article 4	85/358/EEC
Article 25	—	
Article 26	—	

This Directive	Directives 85/358/EEC and 86/469/EEC and Decisions 89/187/EEC and 91/664/EEC	
Article 27	—	
Article 28	—	
Article 29	Article 7	86/469/EEC
	Article 13	85/358/EEC
Article 30	—	
Article 31	Article 12	85/358/EEC
Article 32	Article 14	86/469/EEC
	Article 11	85/358/EEC
Article 33	Article 15	86/469/EEC
	Article 10	85/358/EEC
Article 34	Article 13	86/469/EEC
Article 35	—	
Article 36	—	
Article 37	—	
Article 38	—	
Article 39	—	
Annex I	Annex I	86/469/EEC
Annex II	—	
Annex III	—	
Annex IV	Annex II	86/469/EEC
Annex V Chapter 1	Decision 91/664/EEC	
Annex V Chapter 2	Decision 89/187/EEC	
Annex VI	—	

I

(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 [1],

Having regard to the Opinion of the Economic and Social Committee [2],

Having consulted the Committee of the Regions,

Acting in accordance with the procedure laid down in Article 251 of the Treaty [3],

[1] OJ C 365 E, 19.12.2000, p. 43.
[2] OJ C 155, 29.5.2001, p. 39.
[3] 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 [1]. 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 [2] 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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[1] 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).

[2] 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 [1] 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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[1] 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 [1], 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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[1] 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 [1],

HAVE ADOPTED THIS REGULATION:

[1] 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 [1];

(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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[1] 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;

* 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 [*]; 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 [1].

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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[1] 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 ..... [*], 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.

[*] 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 [1]; 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 [2].

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	For the Council
The President	The President
P. COX	M. McDOWELL

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

[1] See p. of this Official Journal.

[2] See p. of this Official Journal.

ANNEX I

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.

ANNEX II

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.

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 [*],

Having regard to the Opinion of the European Economic and Social Committee [†],

Having consulted the Committee of the Regions,

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

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[*] OJ C 365 E, 19.12.2000, p. 58.

[†] OJ C 155, 29.5.2001, p. 39.

[‡] 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 [*], 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 [*], 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 [*], 95/50/EC [†], 95/160/EC [‡], 95/161/EC [§], 95/168/EC [**], 95/409/EC [††], 95/410/EC [‡‡] and 95/411/EC [§§]. 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 [***] 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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[*] OJ L 371, 31.12.1994, p. 36.
[†] OJ L 53, 9.3.1995, p. 31.
[‡] OJ L 105 9.5.1995, p. 40.
[§] OJ L 105, 9.5.1995, p. 44.
[**] OJ L 109, 16.5.1995, p. 44.
[††] OJ L 243, 11.10.1995, p. 21.
[‡‡] OJ L 243, 11.10.1995, p. 25.
[§§] OJ L 243, 11.10.1995, p. 29.
[***] 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 [*],

[*] 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 [*]. 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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[*] 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 *;

3) the definitions laid down in Annex I; and

4) any technical definitions contained in Annexes II and III.

* 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

* 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 [*], 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 [*]:

(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 [*]. 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.

[*] 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 *; 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 * from meat unless they cut or process it or work upon it in another manner.

* 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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(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 [*]; 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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[*] 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 [*]; 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 [*], 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.

[*] 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 ... [*], 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 [**];

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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 [*]; and

(c) Directive 2004/…/EC [**].

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 Strsbourg, 29.4.2004.

For the European Parliament	For the Council
The President	The President
P. COX	M. McDOWELL

[*] 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.

ANNEX I

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 carcases, 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 40ºC 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 RNA (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.

ANNEX II

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;

* Official Oublications 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."

ANNEX III

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 82ºC, 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 82ºC, 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 carcase 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 carcase with milk or colostrum.

8. Complete skinning of the carcase 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 carcases must not contain visible faecal contamination. Any visible contamination must be removed without delay by trimming or alternative means having an equivalent effect.

11. Carcases 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 carcase; and

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(b) come into contact with no other carcase, 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 carcase 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 carcases 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 carcases 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. Carcases of domestic ungulates may be cut into half-carcases or quarters, and half carcases 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 3ºC for offal and 7ºC for other meat, by means of an ambient temperature of not more than 12ºC 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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* Official Publications Office is to insert the official number of Regulation on the organisation of official controls.

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 3ºC for offal and 7ºC 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 carcases, 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 82ºC, 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 82ºC, 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 ratites 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 carcases of farmed ratites 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 carcase, 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 4ºC as soon as possible, unless the meat is cut while warm.

9. When carcases are subjected to an immersion chilling process, account must be taken of the following.

   (a) Every precaution must be taken to avoid contamination of carcases, taking into account parameters such as carcase 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 4ºC by means of an ambient temperature of 12ºC 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 4ºC. 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 ratites 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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* Official Publications Office is to insert the official number of Regulation on the organisation of official controls.

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 82ºC, 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 4ºC for poultry, 3ºC for offal and 7ºC 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 2ºC 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 carcases 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 carcases 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 carcases 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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* Official Publications Office is to insert the official number of Regulation on the hygiene of foodstuffs.

(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 –18ºC 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 [*], 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.

[*] 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 [**].

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

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^2, 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-immerse 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 *, 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;

* 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 3ºC 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 -18ºC;

2. have refrigeration equipment with sufficient capacity to maintain fishery products in the storage holds at not more than -18ºC. 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 °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.

* 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 °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 °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 -18ºC 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 -9ºC.

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 -18ºC in all parts of the product, possibly with short upward fluctuations of not more than 3°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 [*], 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 [†]; 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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[*] Council Directive 64/432/EEC of 26 June 1964 on animal health problems affecting intra-Community trade in bovine animals and swine (OJ 121, 29.7.1964, p. 1977/64). Directive as last amended by the 2003 Act of Accession.

[†] 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 10ºC.

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)	≤ 100 000 (*)
Somatic cell count (per ml)	≤ 400 000 (**)

(ii) for raw milk from other species:

Plate count at 30 °C (per ml)	≤ 1 500 000 (*)

(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)	≤ 500 000 (*)

(*) 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 [*], 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

[*] 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 30ºC of less than 300 000 per ml; and

   (b) processed cows' milk used to prepare dairy products has a plate count at 30ºC 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.

* 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 [(1)]	Other		Lard [(2)]	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 carcases 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.

* 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 pH < 1.5) over a period of at least two days, followed by an alkaline treatment of saturated lime solution (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_2 (Reith Williams)	50 ppm
H_2O_2 (European Pharmacopoeia 1986 (V_2O_2))	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 carcases 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 * 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.

* 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_2 (Reith Williams)	50 ppm
H_2O_2 (European Pharmacopoeia 1986 (V_2O_2))	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.

Appendix to ANNEX III

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: .....

I

(Acts whose publication is obligatory)

COMMISSION REGULATION (EC) No 2073/2005

of 15 November 2005

on microbiological criteria for foodstuffs

(Text with EEA relevance)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Regulation (EC) No 852/2004 of the European Parliament and of the Council of 29 April 2004 on the hygiene of foodstuffs [1], and in particular Articles 4(4) and 12 thereof,

Whereas:

(1) A high level of protection of public health is one of the fundamental objectives of food law, as laid down in 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 [2]. Microbiological hazards in foodstuffs form a major source of food-borne diseases in humans.

(2) Foodstuffs should not contain micro-organisms or their toxins or metabolites in quantities that present an unacceptable risk for human health.

(3) Regulation (EC) No 178/2002 lays down general food safety requirements, according to which food must not be placed on the market if it is unsafe. Food business operators have an obligation to withdraw unsafe food from the market. In order to contribute to the protection of public health and to prevent differing interpretations, it is appropriate to establish harmonised safety criteria on the acceptability of food, in particular as regards the presence of certain pathogenic micro-organisms.

(4) Microbiological criteria also give guidance on the acceptability of foodstuffs and their manufacturing, handling and distribution processes. The use of microbiological criteria should form an integral part of the implementation of HACCP-based procedures and other hygiene control measures.

(5) The safety of foodstuffs is mainly ensured by a preventive approach, such as implementation of good hygiene practice and application of procedures based on hazard analysis and critical control point (HACCP) principles. Microbiological criteria can be used in validation and verification of HACCP procedures and other hygiene control measures. It is therefore appropriate to set microbiological criteria defining the acceptability of the processes, and also food safety microbiological criteria setting a limit above which a foodstuff should be considered unacceptably contaminated with the micro-organisms for which the criteria are set.

(6) According to Article 4 of Regulation (EC) No 852/2004, food business operators are to comply with microbiological criteria. This should include testing against the values set for the criteria through the taking of samples, the conduct of analyses and the implementation of corrective actions, in accordance with food law and the instructions given by the competent authority. It is therefore appropriate to lay down implementing measures concerning the analytical methods, including, where necessary, the measurement uncertainty, the sampling plan, the microbiological limits, the number of analytical units that should comply with these limits. Furthermore, it is appropriate to lay down implementing measures concerning the foodstuff to which the criterion applies, the points of the food chain where the criterion applies, as well as the actions to be taken when the criterion is not met. The measures to be taken by the food business operators in order to ensure compliance with criteria defining the acceptability of a process may include, among other things, controls of raw materials, hygiene, temperature and shelf-life of the product.

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[1] OJ L 139, 30.4.2004, p. 1, corrected by OJ L 226, 25.6.2004, p. 3.

[2] 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).

(7) Regulation (EC) No 882/2004 of the European Parliament and of the Council of 29 April 2004 on official controls performed to ensure the verification of compliance with feed and food law, animal health and animal welfare rules [1] requires the Member States to ensure that official controls are carried out regularly, on a risk basis and with appropriate frequency. Those controls should take place at appropriate stages of the production, processing and distribution of food to ensure that the criteria laid down in this Regulation are complied with by food business operators.

(8) The Communication from the Commission on the Community Strategy for setting microbiological criteria for foodstuffs [2] describes the strategy to lay down and revise the criteria in Community legislation, as well as the principles for the development and application of the criteria. This strategy should be applied when microbiological criteria are laid down.

(9) The Scientific Committee on Veterinary Measures relating to Public Health (SCVPH) issued an opinion on 23 September 1999 on the evaluation of microbiological criteria for food products of animal origin for human consumption. It highlighted the relevance of basing microbiological criteria on formal risk assessment and internationally approved principles. The opinion recommends that microbiological criteria should be relevant and effective in relation to consumer health protection. The SCVPH proposed, while awaiting formal risk assessments, certain revised criteria as interim measures.

(10) The SCVPH issued at the same time a separate opinion on *Listeria monocytogenes*. That opinion recommended that it be an objective to keep the concentration of *Listeria monocytogenes* in food below 100 cfu/g. The Scientific Committee on Food (SCF) agreed with these recommendations in its opinion of 22 June 2000.

(11) The SCVPH adopted an opinion on *Vibrio vulnificus* and *Vibrio parahaemolyticus* on 19 and 20 September 2001. It concluded that currently available scientific data do not support setting specific criteria for pathogenic *V. vulnificus* and *parahaemolyticus* in seafood. However, it recommended that codes of practice should be established to ensure that good hygiene practice has been applied.

(12) The SCVPH issued an opinion on Norwalk-like viruses (NLVs, noroviruses) on 30-31 January 2002. In that opinion it concluded that the conventional faecal indicators are unreliable for demonstrating the presence or absence of NLVs and that the reliance on faecal bacterial indicator removal for determining shellfish purification times is unsafe practice. It also recommended using *E. coli* rather than faecal coliforms to indicate faecal contamination in shellfish harvesting areas, when applying bacterial indicators.

(13) On 27 February 2002 the SCF adopted an opinion on specifications for gelatine in terms of consumer health. It concluded that the microbiological criteria set in Chapter 4 of Annex II to 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 [3] in terms of consumer health were excessive, and considered it sufficient to apply a mandatory microbiological criterion for salmonella only.

(14) The SCVPH issued an opinion on verotoxigenic *E. coli* (VTEC) in foodstuffs on 21 and 22 January 2003. In its opinion it concluded that applying an end-product microbiological standard for VTEC O157 is unlikely to deliver meaningful reductions in the associated risk for the consumers. However, microbiological guidelines aimed at reducing the faecal contamination along the food chain can contribute to a reduction in public health risks, including VTEC. The SCVPH identified the following food categories where VTEC represents a hazard to public health: raw or undercooked beef and possibly meat from other ruminants, minced meat and fermented beef and products thereof, raw milk and raw milk products, fresh produce, in particular sprouted seeds, and unpasteurised fruit and vegetable juices.

(15) On 26 and 27 March 2003 the SCVPH adopted an opinion on staphylococcal enterotoxins in milk products, particularly in cheeses. It recommended revising the criteria for coagulase-positive staphylococci in cheeses, in raw milk intended for processing and in powdered milk. In addition, criteria for staphylococcal enterotoxins should be laid down for cheeses and powdered milk.

[1] OJ L 165, 30.4.2004, p. 1, corrected by OJ L 191, 28.5.2004, p. 1.

[2] SANCO/1252/2001 Discussion paper on strategy for setting microbiological criteria for foodstuffs in Community legislation, p. 34.

[3] 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).

(16) The SCVPH adopted an opinion on salmonellae in foodstuffs on 14 and 15 April 2003. According to the opinion, food categories possibly posing a high risk to public health include raw meat and some products intended to be eaten raw, raw and undercooked products of poultry meat, eggs and products containing raw eggs, unpasteurised milk and some products thereof. Sprouted seeds and unpasteurised fruit juices are also of concern. It recommended that the decision on the need for microbiological criteria should be taken on the basis of its ability to protect the consumers and its feasibility.

(17) The Scientific Panel on Biological Hazards (BIOHAZ Panel) of the European Food Safety Authority (EFSA) issued an opinion on the microbiological risks in infant formulae and follow-on formulae on 9 September 2004. It concluded that *Salmonella* and *Enterobacter sakazakii* are the micro-organisms of greatest concern in infant formulae, formulae for special medical purposes and follow-on formulae. The presence of these pathogens constitutes a considerable risk if conditions after reconstitution permit multiplication. Enterobacteriaceae, which are more often present, could be used as an indicator for risk. Monitoring and testing of Enterobacteriaceae was recommended in both the manufacturing environment and the finished product by the EFSA. However, besides pathogenic species the family Enterobacteriaceae includes also environmental species, which often appear in the food manufacturing environment without posing any health hazard. Therefore, the family Enterobacteriaceae can be used for routine monitoring, and if they are present testing of specific pathogens can be started.

(18) International guidelines for microbiological criteria in respect of many foodstuffs have not yet been established. However, the Commission has followed the Codex Alimentarius guideline 'Principles for the establishment and application of microbiological criteria for foods CAC/GL 21 — 1997' and in addition, the advice of the SCVPH and the SCF in laying down microbiological criteria. Existing Codex specifications in respect of dried milk products, foods for infants and children and the histamine criterion for certain fish and fishery products have been taken account. The adoption of Community criteria should benefit trade by providing harmonised microbiological requirements for foodstuffs and replacing national criteria.

(19) The microbiological criteria set for certain categories of food of animal origin in Directives that were repealed by Directive 2004/41/EC of the European Parliament and of the Council of 21 April 2004 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 and amending Council Directives 89/662/EEC and 92/118/EEC and Council Decision 95/408/EC [1] should be revised and certain new criteria set in the light of the scientific advice.

(20) The microbiological criteria laid down in Commission Decision 93/51 EEC of 15 December 1992 on the microbiological criteria applicable to the production of cooked crustaceans and molluscan shellfish [2] are incorporated in this Regulation. It is therefore appropriate to repeal that Decision. Since Commission Decision 2001/471/EC of 8 June 2001 laying down rules for the regular checks on the general hygiene carried out by the operators in establishments according to Directive 64/433/EEC on health conditions for the production and marketing of fresh meat and Directive 71/118/EEC on health problems affecting the production and placing on the market of fresh poultrymeat [3] is repealed with effect from the 1 January 2006, it is appropriate to incorporate microbiological criteria set for carcases in this Regulation.

(21) The producer or manufacturer of a food product has to decide whether the product is ready to be consumed as such, without the need to cook or otherwise process it in order to ensure its safety and compliance with the microbiological criteria. According to Article 3 of 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 [4], the instructions for use of a foodstuff are compulsory on the labelling when it would be impossible to make appropriate use of the foodstuff in the absence of such instructions. Such instructions should be taken into account by food business operators when deciding appropriate sampling frequencies for the testing against microbiological criteria.

(22) Sampling of the production and processing environment can be a useful tool to identify and prevent the presence of pathogenic micro-organisms in foodstuffs.

(23) Food business operators should decide themselves the necessary sampling and testing frequencies as part of their procedures based on HACCP principles and other hygiene control procedures. However, it may be necessary in certain cases to set harmonised sampling frequencies at Community level, particularly in order to ensure the same level of controls to be performed throughout the Community.

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[1] OJ L 157, 30.4.2004, p. 33, corrected by OJ L 195, 2.6.2004, p. 12.

[2] OJ L 13, 21.1.1993, p. 11.

[3] OJ L 165, 21.6.2001, p. 48. Decision as amended by Decision 2004/379/EC (OJ L 144, 30.4.2004, p. 1).

[4] OJ L 109, 6.5.2000, p. 29. Directive as last amended by Directive 2003/89/EC (OJ L 308, 25.11.2003, p. 15).

(24) Test results are dependent on the analytical method used, and therefore a given reference method should be associated with each microbiological criterion. However, food business operators should have the possibility to use analytical methods other than the reference methods, in particular more rapid methods, as long as the use of these alternative methods provides equivalent results. Moreover, a sampling plan needs to be defined for each criterion in order to ensure harmonised implementation. It is nevertheless necessary to allow the use of other sampling and testing schemes, including the use of alternative indicator organisms, on condition that these schemes provide equivalent guarantees of food safety.

(25) Trends in test results should be analysed, as they are able to reveal unwanted developments in the manufacturing process enabling the food business operator to take corrective actions before the process is out of control.

(26) The microbiological criteria set in this Regulation should be open to review and revised or supplemented, if appropriate, in order to take into account developments in the field of food safety and food microbiology. This includes progress in science, technology and methodology, changes in prevalence and contamination levels, changes in the population of vulnerable consumers, as well as the possible outputs from risk assessments.

(27) In particular, criteria for pathogenic viruses in live bivalve molluscs should be established when the analytical methods are developed sufficiently. There is a need for development of reliable methods for other microbial hazards too, e.g. *Vibrio parahaemolyticus*.

(28) It has been demonstrated that the implementation of control programmes can markedly contribute to a reduction of the prevalence of salmonella in production animals and products thereof. The purpose of 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 ([1]) is to ensure that proper and effective measures are taken to control salmonella at relevant stages of the food chain. Criteria for meat and products thereof should take into account the expected improvement in the salmonella situation at the level of primary production.

(29) For certain food safety criteria, it is appropriate to grant the Member States a transitional derogation, enabling them to comply with less stringent criteria but provided that the foodstuffs would only be marketed on the national market. The Member States should notify the Commission and other Member States where this transitional derogation is used.

(30) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on the Food Chain and Animal Health,

HAS ADOPTED THIS REGULATION:

Article 1

Subject-matter and scope

This Regulation lays down the microbiological criteria for certain micro-organisms and the implementing rules to be complied with by food business operators when implementing the general and specific hygiene measures referred to in Article 4 of Regulation (EC) No 852/2004. The competent authority shall verify compliance with the rules and criteria laid down in this Regulation in accordance with Regulation (EC) No 882/2004, without prejudice to its right to undertake further sampling and analyses for the purpose of detecting and measuring other micro-organisms, their toxins or metabolites, either as a verification of processes, for food suspected of being unsafe, or in the context of a risk analysis.

This Regulation shall apply without prejudice to other specific rules for the control of micro-organisms laid down in Community legislation and in particular the health standards for foodstuffs laid down in Regulation (EC) No 853/2004 of the European Parliament and of the Council ([2]), the rules on parasites laid down under Regulation (EC) No 854/2004 of the European Parliament and of the Council ([3]) and the microbiological criteria laid down under Council Directive 80/777/EEC ([4]).

Article 2

Definitions

The following definitions shall apply:

(a) 'micro-organisms' means bacteria, viruses, yeasts, moulds, algae, parasitic protozoa, microscopic parasitic helminths, and their toxins and metabolites;

(b) 'microbiological criterion' means a criterion defining the acceptability of a product, a batch of foodstuffs or a process, based on the absence, presence or number of micro-organisms, and/or on the quantity of their toxins/metabolites, per unit(s) of mass, volume, area or batch;

([1]) OJ L 325, 12.12.2003, p. 1.

([2]) OJ L 139, 30.4.2004, p. 55, corrected by OJ L 226, 25.6.2004, p. 22.

([3]) OJ L 139, 30.4.2004, p. 206, corrected by OJ L 226, 25.6.2004, p. 83.

([4]) OJ L 229, 30.8.1980, p. 1.

(c) 'food safety criterion' means a criterion defining the acceptability of a product or a batch of foodstuff applicable to products placed on the market;

(d) 'process hygiene criterion' a criterion indicating the acceptable functioning of the production process. Such a criterion is not applicable to products placed on the market. It sets an indicative contamination value above which corrective actions are required in order to maintain the hygiene of the process in compliance with food law;

(e) 'batch' means a group or set of identifiable products obtained from a given process under practically identical circumstances and produced in a given place within one defined production period;

(f) 'shelf-life' means either the period corresponding to the period preceding the 'use by' or the minimum durability date, as defined respectively in Articles 9 and 10 of Directive 2000/13/EC;

(g) 'ready-to-eat food' means food intended by the producer or the manufacturer for direct human consumption without the need for cooking or other processing effective to eliminate or reduce to an acceptable level micro-organisms of concern;

(h) 'food intended for infants' means food specifically intended for infants, as defined in Commission Directive 91/321/EEC ([1]);

(i) 'food intended for special medical purposes' means dietary food for special medical purposes, as defined in Commission Directive 1999/21/EC ([2]);

(j) 'sample' means a set composed of one or several units or a portion of matter selected by different means in a population or in an important quantity of matter, which is intended to provide information on a given characteristic of the studied population or matter and to provide a basis for a decision concerning the population or matter in question or concerning the process which has produced it;

(k) 'representative sample' means a sample in which the characteristics of the batch from which it is drawn are maintained. This is in particular the case of a simple random sample where each of the items or increments of the batch has been given the same probability of entering the sample;

(l) 'compliance with microbiological criteria' means obtaining satisfactory or acceptable results set in Annex I when testing against the values set for the criteria through the taking of samples, the conduct of analyses and the implementation of corrective action, in accordance with food law and the instructions given by the competent authority.

([1]) OJ L 175, 4.7.1991, p. 35.

([2]) OJ L 91, 7.4.1999, p. 29.

Article 3

General requirements

1. Food business operators shall ensure that foodstuffs comply with the relevant microbiological criteria set out in Annex I. To this end the food business operators at each stage of food production, processing and distribution, including retail, shall take measures, as part of their procedures based on HACCP principles together with the implementation of good hygiene practice, to ensure the following:

(a) that the supply, handling and processing of raw materials and foodstuffs under their control are carried out in such a way that the process hygiene criteria are met,

(b) that the food safety criteria applicable throughout the shelf-life of the products can be met under reasonably foreseeable conditions of distribution, storage and use.

2. As necessary, the food business operators responsible for the manufacture of the product shall conduct studies in accordance with Annex II in order to investigate compliance with the criteria throughout the shelf-life. In particular, this applies to ready-to-eat foods that are able to support the growth of *Listeria monocytogenes* and that may pose a *Listeria monocytogenes* risk for public health.

Food businesses may collaborate in conducting those studies.

Guidelines for conducting those studies may be included in the guides to good practice referred to in Article 7 of Regulation (EC) No 852/2004.

Article 4

Testing against criteria

1. Food business operators shall perform testing as appropriate against the microbiological criteria set out in Annex I, when they are validating or verifying the correct functioning of their procedures based on HACCP principles and good hygiene practice.

2. Food business operators shall decide the appropriate sampling frequencies, except where Annex I provides for specific sampling frequencies, in which case the sampling frequency shall be at least that provided for in Annex I. Food business operators shall make this decision in the context of their procedures based on HACCP principles and good

hygiene practice, taking into account the instructions for use of the foodstuff.

The frequency of sampling may be adapted to the nature and size of the food businesses, provided that the safety of foodstuffs will not be endangered.

Article 5

Specific rules for testing and sampling

1. The analytical methods and the sampling plans and methods in Annex I shall be applied as reference methods.

2. Samples shall be taken from processing areas and equipment used in food production, when such sampling is necessary for ensuring that the criteria are met. In that sampling the ISO standard 18593 shall be used as a reference method.

Food business operators manufacturing ready-to-eat foods, which may pose a *Listeria monocytogenes* risk for public health, shall sample the processing areas and equipment for *Listeria monocytogenes* as part of their sampling scheme.

Food business operators manufacturing dried infant formulae or dried foods for special medical purposes intended for infants below six months which pose an *Enterobacter sakazakii* risk shall monitor the processing areas and equipment for Enterobacteriaceae as part of their sampling scheme.

3. The number of sample units of the sampling plans set out in Annex I may be reduced if the food business operator can demonstrate by historical documentation that he has effective HACCP-based procedures.

4. If the aim of the testing is to specifically assess the acceptability of a certain batch of foodstuffs or a process, the sampling plans set out in Annex I shall be respected as a minimum.

5. Food business operators may use other sampling and testing procedures, if they can demonstrate to the satisfaction of the competent authority that these procedures provide at least equivalent guarantees. Those procedures may include use of alternative sampling sites and use of trend analyses.

Testing against alternative micro-organisms and related microbiological limits as well as testing of analytes other than microbiological ones shall be allowed only for process hygiene criteria.

The use of alternative analytical methods is acceptable when the methods are validated against the reference method in Annex I and if a proprietary method, certified by a third party in accordance with the protocol set out in EN/ISO standard 16140 or other internationally accepted similar protocols, is used.

If the food business operator wishes to use analytical methods other than those validated and certified as described in paragraph 3 the methods shall be validated according to internationally accepted protocols and their use authorised by the competent authority.

Article 6

Labelling requirements

1. When the requirements for *Salmonella* in minced meat, meat preparations and meat products intended to be eaten cooked of all species set down in Annex I are fulfilled, the batches of those products placed on the market must be clearly labelled by the manufacturer in order to inform the consumer of the need for thorough cooking prior to consumption.

2. As from 1 January 2010 labelling as referred to in paragraph 1 in respect of minced meat, meat preparations and meat products made from poultrymeat will no longer be required.

Article 7

Unsatisfactory results

1. When the results of testing against the criteria set out in Annex I are unsatisfactory, the food business operators shall take the measures laid down in paragraphs 2 to 4 of this Article together with other corrective actions defined in their HACCP-based procedures and other actions necessary to protect the health of consumers.

In addition, they shall take measures to find the cause of the unsatisfactory results in order to prevent the recurrence of the unacceptable microbiological contamination. Those measures may include modifications to the HACCP-based procedures or other food hygiene control measures in place.

2. When testing against food safety criteria set out in Chapter 1 of Annex I provides unsatisfactory results, the product or batch of foodstuffs shall be withdrawn or recalled in accordance with Article 19 of Regulation (EC) No 178/2002. However, products placed on the market, which are not yet at retail level and which do not fulfil the food safety criteria, may be submitted to further processing by a treatment eliminating the hazard in question. This treatment may only be carried out by food business operators other than those at retail level.

The food business operator may use the batch for purposes other than those for which it was originally intended, provided that this use does not pose a risk for public or animal health and provided that this use has been decided within the procedures based on HACCP principles and good hygiene practice and authorised by the competent authority.

3. A batch of mechanically separated meat (MSM) produced with the techniques referred to in Chapter III, paragraph 3, in Section V of Annex III to Regulation (EC) No 853/2004, with unsatisfactory results in respect of the *Salmonella* criterion, may be used in the food chain only to manufacture heat-treated meat products in establishments approved in accordance with Regulation (EC) No 853/2004.

4. In the event of unsatisfactory results as regards process hygiene criteria the actions laid down in Annex I, Chapter 2 shall be taken.

Article 8

Transitional derogation

1. A transitional derogation is granted until 31 December 2009 at the latest pursuant to Article 12 of Regulation (EC) No 852/2004 as regards compliance with the value set in Annex I to this Regulation for *Salmonella* in minced meat, meat preparations and meat products intended to be eaten cooked placed on the national market of a Member State.

2. The Member States using this possibility shall notify the Commission and other Member States thereof. The Member State shall:

(a) guarantee that the appropriate means, including labelling and a special mark, which cannot be confused with the identification mark provided for in Annex II, Section I to Regulation (EC) No 853/2004, are in place to ensure that the derogation applies only to the products concerned when placed on the domestic market, and that products dispatched for intra-Community trade comply with the criteria laid down in Annex I;

(b) provide that the products to which such transitional derogation applies shall be clearly labelled that they must be thoroughly cooked prior to consumption;

(c) undertake that when testing against the *Salmonella* criterion pursuant to Article 4, and for the result to be acceptable as regards such transitional derogation, no more than one out of five sample units shall be found to be positive.

Article 9

Analyses of trends

Food business operators shall analyse trends in the test results. When they observe a trend towards unsatisfactory results, they shall take appropriate actions without undue delay to remedy the situation in order to prevent the occurrence of microbiological risks.

Article 10

Review

This Regulation shall be reviewed taking into account progress in science, technology and methodology, emerging pathogenic micro-organisms in foodstuffs, and information from risk assessments. In particular, the criteria and conditions concerning the presence of salmonella in carcases of cattle, sheep, goats, horses, pigs and poultry shall be revised in the light of the changes observed in salmonella prevalence.

Article 11

Repeal

Decision 93/51/EEC is repealed.

Article 12

This Regulation shall enter into force on the 20th day following its publication in the *Official Journal of the European Union*.

It shall apply from 1 January 2006.

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

Done at Brussels, 15 November 2005.

For the Commission

Markos KYPRIANOU

Member of the Commission

ANNEX I

Microbiological criteria for foodstuffs

Chapter 1. Food safety criteria

Food category	Micro-organisms/their toxins, metabolites	Sampling-plan (1)		Limits (2)		Analytical reference method (3)	Stage where the criterion applies
		n	c	m	M		
1.1. Ready-to-eat foods intended for infants and ready-to-eat foods for special medical purposes (4)	*Listeria monocytogenes*	10	0	Absence in 25 g		EN/ISO 11290-1	Products placed on the market during their shelf-life
1.2. Ready-to-eat foods able to support the growth of *L. monocytogenes,* other than those intended for infants and for special medical purposes	*Listeria monocytogenes*	5	0	100 cfu/g (5)		EN/ISO 11290-2 (6)	Products placed on the market during their shelf-life
		5	0	Absence in 25 g (7)		EN/ISO 11290-1	Before the food has left the immediate control of the food business operator, who has produced it
1.3. Ready-to-eat foods unable to support the growth of *L. monocytogenes,* other than those intended for infants and for special medical purposes (4) (8)	*Listeria monocytogenes*	5	0	100 cfu/g		EN/ISO 11290-2 (6)	Products placed on the market during their shelf-life
1.4. Minced meat and meat preparations intended to be eaten raw	*Salmonella*	5	0	Absence in 25 g		EN/ISO 6579	Products placed on the market during their shelf-life
1.5. Minced meat and meat preparations made from poultry meat intended to be eaten cooked	*Salmonella*	5	0	From 1.1.2006 Absence in 10 g From 1.1.2010 Absence in 25 g		EN/ISO 6579	Products placed on the market during their shelf-life
1.6. Minced meat and meat preparations made from other species than poultry intended to be eaten cooked	*Salmonella*	5	0	Absence in 10 g		EN/ISO 6579	Products placed on the market during their shelf-life
1.7. Mechanically separated meat (MSM) (9)	*Salmonella*	5	0	Absence in 10 g		EN/ISO 6579	Products placed on the market during their shelf-life
1.8. Meat products intended to be eaten raw, excluding products where the manufacturing process or the composition of the product will eliminate the salmonella risk	*Salmonella*	5	0	Absence in 25 g		EN/ISO 6579	Products placed on the market during their shelf-life

Food category	Micro-organisms/their toxins, metabolites	Sampling-plan (1)		Limits (2)		Analytical reference method (3)	Stage where the criterion applies
		n	c	m	M		
1.9. Meat products made from poultry meat intended to be eaten cooked	*Salmonella*	5	0	From 1.1.2006 Absence in 10 g From 1.1.2010 Absence in 25 g		EN/ISO 6579	Products placed on the market during their shelf-life
1.10. Gelatine and collagen	*Salmonella*	5	0	Absence in 25 g		EN/ISO 6579	Products placed on the market during their shelf-life
1.11. Cheeses, butter and cream made from raw milk or milk that has undergone a lower heat treatment than pasteurisation (10)	*Salmonella*	5	0	Absence in 25 g		EN/ISO 6579	Products placed on the market during their shelf-life
1.12. Milk powder and whey powder (10)	*Salmonella*	5	0	Absence in 25 g		EN/ISO 6579	Products placed on the market during their shelf-life
1.13. Ice cream (11), excluding products where the manufacturing process or the composition of the product will eliminate the salmonella risk	*Salmonella*	5	0	Absence in 25 g		EN/ISO 6579	Products placed on the market during their shelf-life
1.14. Egg products, excluding products where the manufacturing process or the composition of the product will eliminate the salmonella risk	*Salmonella*	5	0	Absence in 25g		EN/ISO 6579	Products placed on the market during their shelf-life
1.15. Ready-to-eat foods containing raw egg, excluding products where the manufacturing process or the composition of the product will eliminate the salmonella risk	*Salmonella*	5	0	Absence in 25 g or ml		EN/ISO 6579	Products placed on the market during their shelf-life
1.16. Cooked crustaceans and molluscan shellfish	*Salmonella*	5	0	Absence in 25 g		EN/ISO 6579	Products placed on the market during their shelf-life
1.17. Live bivalve molluscs and live echinoderms, tunicates and gastropods	*Salmonella*	5	0	Absence in 25g		EN/ISO 6579	Products placed on the market during their shelf-life

Food category	Micro-organisms/their toxins, metabolites	Sampling-plan (1)		Limits (2)		Analytical reference method (3)	Stage where the criterion applies
		n	c	m	M		
1.18. Sprouted seeds (ready-to-eat) (12)	*Salmonella*	5	0	Absence in 25 g		EN/ISO 6579	Products placed on the market during their shelf-life
1.19. Pre-cut fruit and vegetables (ready-to-eat)	*Salmonella*	5	0	Absence in 25 g		EN/ISO 6579	Products placed on the market during their shelf-life
1.20. Unpasteurised fruit and vegetable juices (ready-to-eat)	*Salmonella*	5	0	Absence in 25 g		EN/ISO 6579	Products placed on the market during their shelf-life
1.21. Cheeses, milk powder and whey powder, as referred to in the coagulase-positive staphylococci criteria in Chapter 2.2 of this Annex	Staphylococcal entero-toxins	5	0	Not detected in 25g		European screening method of the CRL for Milk (13)	Products placed on the market during their shelf-life
1.22. Dried infant formulae and dried dietary foods for special medical purposes intended for infants below six months of age, as referred to in the Enterobacter-iaceae criterion in Chapter 2.2 of this Annex	*Salmonella*	30	0	Absence in 25 g		EN/ISO 6579	Products placed on the market during their shelf-life
1.23. Dried infant formulae and dried dietary foods for special medical purposes intended for infants below six months of age, as referred to in the Enterobacter-iaceae criterion in Chapter 2.2 of this Annex	*Enterobacter sakazakii*	30	0	Absence in 10 g		ISO/DTS 22964	Products placed on the market during their shelf-life
1.24. Live bivalve molluscs and live echino-derms, tunicates and gastropods	*E.coli* (14)	1 (15)	0	230 MPN/100g of flesh and intra-valvular liquid		ISO TS 16649-3	Products placed on the market during their shelf-life
1.25. Fishery products from fish species asso-ciated with a high amount of histidine (16)	Histamine	9 (17)	2	100 mg/kg	200 mg/kg	HPLC (18)	Products placed on the market during their shelf-life

Food category	Micro-organisms/their toxins, metabolites	Sampling-plan (1)		Limits (2)		Analytical reference method (3)	Stage where the criterion applies
		n	c	m	M		
1.26. Fishery products which have undergone enzyme maturation treatment in brine, manufactured from fish species associated with a high amount of histidine (16)	Histamine	9	2	200 mg/kg	400 mg/kg	HPLC (18)	Products placed on the market during their shelf-life

(1) n = number of units comprising the sample; c = number of sample units giving values over m or between m and M.

(2) For points 1.1-1.24 m=M.

(3) The most recent edition of the standard shall be used.

(4) Regular testing against the criterion is not useful in normal circumstances for the following ready-to-eat foods:
- those which have received heat treatment or other processing effective to eliminate *L. monocytogenes*, when recontamination is not possible after this treatment (e.g. products heat treated in their final package),
- fresh, uncut and unprocessed vegetables and fruits, excluding sprouted seeds,
- bread, biscuits and similar products,
- bottled or packed waters, soft drinks, beer, cider, wine, spirits and similar products,
- sugar, honey and confectionery, including cocoa and chocolate products,
- live bivalve molluscs.

(5) This criterion applies if the manufacturer is able to demonstrate, to the satisfaction of the competent authority, that the product will not exceed the limit 100 cfu/g throughout the shelf-life. The operator may fix intermediate limits during the process that should be low enough to guarantee that the limit of 100 cfu/g is not exceeded at the end of the shelf-life.

(6) 1 ml of inoculum is plated on a Petri dish of 140 mm diameter or on three Petri dishes of 90 mm diameter.

(7) This criterion applies to products before they have left the immediate control of the producing food business operator, when he is not able to demonstrate, to the satisfaction of the competent authority, that the product will not exceed the limit of 100 cfu/g throughout the shelf-life.

(8) Products with pH ≤ 4,4 or a_w ≤ 0,92, products with pH ≤ 5,0 and a_w ≤ 0,94, products with a shelf-life of less than five days are automatically considered to belong to this category. Other categories of products can also belong to this category, subject to scientific justification.

(9) This criterion applies to mechanically separated meat (MSM) produced with the techniques referred to in Chapter III, paragraph 3, in section V of Annex III to Regulation (EC) No 853/2004 of the European Parliament and of the Council of 29 April 2004 laying down specific hygiene rules for food of animal origin.

(10) Excluding products when the manufacturer can demonstrate to the satisfaction of the competent authorities that, due to the ripening time and a_w of the product where appropriate, there is no salmonella risk.

(11) Only ice creams containing milk ingredients.

(12) Preliminary testing of the batch of seeds before starting the sprouting process or the sampling to be carried out at the stage where the highest probability of finding *Salmonella* is expected.

(13) Reference: Hennekinne et al., J. AOAC Internat. Vol. 86, No 2, 2003.

(14) *E. coli* is used here as an indicator of faecal contamination.

(15) A pooled sample comprising a minimum of 10 individual animals.

(16) Particularly fish species of the families: *Scombridae, Clupeidae, Engraulidae, Coryfenidae, Pomatomidae, Scombresosidae*.

(17) Single samples may be taken at retail level. In such a case the presumption laid down in Article 14(6) of Regulation (EC) No 178/2002, according to which the whole batch should be deemed unsafe, shall not apply.

(18) References: 1. Malle P., Valle M., Bouquelet S. Assay of biogenic amines involved in fish decomposition. J. AOAC Internat. 1996, 79, 43-49.
2. Duflos G., Dervin C., Malle P., Bouquelet S. Relevance of matrix effect in determination of biogenic amines in plaice (*Pleuronectes platessa*) and whiting (*Merlangus merlangus*). J. AOAC Internat. 1999, 82, 1097-1101.

Interpretation of the test results

The limits given refer to each sample unit tested, excluding live bivalve molluscs and live echinoderms, tunicates and gastropods in relation to testing *E. coli*, where the limit refers to a pooled sample.

The test results demonstrate the microbiological quality of the batch tested ([1]).

L. monocytogenes in ready-to-eat foods intended for infants and for special medical purposes:

— satisfactory, if all the values observed indicate the absence of the bacterium,

— unsatisfactory, if the presence of the bacterium is detected in any of the sample units.

L. monocytogenes in ready-to-eat foods able to support the growth of *L. monocytogenes* before the food has left the immediate control of the producing food business operator when he is not able to demonstrate that the product will not exceed the limit of 100 cfu/g throughout the shelf-life:

— satisfactory, if all the values observed indicate the absence of the bacterium,

— unsatisfactory, if the presence of the bacterium is detected in any of the sample units.

L. monocytogenes in other ready-to-eat foods and *E. coli* in live bivalve molluscs:

— satisfactory, if all the values observed are ≤ the limit,

— unsatisfactory, if any of the values are > the limit.

Salmonella in different food categories:

— satisfactory, if all the values observed indicate the absence of the bacterium,

— unsatisfactory, if the presence of the bacterium is detected in any of the sample units.

([1]) The test results can be used also for demonstrating the effectiveness of the HACCP or good hygiene procedure of the process.

Staphylococcal enterotoxins in dairy products:

— satisfactory, if in all the sample units the enterotoxins are not detected,

— unsatisfactory, if the enterotoxins are detected in any of the sample units.

Enterobacter sakazakii in dried infant formulae and dried dietary foods for special medical purposes intended for infants below 6 months of age:

— satisfactory, if all the values observed indicate the absence of the bacterium,

— unsatisfactory, if the presence of the bacterium is detected in any of the sample units.

Histamine in fishery products from fish species associated with a high amount of histidine:

— satisfactory, if the following requirements are fulfilled:

1. the mean value observed is ≤ m
2. a maximum of c/n values observed are between m and M
3. no values observed exceed the limit of M,

— unsatisfactory, if the mean value observed exceeds m or more than c/n values are between m and M or one or more of the values observed are >M.

Chapter 2. Process hygiene criteria

2.1. Meat and products thereof

Food category	Micro-organisms	Sampling plan (1)		Limits (2)		Analytical reference method (3)	Stage where the criterion applies	Action in case of unsatisfactory results
		n	c	m	M			
2.1.1. Carcases of cattle, sheep, goats and horses (4)	Aerobic colony count			3,5 log cfu/cm^2 daily mean log	5,0 log cfu/cm^2 daily mean log	ISO 4833	Carcases after dressing but before chilling	Improvements in slaughter hygiene and review of process controls
	Enterobacteriaceae			1,5 log cfu/cm^2 daily mean log	2,5 log cfu/cm^2 daily mean log	ISO 21528-2	Carcases after dressing but before chilling	Improvements in slaughter hygiene and review of process controls
2.1.2. Carcases of pigs (4)	Aerobic colony count			4,0 log cfu/cm^2 daily mean log	5,0 log cfu/cm^2 daily mean log	ISO 4833	Carcases after dressing but before chilling	Improvements in slaughter hygiene and review of process controls
	Enterobacteriaceae			2,0 log cfu/cm^2 daily mean log	3,0 log cfu/cm^2 daily mean log	ISO 21528-2	Carcases after dressing but before chilling	Improvements in slaughter hygiene and review of process controls
2.1.3. Carcases of cattle, sheep, goats and horses	*Salmonella*	50 (5)	2 (6)	Absence in the area tested per carcase		EN/ISO 6579	Carcases after dressing but before chilling	Improvements in slaughter hygiene, review of process controls and of origin of animals
2.1.4. Carcases of pig	*Salmonella*	50 (5)	5 (6)	Absence in the area tested per carcase		EN/ISO 6579	Carcases after dressing but before chilling	Improvements in slaughter hygiene and review of process controls, origin of animals and of the biosecurity measures in the farms of origin
2.1.5. Poultry carcases of broilers and turkeys	*Salmonella*	50 (5)	7 (6)	Absence in 25 g of a pooled sample of neck skin		EN/ISO 6579	Carcases after chilling	Improvements in slaughter hygiene and review of process controls, origin of animals and biosecurity measures in the farms of origin

Food category	Micro-organisms	Sampling plan (1)		Limits (2)		Analytical reference method (3)	Stage where the criterion applies	Action in case of unsatisfactory results
		n	c	m	M			
2.1.6. Minced meat	Aerobic colony count (7)	5	2	$5x10^5$ cfu/g	$5x10^6$ cfu/g	ISO 4833	End of the manufacturing process	Improvements in production hygiene and improvements in selection and/or origin of raw materials
	E.coli (8)	5	2	50 cfu/g	500 cfu/g	ISO 16649-1 or 2	End of the manufacturing process	Improvements in production hygiene and improvements in selection and/or origin of raw materials
2.1.7. Mechanically separated meat (MSM) (9)	Aerobic colony count	5	2	$5x10^5$ cfu/g	$5x10^6$ cfu/g	ISO 4833	End of the manufacturing process	Improvements in production hygiene and improvements in selection and/or origin of raw materials
	E.coli (8)	5	2	50 cfu/g	500 cfu/g	ISO 16649-1 or 2	End of the manufacturing process	Improvements in production hygiene and improvements in selection and/or origin of raw materials
2.1.8. Meat preparations	*E.coli* (8)	5	2	500 cfu/g or cm^2	5 000 cfu/g or cm^2	ISO 16649-1 or 2	End of the manufacturing process	Improvements in production hygiene and improvements in selection and/or origin of raw materials

(1) n = number of units comprising the sample; c = number of sample units giving values between m and M.
(2) For points 2.1.3 — 2.1.5 m=M.
(3) The most recent edition of the standard shall be used.
(4) The limits (m and M) apply only to samples taken by the destructive method. The daily mean log is calculated by first taking a log value of each individual test result and then calculating the mean of these log values.
(5) The 50 samples are derived from 10 consecutive sampling sessions in accordance with the sampling rules and frequencies laid down in this Regulation.
(6) The number of samples where the presence of salmonella is detected. The c value is subject to review in order to take into account the progress made in reducing the salmonella prevalence. Member States or regions having low salmonella prevalence may use lower c values even before the review.
(7) This criterion does not apply to minced meat produced at retail level when the shelf-life of the product is less then 24 hours.
(8) *E. coli* is used here as an indicator of faecal contamination.
(9) These criteria apply to mechanically separated meat (MSM) produced with the techniques referred to in Chapter III, paragraph 3, in section V of Annex III of Regulation (EC) No 853/2004 of the European Parliament and of the Council of 29 April 2004 laying down specific hygiene rules for food of animal origin.

Interpretation of the test results

The limits given refer to each sample unit tested, excluding testing of carcases where the limits refer to pooled samples.

The test results demonstrate the microbiological quality of the process tested.

Enterobacteriaceae and aerobic colony count in carcases of cattle, sheep, goats, horses and pigs:

— satisfactory, if the daily mean log is < m,

— acceptable, if the daily mean log is between m and M,

— unsatisfactory, if the daily mean log is >M.

Salmonella in carcases:

— satisfactory, if the presence of *Salmonella* is detected in a maximum of c/n samples,

— unsatisfactory, if the presence of *Salmonella* is detected in more than c/n samples.

After each sampling session, the results of the last ten sampling sessions are assessed in order to obtain the n number of samples.

E. coli and aerobic colony count in minced meat, meat preparations and mechanically separated meat (MSM):

— satisfactory, if all the values observed are < m,

— acceptable, if a maximum of c/n values are between m and M, and the rest of the values observed are < m,

— unsatisfactory, if one or more of the values observed are >M or more than c/n values are between m and M.

2.2. Milk and dairy products

Food category	Micro-organisms	Sampling plan (1)		Limits (2)		Analytical reference method (3)	Stage where the criterion applies	Action in case of unsatisfactory results
		n	c	m	M			
2.2.1. Pasteurised milk and other pasteurised liquid dairy products (4)	Enterobacteriaceae	5	2	<1 cfu/ml	5 cfu/ml	ISO 21528-1	End of the manufacturing process	Check on the efficiency of heat- treatment and prevention of recontamination as well as the quality of raw materials
2.2.2. Cheeses made from milk or whey that has undergone heat treatment	*E.coli* (5)	5	2	100 cfu/g	1 000 cfu/g	ISO 16649- 1 or 2	At the time during the manufacturing process when the *E. coli* count is expected to be highest (6)	Improvements in production hygiene and selection of raw materials
2.2.3. Cheeses made from raw milk	Coagulase-positive staphylococci	5	2	10^4 cfu/g	10^5 cfu/g	EN/ISO 6888-2	At the time during the manufacturing process when the number of staphylococci is expected to be highest	Improvements in production hygiene and selection of raw materials. If values >10^5 cfu/g are detected, the cheese batch has to be tested for staphylococcal enterotoxins.
2.2.4. Cheeses made from milk that has undergone a lower heat treatment than pasteurisation (7) and ripened cheeses made from milk or whey that has undergone pasteurisation or a stronger heat treatment (7)	Coagulase-positive staphylococci	5	2	100 cfu/g	1 000 cfu/g	EN/ISO 6888-1 or 2		
2.2.5. Unripened soft cheeses (fresh cheeses) made from milk or whey that has undergone pasteurisation or a stronger heat treatment (7)	Coagulase-positive staphylococci	5	2	10 cfu/g	100 cfu/g	EN/ISO 6888-1 or 2	End of the manufacturing process	Improvements in production hygiene. If values > 10^5 cfu/g are detected, the cheese batch has to be tested for staphylococcal enterotoxins.
2.2.6. Butter and cream made from raw milk or milk that has undergone a lower heat treatment than pasteurisation	*E.coli* (5)	5	2	10 cfu/g	100 cfu/g	ISO 16649- 1 or 2	End of the manufacturing process	Improvements in production hygiene and selection of raw materials

Food category	Micro-organisms	Sampling plan (1)		Limits (2)		Analytical reference method (3)	Stage where the criterion applies	Action in case of unsatisfactory results
		n	c	m	M			
2.2.7. Milk powder and whey powder (4)	Enterobacteriaceae	5	0	10 cfu/g		ISO 21528- 1	End of the manufacturing process	Check on the efficiency of heat treatment and prevention of recontamination
	Coagulase-positive staphylococci	5	2	10 cfu/g	100 cfu/g	EN/ISO 6888-1 or 2	End of the manufacturing process	Improvements in production hygiene. If values > 10^5 cfu/g are detected, the batch has to be tested for staphylococcal enterotoxins.
2.2.8. Ice cream (8) and frozen dairy desserts	Enterobacteriaceae	5	2	10 cfu/g	100 cfu/g	ISO 21528- 2	End of the manufacturing process	Improvements in production hygiene
2.2.9. Dried infant formulae and dried dietary foods for special medical purposes intended for infants below six months of age	Enterobacteriaceae	10	0	Absence in 10 g		ISO 21528- 1	End of the manufacturing process	Improvements in production hygiene to minimise contamination. If Enterobacteriaceae are detected in any of the sample units, the batch has to be tested for *E. sakazakii* and *Salmonella*

(1) n = number of units comprising the sample; c = number of sample units giving values between m and M.
(2) For point 2.2.7 m=M.
(3) The most recent edition of the standard shall be used.
(4) The criterion does not apply to products intended for further processing in the food industry.
(5) *E. coli* is used here as an indicator for the level of hygiene.
(6) For cheeses which are not able to support the growth of *E. coli*, the *E. coli* count is usually the highest at the beginning of the ripening period, and for cheeses which are able to support the growth of *E. coli*, it is normally at the end of the ripening period.
(7) Excluding cheeses where the manufacturer can demonstrate, to the satisfaction of the competent authorities, that the product does not pose a risk of staphylococcal enterotoxins.
(8) Only ice creams containing milk ingredients.

Interpretation of the test results

The limits given refer to each sample unit tested.

The test results demonstrate the microbiological quality of the process tested.

Enterobacteriaceae in dried infant formulae and dried dietary foods for special medical purposes intended for infants below six months of age:

— satisfactory, if all the values observed indicate the absence of the bacterium,

— unsatisfactory, if the presence of the bacterium is detected in any of the sample units

E. coli, enterobacteriaceae (other food categories) and coagulase-positive staphylococci:

— satisfactory, if all the values observed are < m,

— acceptable, if a maximum of c/n values are between m and M, and the rest of the values observed are < m,

— unsatisfactory, if one or more of the values observed are >M or more than c/n values are between m and M.

2.3. Egg products

Food category	Micro-organisms	Sampling plan (1)		Limits		Analytical reference method (2)	Stage where the criterion applies	Action in case of unsatisfactory results
		n	c	m	M			
2.3.1. Egg products	Enterobacteriaceae	5	2	10 cfu/g or ml	100 cfu/g or ml	ISO 21528-2	End of the manufacturing process	Checks on the efficiency of the heat treatment and prevention of recontamination

(1) n = number of units comprising the sample; c = number of sample units giving values between m and M.
(2) The most recent edition of the standard shall be used.

Interpretation of the test results

The limits given refer to each sample unit tested.

The test results demonstrate the microbiological quality of the process tested.

Enterobacteriaceae in egg products:

— satisfactory, if all the values observed are < m,

— acceptable, if a maximum of c/n values are between m and M, and the rest of the values observed are $\leq$ m,

— unsatisfactory, if one or more of the values observed are >M or more than c/n values are between m and M.

2.4. Fishery products

Food category	Micro-organisms	Sampling plan (1)		Limits		Analytical reference method (2)	Stage where the criterion applies	Action in case of unsatisfactory results
		n	c	m	M			
2.4.1. Shelled and shucked products of cooked crustaceans and molluscan shellfish	*E.coli*	5	2	1 cfu/g	10 cfu/g	ISO TS 16649-3	End of the manufacturing process	Improvements in production hygiene
	Coagulase-positive staphylococci	5	2	100 cfu/g	1 000 cfu/g	EN/ISO 6888-1 or 2	End of the manufacturing process	Improvements in production hygiene

(1) n = number of units comprising the sample; c = number of sample units giving values between m and M.
(2) The most recent edition of the standard shall be used.

Interpretation of the test results

The limits given refer to each sample unit tested.

The test results demonstrate the microbiological quality of the process tested.

E. coli in shelled and shucked products of cooked crustaceans and molluscan shellfish:

— satisfactory, if all the values observed are $\leq$ m,

— acceptable, if a maximum of c/n values are between m and M, and the rest of the values observed are ≤ m,

— unsatisfactory, if one or more of the values observed are >M or more than c/n values are between m and M.

Coagulase-positive staphylococci in shelled and cooked crustaceans and molluscan shellfish:

— satisfactory, if all the values observed are < m,

— acceptable, if a maximum of c/n values are between m and M, and the rest of the values observed are < m,

— unsatisfactory, if one or more of the values observed are >M or more than c/n values are between m and M.

2.5. Vegetables, fruits and products thereof

Food category	Micro-organisms	Sampling plan (1)		Limits		Analytical reference method (2)	Stage where the criterion applies	Action in case of unsatisfactory results
		n	c	m	M			
2.5.1. Pre-cut fruit and vegetables (ready-to-eat)	*E.coli*	5	2	100 cfu/g	1 000 cfu/g	ISO 16649- 1 or 2	Manufacturing process	Improvements in production hygiene, selection of raw materials
2.5.2. Unpasteurised fruit and vegetable juices (ready-to-eat)	*E.coli*	5	2	100 cfu/g	1 000 cfu/g	ISO 16649- 1 or 2	Manufacturing process	Improvements in production hygiene, selection of raw materials

(1) n = number of units comprising the sample; c = number of sample units giving values between m and M.
(2) The most recent edition of the standard shall be used.

Interpretation of the test results

The limits given refer to each sample unit tested.

The test results demonstrate the microbiological quality of the process tested.

E. coli in pre-cut fruit and vegetables (ready-to-eat) and in unpasteurised fruit and vegetable juices (ready-to-eat):

— satisfactory, if all the values observed are $\leq$ m,

— acceptable, if a maximum of c/n values are between m and M, and the rest of the values observed are $\leq$ m,

— unsatisfactory, if one or more of the values observed are >M or more than c/n values are between m and M.

Chapter 3. Rules for sampling and preparation of test samples

3.1. General rules for sampling and preparation of test samples

In the absence of more specific rules on sampling and preparation of test samples, the relevant standards of the ISO (International Organisation for Standardisation) and the guidelines of the Codex Alimentarius shall be used as reference methods.

3.2. Bacteriological sampling in slaughterhouses and at premises producing minced meat and meat preparations

Sampling rules for carcases of cattle, pigs, sheep, goats and horses

The destructive and non-destructive sampling methods, the selection of the sampling sites and the rules for storage and transport of samples are described in standard ISO 17604.

Five carcases shall be sampled at random during each sampling session. Sample sites should be selected taking into account the slaughter technology used in each plant.

When sampling for analyses of enterobacteriaceae and aerobic colony counts, four sites of each carcase shall be sampled. Four tissue samples representing a total of 20 cm^2 shall be obtained by the destructive method. When using the non-destructive method for this purpose, the sampling area shall cover a minimum of 100 cm^2 (50 cm^2 for small ruminant carcases) per sampling site.

When sampling for *Salmonella* analyses, an abrasive sponge sampling method shall be used. The sampling area shall cover a minimum of 100 cm^2 per site selected.

When samples are taken from the different sampling sites on the carcase, they shall be pooled before examination.

Sampling rules for poultry carcases

For the *Salmonella* analyses, a minimum of 15 carcases shall be sampled at random during each sampling session and after chilling. A piece of approximately 10 g from neck skin shall be obtained from each carcase. On each occasion the neck skin samples from three carcases shall be pooled before examination in order to form 5 x 25 g final samples.

Guidelines for sampling

More detailed guidelines on the sampling of carcases, in particular concerning the sampling sites, may be included in the guides to good practice referred to in Article 7 of Regulation (EC) No 852/2004.

Sampling frequencies for carcases, minced meat, meat preparations and mechanically separated meat

However, when justified on the basis of a risk analysis and consequently authorised by the competent authority, small slaughterhouses and establishments producing minced meat and meat preparations in small quantities may be exempted from these sampling frequencies.

In the case of sampling for *Salmonella* analyses of minced meat, meat preparations and carcases, the frequency can be reduced to fortnightly if satisfactory results have been obtained for 30 consecutive weeks. The salmonella sampling frequency may also be reduced if there is a national or regional salmonella control programme in place and if this programme includes testing that replaces the described sampling. The sampling frequency may be further reduced if the national or regional salmonella control programme demonstrates that the salmonella prevalence is low in animals purchased by the slaughterhouse.

As regards the sampling of minced meat and meat preparations for *E. coli* and aerobic colony count analyses and the sampling of carcases for enterobacteriaceae and aerobic colony count analyses, the frequency may be reduced to fortnightly testing if satisfactory results are obtained for six consecutive weeks.

The food business operators of slaughterhouses or establishments producing minced meat, meat preparations or mechanically separated meat shall take samples for microbiological analysis at least once a week. The day of sampling shall be changed each week to ensure that each day of the week is covered.

ANNEX II

The studies referred to in Article 3(2) shall include:

— specifications for physico-chemical characteristics of the product, such as pH, a_w, salt content, concentration of preservatives and the type of packaging system, taking into account the storage and processing conditions, the possibilities for contamination and the foreseen shelf-life, and

— consultation of available scientific literature and research data regarding the growth and survival characteristics of the micro-organisms of concern.

When necessary on the basis of the abovementioned studies, the food business operator shall conduct additional studies, which may include:

— predictive mathematical modelling established for the food in question, using critical growth or survival factors for the micro-organisms of concern in the product,

— tests to investigate the ability of the appropriately inoculated micro-organism of concern to grow or survive in the product under different reasonably foreseeable storage conditions,

— studies to evaluate the growth or survival of the micro-organisms of concern that may be present in the product during the shelf-life under reasonably foreseeable conditions of distribution, storage and use.

The above mentioned studies shall take into account the inherent variability linked to the product, the micro-organisms in question and the processing and storage conditions.

COMMISSION IMPLEMENTING REGULATION (EU) 2019/627

of 15 March 2019

laying down uniform practical arrangements for the performance of official controls on products of animal origin intended for human consumption in accordance with Regulation (EU) 2017/625 of the European Parliament and of the Council and amending Commission Regulation (EC) No 2074/2005 as regards official controls

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Regulation (EU) 2017/625 of the European Parliament and of the Council of 15 March 2017 on official controls and other official activities performed to ensure the application of food and feed law, rules on animal health and welfare, plant health and plant protection products, amending Regulations (EC) No 999/2001, (EC) No 396/2005, (EC) No 1069/2009, (EC) 1107/2009, (EU) 1151/2012, (EU) No 652/2014, (EU) 2016/429 and (EU) 2016/2031 of the European Parliament and of the Council, Council Regulations (EC) No 1/2005 and (EC) No 1099/2009 and Council Directives 98/58/EC, 1999/74/EC, 2007/43/EC, 2008/119/EC and 2008/120/EC, and repealing Regulations (EC) No 854/2004 and (EC) No 882/2004 of the European Parliament and of the Council, Council Directives 89/608/EEC, 89/662/EEC, 90/425/EEC, 91/496/EEC, 96/23/EC, 96/93/EC and 97/78/EC and Council Decision 92/438/EEC (Official Controls Regulation) ([1]), and in particular Article 18(8) thereof,

Whereas:

(1) Regulation (EU) 2017/625 lays down rules for the official controls and other official activities performed by the competent authorities of the Member States to verify compliance with Union legislation, inter alia, in the area of food safety at all stages of production, processing and distribution. In particular, it provides for official controls in relation to products of animal origin intended for human consumption. In addition, it repeals Regulation (EC) No 854/2004 of the European Parliament and of the Council ([2]) with effect from 14 December 2019. That Regulation currently lays down specific rules for official controls on products of animal origin intended for human consumption, including requirements on uniform practical arrangements for the performance of the controls.

(2) The rules laid down in this Regulation should ensure a continuation of the requirements to ensure the verification of food business operators' compliance with the rules for the safe handling of products of animal origin, in particular as laid down in:

— Council Directive 96/23/EC ([3]) as regards measures to monitor certain substances and residues;

— Regulation (EC) No 999/2001 of the European Parliament and of the Council ([4]) as regards controls on transmissible spongiform encephalopathies;

— Council Directive 2002/99/EC ([5]) as regards animal health rules on products of animal origin;

— Regulation (EC) No 178/2002 of the European Parliament and of the Council ([6]) as regards the general principles and requirements of food law;

([1]) OJ L 95, 7.4.2017, p. 1.

([2]) Regulation (EC) No 854/2004 of the European Parliament and of the Council of 29 April 2004 laying down specific rules for the organisation of official controls on products of animal origin intended for human consumption (OJ L 139, 30.4.2004, p. 206).

([3]) Council Directive 96/23/EC of 29 April 1996 on measures to monitor certain substances and residues thereof in live animals and animal products and repealing Directives 85/358/EEC and 86/469/EEC and Decisions 89/187/EEC and 91/664/EEC (OJ L 125, 23.5.1996, p. 10).

([4]) Regulation (EC) No 999/2001 of the European Parliament and of the Council of 22 May 2001 laying down rules for the prevention, control and eradication of certain transmissible spongiform encephalopathies (OJ L 147, 31.5.2001, p. 1).

([5]) 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).

([6]) 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).

— Directive 2003/99/EC of the European Parliament and of the Council ([7]) as regards the monitoring of zoonoses and zoonotic agents;

— Commission Decision 2003/467/EC ([8]) as regards control of tuberculosis, brucellosis and enzootic-bovine-leukosis;

— Regulation (EC) No 2160/2003 of the European Parliament and of the Council ([9]) as regards Salmonella controls;

— Regulation (EC) No 852/2004 of the European Parliament and of the Council ([10]) as regards the hygiene of foodstuffs;

— Regulation (EC) No 853/2004 of the European Parliament and of the Council ([11]) as regards the specific hygiene rules for food of animal origin;

— Council Regulation (EC) No 1/2005 ([12]) as regards the protection of animals during transport and related operations;

— Commission Regulation (EC) No 2073/2005 ([13]) as regards microbiological criteria in foodstuffs;

— Commission Regulations (EC) No 1881/2006 ([14]) and (EC) No 124/2009 ([15]) as regards maximum levels for certain contaminants in foodstuffs;

— Council Directive 2007/43/EC ([16]) as regards the protection of chickens;

— Regulation (EC) No 1069/2009 of the European Parliament and of the Council ([17]) as regards health rules on animal by-products;

— Council Regulation (EC) No 1099/2009 ([18]) as regards the protection of animals at the time of killing;

— Directive 2010/63/EU of the European Parliament and of the Council ([19]) as regards the protection of animals used for scientific purposes;

— Commission Implementing Regulation (EU) No 636/2014 ([20]) as regards trade in unskinned large wild game;

([7]) Directive 2003/99/EC of the European Parliament and of the Council of 17 November 2003 on the monitoring of zoonoses and zoonotic agents, amending Council Decision 90/424/EEC and repealing Council Directive 92/117/EEC (OJ L 325, 12.12.2003, p. 31).
([8]) Commission Decision 2003/467/EC of 23 June 2003 establishing the official tuberculosis, brucellosis and enzootic-bovine-leukosis-free status of certain Member States and regions of Member States as regards bovine herds (OJ L 156, 25.6.2003, p. 74).
([9]) 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 (OJ L 325, 12.12.2003, p. 1).
([10]) Regulation (EC) No 852/2004 of the European Parliament and of the Council of 29 April 2004 on the hygiene of foodstuffs (OJ L 139, 30.4.2004, p. 1).
([11]) Regulation (EC) No 853/2004 of the European Parliament and of the Council of 29 April 2004 laying down specific hygiene rules for food of animal origin (OJ L 139, 30.4.2004, p. 55).
([12]) Council Regulation (EC) No 1/2005 of 22 December 2004 on the protection of animals during transport and related operations and amending Directives 64/432/EEC and 93/119/EC and Regulation (EC) No 1255/97 (OJ L 3, 5.1.2005, p. 1).
([13]) Commission Regulation (EC) No 2073/2005 of 15 November 2005 on microbiological criteria for foodstuffs (OJ L 338, 22.12.2005, p. 1).
([14]) Commission Regulation (EC) No 1881/2006 of 19 December 2006 setting maximum levels for certain contaminants in foodstuffs (OJ L 364, 20.12.2006, p. 5).
([15]) Commission Regulation (EC) No 124/2009 of 10 February 2009 setting maximum levels for the presence of coccidiostats or histomonostats in food resulting from the unavoidable carry-over of these substances in non-target feed (OJ L 40, 11.2.2009, p. 7).
([16]) Council Directive 2007/43/EC of 28 June 2007 laying down minimum rules for the protection of chickens kept for meat production (OJ L 182, 12.7.2007, p. 19).
([17]) Regulation (EC) No 1069/2009 of the European Parliament and of the Council of 21 October 2009 laying down health rules as regards animal by-products and derived products not intended for human consumption and repealing Regulation (EC) No 1774/2002 (Animal By-products Regulation) (OJ L 300, 14.11.2009, p. 1).
([18]) Council Regulation (EC) No 1099/2009 of 24 September 2009 on the protection of animals at the time of killing (OJ L 303, 18.11.2009, p. 1).
([19]) Directive 2010/63/EU of the European Parliament and of the Council of 22 September 2010 on the protection of animals used for scientific purposes (OJ L 276, 20.10.2010, p. 33).
([20]) Commission Implementing Regulation (EU) No 636/2014 of 13 June 2014 on a model certificate for the trade of unskinned large wild game (OL L 175, 14.6.2014, p. 16).

— Commission Implementing Regulation (EU) 2015/1375 ([21]) as regards official controls for *Trichinella*; and

— Regulation (EU) 2016/429 of the European Parliament and of the Council ([22]) as regards animal health rules.

(3) The practical arrangements for the performance of official controls on products of animal origin should be considered where a minimum level of official controls is necessary to respond to recognised uniform hazards and risks that might be posed by products of animal origin, covering all aspects that are important for protecting human health and, where appropriate, animal health and animal welfare. They should be based on the most recent relevant information available and scientific evidence from opinions of the European Food Safety Authority (EFSA).

(4) On 31 August 2011, EFSA adopted a scientific opinion on the human health hazards to be covered by the inspection of meat (swine) ([23]). The recommendations of that opinion were taken into account in the requirements for pig meat inspections laid down in Regulation (EC) No 854/2004 and should be maintained in the requirements laid down in this Regulation.

(5) On 23 May 2012, EFSA adopted a scientific opinion on the human health hazards to be covered by the inspection of meat (poultry) ([24]). That opinion identifies *Campylobacter* spp. and *Salmonella* spp. as the main hazards to be covered in poultry meat inspections through an integrated food safety assurance system, achievable through improved food chain information (FCI) and risk-based interventions.

(6) On 6 June 2013, EFSA adopted a scientific opinion on the human health hazards to be covered by the inspection of meat (bovine animals) ([25]). That opinion identifies *Salmonella* spp. and pathogenic verocytotoxin-producing *Escherichia coli* (*E. coli*) as the most relevant hazards for meat inspections in bovine animals. It recommends the omission of palpation and incision during the post-mortem inspection of animals subjected to routine slaughter, since it may reduce spreading and cross-contamination with the high-priority biological hazards. However, palpations and incisions during post-mortem inspection, necessary to survey the occurrence of tuberculosis and *Taenia saginata* (tapeworm) cysticercosis, should be maintained.

(7) Also on 6 June 2013, EFSA adopted a scientific opinion on the human health hazards to be covered by the inspection of meat from sheep and goats ([26]). That opinion identifies pathogenic verocytotoxin-producing *E. coli* as the most relevant hazard for meat inspections in sheep and goats. It also recommends omitting palpation and incisions to the extent possible from the post-mortem inspection of sheep and goats subject to routine slaughter. However, palpation and incisions for the surveillance of tuberculosis and fascioliasis should be maintained in older animals for reasons of animal and human health surveillance.

(8) Also on 6 June 2013, EFSA adopted a scientific opinion on the human health hazards to be covered by the inspection of meat (solipeds) ([27]). That opinion recommends the use of visual-only inspection in solipeds, which may have a significant favourable effect on the microbiological status of soliped carcase meat. Such inspection is considered unlikely to affect the overall surveillance of animal diseases.

(9) Also on 6 June 2013, EFSA adopted a scientific opinion on the meat inspection of farmed game. That opinion recommends omitting palpation and incision unless abnormalities are detected, while at the same time underlining that such omission might have consequences for the overall surveillance of tuberculosis.

(10) The recommendations set out in these EFSA opinions should be taken into account when laying down uniform practical arrangements for the performance of official controls on products of animal origin intended for human consumption. The possible impact on trade with third countries should also be taken into account. At the same time, a smooth transition from the current requirements, as laid down in Regulation (EC) No 854/2004, should be ensured.

([21]) Commission Implementing Regulation (EU) 2015/1375 of 10 August 2015 laying down specific rules on official controls for *Trichinella* in meat (OJ L 212, 11.8.2015, p. 7).

([22]) Regulation (EU) 2016/429 of the European Parliament and of the Council of 9 March 2016 on transmissible animal diseases and amending and repealing certain acts in the area of animal health (Animal Health Law) (OJ L 84, 31.3.2016, p. 1).

([23]) *EFSA Journal 2011*;9(10):2351

([24]) *EFSA Journal 2012*;10(6):2741.

([25]) *EFSA Journal 2013*;11(6):3266.

([26]) *EFSA Journal 2013*;11(6):3265.

([27]) *EFSA Journal 2013*;11(6):3263.

(11) These practical arrangements should apply to official controls on products of animal origin laid down in Article 18 of Regulation (EU) 2017/625 and in Commission Delegated Regulation (EU) 2019/624 ([28]). These practical arrangements for the performance of official controls should be uniform and facilitate the application of the requirements for a minimum level of official controls, taking into account the size of small businesses as laid down in Article 16 of Regulation (EU) 2017/625 by the use of a threshold in a non-discriminatory way.

(12) Since the structure of slaughterhouses and game-handling establishments differs across Member States, a threshold should be based on the number of animals slaughtered or handled, or on the demonstration that it represents a limited and fixed percentage of the meat placed on the market. Article 17(6) of Regulation (EC) No 1099/2009 defines livestock units and lays down conversion rates to express the number of animals of a certain species in such livestock units. These provisions should be used to set thresholds and harmonise derogations from certain requirements based on the size of a slaughterhouse to the extent possible.

(13) Specific requirements for auditing by the competent authorities should also be maintained to ensure the uniform practical verification of compliance with Union requirements on products of animal origin. Auditing is of particular interest for the verification of general and specific hygiene requirements and the application of procedures based on hazard analysis and critical control points (HACCP).

(14) Verification of compliance with the requirements on identification marking in Section I of Annex II to Regulation (EC) No 853/2004, as currently laid down in Regulation (EC) No 854/2004, should be maintained to allow tracing back the animals.

(15) Ante-mortem and post-mortem inspections are essential to verify compliance with requirements on human and animal health and animal welfare. In order to ensure at least the same level of human and animal health and animal welfare protection as provided by Regulation (EC) No 854/2004 and fair trade in an open market, it is necessary to lay down uniform practical requirements for such inspections, including cases where official controls are performed under the responsibility of the official veterinarian. As regards official controls on fresh meat, these inspections should be supplemented by appropriate documentary checks, controls on the safe disposal of specified risk material, as defined in Article 3(1)(g) of Regulation (EC) No 999/2001, and other animal by-products, and laboratory testing where appropriate.

(16) It is important to identify cases of suspected and established non-compliance where competent authorities must take measures with respect to certain products of animal origin. Non-compliance with good hygiene practices should also result in corrective action by competent authorities.

(17) The health mark defined in point 51 in Article 3 of Regulation (EU) 2017/625 covers meat of certain species and attests that the meat is fit for human consumption. Technical requirements of the health mark and practical arrangements for its application should be laid down in a specific and uniform way in order to indicate the fitness of the meat for human consumption and to prevent any trade disruption.

(18) Commission Regulation (EC) No 2074/2005 ([29]) lays down, inter alia, implementing measures for the organisation of official controls under Regulation (EC) No 854/2004 as regards recognised testing methods for marine biotoxins in live bivalve molluscs, testing methods for raw milk and heat-treated milk, official controls in fishery products and the inspection of meat. It is appropriate to merge all implementing measures for the organisation of official controls and include the ones from Regulation (EC) No 2074/2005 in this Regulation. They should be deleted in Regulation (EC) No 2074/2005.

(19) The current conditions for the classification and monitoring of classified production and relaying areas for live bivalve molluscs have proven to be effective and ensure a high level of consumer protection. They should therefore be maintained.

([28]) Commission Delegated Regulation (EU) 2019/624 of 8 February 2019 concerning specific rules for the performance of official controls on the production of meat and for production and relaying areas of live bivalve molluscs in accordance with Regulation (EU) 2017/625 of the European Parliament and of the Council (see page 1 of this Official Journal).

([29]) Commission Regulation (EC) No 2074/2005 of 5 December 2005 laying down implementing measures for certain products under Regulation (EC) No 853/2004 of the European Parliament and of the Council and for the organisation of official controls under Regulation (EC) No 854/2004 of the European Parliament and of the Council and Regulation (EC) No 882/2004 of the European Parliament and of the Council, derogating from Regulation (EC) No 852/2004 of the European Parliament and of the Council and amending Regulations (EC) No 853/2004 and (EC) No 854/2004 (OJ L 338, 22.12.2005, p. 27).

(20) A reference method for the analysis of *E. coli* in live bivalve molluscs, as currently laid down in Regulation (EC) No 854/2004, should be maintained.

(21) The limits for marine biotoxins are laid down in Regulation (EC) No 853/2004. In particular, point 2 in Chapter V of Section VII of Annex III to that Regulation provides that live bivalve molluscs must not contain marine biotoxins in total quantities (measured in the whole body or any part edible separately) that exceed the limits established in that Chapter.

(22) Specific requirements for the performance of official controls and the uniform minimum frequency for such controls on raw milk and dairy products should be laid down to ensure a high level of consumer protection and fair competition between food business operators.

(23) Specific requirements for the performance of official controls and the uniform minimum frequency for such controls on fishery products should be laid down to ensure a high level of consumer protection and fair competition between food business operators. Those controls should include at least regular checks on the hygiene conditions of landing and first sale, regular inspections of vessels and establishments, including fish auctions and wholesale markets, and checks on storage and transport. Specific requirements for the control of vessels should also be established.

(24) Those controls should also include practical arrangements as regards organoleptic examinations, freshness indicators, controls on histamine, residues and contaminants, microbiological checks. Special attention should be paid to the controls of parasites and on poisonous fishery products. Fishery products not meeting those hygiene requirements should be declared as unfit for human consumption.

(25) Special requirements concerning the official controls on fishery products caught by vessels flying the flag of Member States entering the Union after being transferred in a third country with or without storage should also be established.

(26) There is an increasing interest in the production and placing on the market of reptile meat. In order to ensure the safety of reptile meat, it is relevant to introduce specific official controls at slaughter in addition to the existing general hygiene rules laid down in Regulation (EC) No 852/2004 and the *Trichinella* controls laid down in Implementing Regulation (EU) 2015/1375.

(27) Regulation (EC) No 2074/2005 should be amended accordingly.

(28) As Regulation (EU) 2017/625 repeals Regulation (EC) No 854/2004 with effect from 14 December 2019, this Regulation should also apply from that date.

(29) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on Plants, Animals, Food and Feed,

HAS ADOPTED THIS REGULATION:

TITLE I

SUBJECT MATTER, SCOPE AND DEFINITIONS

Article 1

Subject matter and scope

This Regulation lays down uniform practical arrangements for the performance of official controls and actions in relation to the production of products of animal origin intended for human consumption. These official controls and actions shall be performed by the competent authorities taking into account the requirements of Article 18(2), (3) and (5) of Regulation (EU) 2017/625 and Delegated Regulation (EU) 2019/624.

The specific rules cover:

(a) specific requirements and uniform minimum frequency of official controls on any product of animal origin, as regards audits and identification marking;

(b) specific requirements and uniform minimum frequency of official controls on fresh meat, including specific requirements for audits and specific tasks as regards controls on fresh meat;

(c) measures to be taken in cases of non-compliance of fresh meat with Union requirements for the protection of human health and animal health and welfare;

(d) technical requirements and practical arrangements as regards the health mark referred to in Article 5 of Regulation (EC) No 853/2004;

(e) specific requirements and uniform minimum frequency of official controls on milk, colostrum, dairy products and colostrum-based products;

(f) conditions for the classification and monitoring of classified production and relaying areas for live bivalve molluscs, including decisions to be taken after monitoring classified production and relaying areas;

(g) specific requirements and uniform minimum frequency of official controls on fishery products.

Article 2

Definitions

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

(1) 'fresh meat' means fresh meat as defined in point 1.10 of Annex I to Regulation (EC) No 853/2004;

(2) 'colostrum' means colostrum as defined in point 1 of Section IX of Annex III of Regulation (EC) No 853/2004;

(3) 'dairy products' means dairy products as defined in point 7.2. of Annex I to Regulation (EC) No 853/2004;

(4) 'colostrum-based products' means colostrum-based products as defined in point 2 of Section IX of Annex III of Regulation (EC) No 853/2004;

(5) 'production area' means a production area as defined in point 2.5 of Annex I of Regulation (EC) No 853/2004;

(6) 'relaying area' means relaying area as defined in point 2.6 of Annex I of Regulation (EC) No 853/2004;

(7) 'bivalve molluscs' means bivalve molluscs as defined in point 2.1 of Annex I of Regulation (EC) No 853/2004;

(8) 'fishery products' means fishery products as defined in point 3.1 of Annex I to Regulation (EC) No 853/2004;

(9) 'establishment' means an establishment as defined in Article 2(1)(c) of Regulation (EC) No 852/2004;

(10) 'food business operator' means a food business operator as defined in Article 3(3) of Regulation (EC) No 178/2002 of the European Parliament and of the Council ([30]);

(11) 'microbiological criterion' means microbiological criterion as defined in Article 2(b) of Regulation (EC) No 2073/2005;

(12) 'slaughterhouse' means slaughterhouse as defined in point 1.16 of Annex I of Regulation (EC) No 853/2004;

(13) 'traceability' means traceability as defined in Article 3(15) of Regulation (EC) No 178/2002;

(14) 'specified risk material' means specified risk material as defined in Article 3(1)(g) of Regulation (EC) No 999/2001;

(15) 'contamination' means contamination as defined in Article 2(1)(f) of Regulation (EC) No 852/2004;

(16) 'holding of provenance' means a holding of provenance as defined in point 2 of Article 2 of Delegated Regulation (EU) 2019/624;

(17) 'primary production' means primary production as defined in Article 3(17) of Regulation (EC) No 178/2002;

([30]) 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).

(18) 'domestic ungulates' means domestic ungulates as defined in point 1.2 of Annex I of Regulation (EC) No 853/2004;

(19) 'game-handling establishment' means a game-handling establishment as defined in point 1.18 of Annex I of Regulation (EC) No 853/2004;

(20) 'large wild game' means large wild game as defined in point 1.8 of Annex I to Regulation (EC) No 853/2004;

(21) 'flock' means a flock as defined in Article 2(3)(b) of Regulation (EC) No 2160/2003;

(22) 'lagomorphs' means lagomorphs as defined in point 1.4 of Annex I of Regulation (EC) No 853/2004;

(23) 'carcase' means a carcase as defined in point 1.9 of Annex I to Regulation (EC) No 853/2004;

(24) 'offal' means offal as defined in point 1.11 of Annex I to Regulation (EC) No 853/2004;

(25) 'low-capacity slaughterhouse' means a low-capacity slaughterhouse as defined in Article 2(17) of Delegated Regulation (EU) 2019/624;

(26) 'low-capacity game-handling establishment' means a game-handling establishment as defined in Article 2(18) of Delegated Regulation (EU) 2019/624;

(27) 'livestock unit' means a livestock unit as defined in Article 17(6) of Regulation (EC) No 1099/2009;

(28) 'small wild game' means small wild game as defined in point 1.7 of Annex I of Regulation (EC) No 853/2004;

(29) 'poultry' means poultry as defined in point 1.3 of Annex I of Regulation (EC) No 853/2004;

(30) 'cutting plant' means a cutting plant as defined in point 1.17 of Annex I of Regulation (EC) No 853/2004;

(31) 'viscera' means viscera as defined in point 1.12 of Annex I of Regulation (EC) No 853/2004;

(32) 'meat' means meat as defined in point 1.1 of Annex I of Regulation (EC) No 853/2004;

(33) 'farmed game' means farmed game as defined in point 1.6 of Annex I of Regulation (EC) No 853/2004;

(34) 'wild game' means wild game as defined in point 1.5 of Annex I to Regulation (EC) No 853/2004;

(35) 'milk production holding' means a milk production holding as defined in point 4.2 of Annex I of Regulation (EC) No 853/2004;

(36) 'raw milk' means raw milk as defined in point 4.1 of Annex I to Regulation (EC) No 853/2004;

(37) 'purification centre' means a purification centre as defined in point 2.8 of Annex I to Regulation (EC) No 853/2004;

(38) 'marine biotoxins' means marine biotoxins as defined in point 2.2 of Annex I to Regulation (EC) No 853/2004;

(39) 'stages of production, processing and distribution' means stages of production, processing and distribution as defined in Article 3(16) of Regulation (EC) No 178/2002;

(40) 'dispatch centre' means a dispatch centre as defined in point 2.7 of Annex I of Regulation (EC) No 853/2004;

(41) 'placing on the market' means placing on the market as defined in Article 3(8) of Regulation (EC) No 178/2002;

(42) 'factory vessel' means factory vessel as defined in point 3.2 of Annex I to Regulation (EC) No 853/2004;

(43) 'freezer vessel' means freezer vessel as defined in point 3.3 of Annex I to Regulation (EC) No 853/2004;

(44) 'reptiles' means reptiles as defined in point 15 of Article 2 of Commission Delegated Regulation (EU) 2019/625 ([31]);

([31]) Commission Delegated Regulation (EU) 2019/625 of 4 March 2019 supplementing Regulation (EU) 2017/625 of the European Parliament and of the Council with regard to requirements for the entry into the Union of consignments of certain animals and goods intended for human consumption (see page 18 of this Official Journal).

(45) 'reptile meat' means reptile meat as defined in point 16 of Article 2 of Delegated Regulation (EU) 2019/625;

(46) 'fresh fishery products' means fresh fishery products as defined in point 3.5 of Annex I to Regulation (EC) No 853/2004;

(47) 'prepared fishery products' means prepared fishery products as defined in point 3.6 of Annex I to Regulation (EC) No 853/2004;

(48) 'processed fishery products' means processed fishery products as defined in point 7.4 of Annex I to Regulation (EC) No 853/2004.

TITLE II

SPECIFIC REQUIREMENTS FOR THE PERFORMANCE OF OFFICIAL CONTROLS AND THE UNIFORM MINIMUM FREQUENCY FOR OFFICIAL CONTROLS ON PRODUCTS OF ANIMAL ORIGIN

CHAPTER I

Specific requirements for audits by the competent authorities in establishments handling products of animal origin

Article 3

Requirements subject to auditing

1. When auditing good hygiene practices in establishments, the competent authorities shall verify that food business operators handling products of animal origin apply procedures continuously and properly concerning at least the following:

(a) the design and maintenance of premises and equipment;

(b) pre-operational, operational and post-operational hygiene;

(c) personal hygiene;

(d) training in hygiene and in work procedures;

(e) pest control;

(f) water quality;

(g) temperature control;

(h) controls on animals or food entering and leaving the establishment, and any accompanying documentation.

2. When auditing procedures based on hazard analysis and critical control points (HACCP), as laid down in Article 5 of Regulation (EC) No 852/2004, the competent authorities shall verify that food business operators handling products of animal origin apply such procedures continuously and properly.

3. They shall, in particular, determine whether the procedures guarantee, to the extent possible, that products of animal origin:

(a) comply with Article 3 of Regulation (EC) No 2073/2005 as regards microbiological criteria;

(b) comply with Union legislation on:

— the monitoring of chemical residues, in accordance with Council Directive 96/23/EC and Commission Decision 97/747/EC ([32]);

— maximum residue limits for pharmacologically active substances, in accordance with Commission Regulation (EU) No 37/2010 ([33]) and Commission Implementing Regulation (EU) 2018/470 ([34]);

([32]) Commission Decision 97/747/EC of 27 October 1997 fixing the levels and frequencies of sampling provided for by Council Directive 96/23/EC for the monitoring of certain substances and residues thereof in certain animal products (OJ L 303, 6.11.1997, p. 12).

([33]) Commission Regulation (EU) No 37/2010 of 22 December 2009 on pharmacologically active substances and their classification regarding maximum residue limits in foodstuffs of animal origin (OJ L 15, 20.1.2010, p. 1).

([34]) Commission Implementing Regulation (EU) 2018/470 of 21 March 2018 on detailed rules on the maximum residue limit to be considered for control purposes for foodstuffs derived from animals which have been treated in the EU under Article 11 of Directive 2001/82/EC (OJ L 79, 22.3.2018, p. 16).

— prohibited and unauthorised substances, in accordance with Commission Regulation (EU) No 37/2010, Council Directive 96/22/EC ([35]), Commission Decision 2005/34/EC ([36]);

— contaminants, in accordance with Regulations (EC) No 1881/2006 and (EC) No 124/2009 setting maximum levels for certain contaminants in food;

— pesticide residues, in accordance with Regulation (EC) No 396/2005 of the European Parliament and of the Council ([37]);

(c) do not contain physical hazards, such as foreign bodies.

4. Where a food business operator uses procedures set out in guides to the application of HACCP-based principles, in accordance with Article 5(5) of Regulation (EC) No 852/2004, the audit shall cover the correct use of those guides.

5. When carrying out auditing tasks, the competent authorities shall take special care:

(a) to determine whether staff and staff activities in the establishment at all stages of the production process comply with the requirements, as regards hygienic practices and HACCP laid down in Article 3 of Regulation (EC) No 2073/2005, Articles 4 and 5 of Regulation (EC) No 852/2004 and Article 3(1) of Regulation (EC) No 853/2004. To complement the audit, the competent authorities may carry out performance tests, in order to ascertain that staff are sufficiently skilled;

(b) to verify the food business operator's relevant records;

(c) to take samples for laboratory analysis where necessary;

(d) to document elements taken into account and the findings of the audit.

Article 4

Nature and frequency of auditing

1. The nature and frequency of auditing tasks in respect of individual establishments shall depend on the assessed risk. To this end, the competent authorities shall regularly assess:

(a) human and, where appropriate, animal health risks;

(b) in the case of slaughterhouses, animal welfare aspects;

(c) the type and throughput of the processes carried out;

(d) the food business operator's past record as regards compliance with food law.

2. Where food business operators in the food chain take additional measures to guarantee food safety by implementing integrated systems, private control systems or independent third-party certification, or by other means, and where these measures are documented and animals covered by such schemes are clearly identifiable, the competent authorities may take such measures into account when carrying out audits to review good hygiene practices and the HACCP-based procedures.

CHAPTER II

Specific requirements for identification marking

Article 5

Compliance with the requirements of Regulation (EC) No 853/2004 concerning the application of identification marks shall be verified in all establishments approved in accordance with that Regulation, in addition to verification of compliance with other traceability requirements in accordance with Article 18 of Regulation (EC) No 178/2002.

([35]) Council Directive 96/22/EC of 29 April 1996 concerning the prohibition on the use in stock farming of certain substances having a hormonal or thyrostatic action and of β-agonists, and repealing Directives 81/602/EEC, 88/146/EEC and 88/299/EEC (OJ L 125, 23.5.1996, p. 3).

([36]) Commission Decision 2005/34/EC of 11 January 2005 laying down harmonised standards for the testing for certain residues in products of animal origin imported from third countries (OJ L 16, 20.1.2005, p. 61).

([37]) Regulation (EC) No 396/2005 of the European Parliament and of the Council of 23 February 2005 on maximum residue levels of pesticides in or on food and feed of plant and animal origin and amending Council Directive 91/414/EEC (OJ L 70, 16.3.2005, p. 1).

CHAPTER III

Scientific and technological developments

Article 6

The Member States shall inform the Commission and other Member States on scientific and technological developments, as referred to in Article 16(2)(b) of Regulation (EU) 2017/625 for consideration and further action as appropriate.

TITLE III

SPECIFIC REQUIREMENTS FOR THE PERFORMANCE OF OFFICIAL CONTROLS AND THE UNIFORM MINIMUM FREQUENCY FOR OFFICIAL CONTROLS ON FRESH MEAT

CHAPTER I

Audits

Article 7

Additional requirements for audits in establishments handling fresh meat

1. In addition to the requirements for audits laid down in Articles 3 and 4, the competent authorities shall, when carrying out an audit in establishments handling fresh meat, verify continuous compliance with food business operators' own procedures concerning the collection, transport, storage and handling of fresh meat, and the use or disposal of animal by-products, including specified risk material, for which they are responsible.

2. In the course of audits in slaughterhouses, the competent authorities shall verify the evaluation of food chain information, as laid down in Section III of Annex II to Regulation (EC) No 853/2004.

3. When carrying out audits of HACCP-based procedures, the competent authorities shall check that due regard is given to the procedures set out in Section II of Annex II to Regulation (EC) No 853/2004 and that the food business operators' procedures guarantee, to the extent possible, that fresh meat:

(a) does not contain pathological abnormalities or changes;

(b) does not bear

  (i) faecal contamination; or,

  (ii) any other contamination considered to pose an unacceptable human health risk;

(c) complies with the microbiological criteria in Article 3 of Regulation (EC) No 2073/2005;

(d) does not contain specified risk material, in accordance with the requirements in Regulation (EC) No 999/2001.

CHAPTER II

Official controls on fresh meat

Article 8

Relevance of audit results

When carrying out official controls in accordance with this Chapter, the official veterinarian shall take into account the results of the audits carried out in accordance with Chapter I. Where appropriate, the official veterinarian shall target official controls to deficiencies detected during previous audits.

Section 1

Checks of documents

Article 9

Obligations of the competent authorities as regards checks of documents

1. The competent authorities shall inform the food business operator of the holding of provenance of the minimum elements of food chain information to be supplied to the slaughterhouse operator in accordance with Section III of Annex II to Regulation (EC) No 853/2004.

2. The competent authorities shall perform the necessary checks of documents to verify that:

(a) the food chain information is consistently and effectively communicated between the food business operator who raised or kept the animals before dispatch and the slaughterhouse operator;

(b) the food chain information is valid and reliable;

(c) feedback of relevant information to the holding of provenance, if applicable, is provided in accordance with Article 39(5).

3. Where animals are dispatched for slaughter to another Member State, the competent authorities at the holding of provenance and the place of slaughter shall cooperate to ensure that the food chain information provided by the food business operator of the holding of provenance is easily accessible to the slaughterhouse operator receiving it.

Article 10

Obligations of the official veterinarian as regards checks of documents

1. The official veterinarian shall verify the results of the checks and evaluations of food chain information provided by the slaughterhouse operator in accordance with Section III of Annex II to Regulation (EC) No 853/2004. The official veterinarian shall take those checks and evaluations into account when carrying out ante-mortem and post-mortem inspections, together with any other relevant information from the records of the animals' holding of provenance.

2. When carrying out ante-mortem and post-mortem inspections, the official veterinarian shall take into account official certificates provided for in accordance with Article 29 of Commission Implementing Regulation (EU) 2019/628 ([38]), and any declarations by veterinarians carrying out official controls or other checks at the level of primary production.

3. In the case of the emergency slaughter of domestic ungulates outside the slaughterhouse, the official veterinarian at the slaughterhouse shall examine the certification provided for in accordance with Article 29 of Implementing Regulation (EU) 2019/628 and issued by the official veterinarian who carried out the ante-mortem inspection in accordance with point 6 of Chapter VI of Section I of Annex III to Regulation (EC) No 853/2004 and any other relevant information provided by the food business operator.

4. In the case of large wild game, the official veterinarian at the game-handling establishment shall examine and take into account the declaration accompanying the body of the animal, as issued by a trained person in accordance with point 4(a) of Chapter II of Section IV of Annex III to Regulation (EC) No 853/2004.

Section 2

Ante-mortem inspection

Article 11

Requirements as regards ante-mortem inspection at the slaughterhouse

1. All animals shall be subjected to ante-mortem inspection before slaughter. However, inspection can be limited to a representative sample of birds from each flock and a representative sample of lagomorphs from each holding of provenance of lagomorphs.

2. Ante-mortem inspection shall take place within 24 hours of arrival of the animals at the slaughterhouse and less than 24 hours before slaughter. The official veterinarian may require an additional ante-mortem inspection at any other time.

3. Ante-mortem inspections shall determine whether, as regards the particular animal inspected, there is any sign:

(a) that the health and welfare of the animal has been compromised;

([38]) Commission Implementing Regulation (EU) 2019/628 of 8 April 2019 concerning model official certificates for certain animals and goods and amending Regulation (EC) No 2074/2005 and Implementing Regulation (EU) 2016/759 as regards these model certificates (see page 101 of this Official Journal).

(b) of any condition, abnormalities or disease that make the fresh meat unfit for human consumption or that might adversely affect animal health, paying particular attention to the detection of zoonotic diseases and animal diseases for which animal health rules are laid down in Regulation (EU) 2016/429;

(c) of the use of prohibited or unauthorised substances, misuse of veterinary medicinal products or the presence of chemical residues or contaminants.

4. Ante-mortem inspection shall include verification of food business operators' compliance with their obligation to ensure that animals have a clean hide, skin or fleece, so as to avoid any unacceptable risk of contamination of the fresh meat during slaughter.

5. The official veterinarian shall carry out a clinical inspection of all animals that the food business operator or an official auxiliary may have put aside for a more thorough ante-mortem inspection.

6. Where the ante-mortem inspection is carried out at the holding of provenance in accordance with Article 5 of Delegated Regulation (EU) 2019/624, the official veterinarian at the slaughterhouse shall carry out ante-mortem inspection only when and to the extent specified.

Section 3

Post-mortem inspection

Article 12

Requirements for post-mortem inspection

1. Subject to the derogation stipulated in Point 4 of Chapter II of Section IV to Annex III of Regulation (EC) No 853/2004, carcases and accompanying offals, shall be subjected to post-mortem inspection:

(a) without delay after slaughter, or

(b) as soon as possible after arrival at the game-handling establishment.

2. The competent authorities may require the food business operator to provide special technical facilities and sufficient space to check offal.

3. The competent authorities shall:

(a) check all external surfaces, including those of body cavities of carcases, as well as offal;

(b) pay particular attention to the detection of zoonotic diseases and animal diseases for which animal health rules are laid down in Regulation (EU) 2016/429.

4. The speed of the slaughter line and the number of inspection staff present shall be such as to allow for proper inspection.

Article 13

Derogation on the timing of post-mortem inspection

1. By way of derogation from Article 12(1), the competent authorities may allow that, when neither the official veterinarian nor the official auxiliary are present in the game-handling establishment or slaughterhouse during slaughter and dressing, the post-mortem inspection is delayed by a maximum period of 24 hours from slaughter or arrival in the game-handling establishment, provided that:

(a) the animals concerned are slaughtered in a low-capacity slaughterhouse or handled in a low-capacity game-handling establishment that slaughters or handles:

  (i) fewer than 1 000 livestock units per year; or

  (ii) fewer than 150 000 poultry, lagomorphs and small wild game per year;

(b) sufficient facilities exist within an establishment to store the fresh meat and offal so that they can be examined;

(c) the post-mortem inspection is carried out by the official veterinarian.

2. The competent authorities may increase the thresholds laid down in point (a) (i) and (ii) of paragraph 1 ensuring that the derogation is applied in the smallest slaughterhouses and game-handling establishments complying with the definition of low-capacity slaughterhouse or low-capacity game-handling establishment and provided that the combined annual production of these establishments does not exceed 5 % of the total amount of fresh meat produced in a Member State:

(a) for the species concerned;

(b) or for all ungulates together;

(c) of all poultry together; or,

(d) of all birds and lagomorphs together.

In such case, the competent authorities shall notify this derogation and the evidence to support it in accordance with the procedure laid down in Directive (EU) 2015/1535 of the European Parliament and of the Council ([39]);

3. For the purpose of point (a) (i) of paragraph 1, the conversion rates laid down in Article 17(6) of Regulation (EC) No 1099/2009 shall be used. However in case of ovine and caprine animals and small (< 100 kg life weight) *Cervidae* a conversion rate of 0,05 livestock units, and in case of other large game a conversion rate of 0,2 livestock units shall be used.

Article 14

Additional examination requirements for post-mortem inspection

1. Additional examinations, such as palpation and incision of parts of the carcase and offal, and laboratory tests, shall be carried out if needed to:

(a) reach a definitive diagnosis of a suspected hazard; or

(b) detect the presence of:

(i) an animal disease for which animal health rules are laid down in Regulation (EU) 2016/429;

(ii) chemical residues or contaminants as referred to in Directive 96/23/EC and Decision 97/747/EC, especially:

— chemical residues in excess of the levels laid down in Regulations (EU) No 37/2010 and (EC) No 396/2005;

— contaminants exceeding the maximum levels laid down in Regulations (EC) No 1881/2006 and (EC) No 124/2009; or

— residues of substances that are prohibited or unauthorised in accordance with Regulation (EU) No 37/2010 or Directive 96/22/EC;

(iii) non-compliance with the microbiological criteria referred to in Article 3(1)(b) of Regulation (EC) No 2073/2005 or the possible presence of other microbiological hazards that would make the fresh meat unfit for human consumption;

(iv) other factors that might require the fresh meat to be declared unfit for human consumption or restrictions to be placed on its use.

2. During the post-mortem inspection, precautions shall be taken to ensure that contamination of fresh meat by actions such as palpation, cutting or incision is kept to a minimum.

Article 15

Requirements for post-mortem inspection of domestic solipeds, bovine animals over eight months old and domestic swine more than five weeks old, and large wild game

1. The requirements in this Article shall apply in addition to the requirements in Articles 12 and 14.

([39]) Directive (EU) 2015/1535 of the European Parliament and of the Council of 9 September 2015 laying down a procedure for the provision of information in the field of technical regulations and of rules on Information Society services (OJ L 241, 17.9.2015, p. 1).

2. The official veterinarian shall require that carcases of domestic solipeds, bovine animals over eight months old and domestic swine more than five weeks old are submitted for post-mortem inspection split lengthways into half carcases down the spinal column.

3. If the post-mortem inspection so necessitates, the official veterinarian may require any head or any carcase to be split lengthways. However, to take account of particular eating habits, technological developments or specific sanitary situations, the official veterinarian may authorise the submission for post-mortem inspection of carcases of domestic solipeds, bovine animals more than eight months old and domestic swine more than five weeks old that are not split in half.

4. In low-capacity slaughterhouses or low-capacity game-handling establishments handling fewer than 1 000 livestock units per year, the official veterinarian may, for sanitary reasons, authorise the cutting into quarter carcases of adult domestic solipeds, adult bovine animals and adult large wild game before post-mortem inspection.

Article 16

Additional requirements for post-mortem inspection in cases of emergency slaughter

In the event of emergency slaughter, the carcase shall be subjected to post-mortem inspection as soon as possible in accordance with Articles 12, 13, 14 and 15 before it is released for human consumption.

Article 17

Practical arrangements for post-mortem inspection of domestic bovine animals, domestic sheep and goats, domestic solipeds and domestic swine

Where the post-mortem inspection is performed by an official veterinarian, under the supervision of the official veterinarian or, where sufficient guarantees are in place, under the responsibility of the official veterinarian in accordance with Article 18(2)(c) of Regulation (EU) 2017/625 and Article 7 of Delegated Regulation (EU) 2019/624, the competent authorities shall ensure that the practical arrangements laid down in the following Articles 18 to 24 are complied with in the cases of domestic bovine animals, domestic sheep and goats, domestic solipeds and domestic swine in addition to the requirements laid down in Articles 12, 14 and 15.

Article 18

Young bovine animals

1. Carcases and offal of the following bovine animals shall undergo the post-mortem inspection procedures laid down in paragraph 2:

(a) animals under eight months old; and,

(b) animals under 20 months old if reared without access to pasture land during their whole life in an officially tuberculosis-free Member State or region of a Member State in accordance with Article 1 of Decision 2003/467/EC.

2. The post-mortem inspection procedures shall include at least a visual inspection of the following:

(a) the head and throat; together with palpation and examination of the retropharyngeal lymph nodes (*Lnn. retropharyngiales*), however, in order to ensure the surveillance of the officially tuberculosis free status, Member States may decide to carry out further investigations; inspection of the mouth and fauces;

(b) the lungs, trachea and oesophagus; palpation of the lungs; palpation and examination of the bronchial and mediastinal lymph nodes (*Lnn. bifurcationes, eparteriales* and *mediastinales*);

(c) the pericardium and heart;

(d) the diaphragm;

(e) the liver and the hepatic and pancreatic lymph nodes, (*Lnn. portales*);

(f) the gastro-intestinal tract, the mesentery and gastric and mesenteric lymph nodes (*Lnn. gastrici, mesenterici, craniales* and *caudales*);

(g) the spleen;

(h) the kidneys;

(i) the pleura and peritoneum;

(j) the umbilical region and the joints of young animals.

3. The official veterinarian shall proceed with the following post-mortem inspection procedures using incision and palpation of the carcase and offal, when there are indications of a possible risk to human health, animal health or animal welfare indicated in accordance with Article 24:

(a) incision of the retropharyngeal lymph nodes (*Lnn. retropharyngiales*); palpation of the tongue;

(b) incision of the bronchial and mediastinal lymph nodes (*Lnn. bifurcationes, eparteriales* and *mediastinales*); lengthwise opening of the trachea and the main branches of the bronchi; the lungs shall be incised in their posterior third, perpendicular to their main axes; these incisions are not necessary where the lungs are excluded from human consumption;

(c) lengthways incision of the heart so as to open the ventricles and cut through the interventricular septum;

(d) incision of the gastric and mesenteric lymph nodes;

(e) palpation of the spleen;

(f) incision of the kidneys and the renal lymph nodes (*Lnn. renales*);

(g) palpation of the umbilical region and the joints. The umbilical region shall be incised and the joints opened; the synovial fluid must be examined.

Article 19

Other bovine animals

1. Carcases and offal of bovine animals other than those referred to in Article 18(1) shall undergo the following post-mortem inspection procedures:

(a) a visual inspection of the head and throat; incision and examination of the retropharyngeal lymph nodes (*Lnn. retropharyngiales*); examination of the external masseters, in which two incisions shall be made parallel to the mandible, and the internal masseters (internal pterygoid muscles), which shall be incised along one plane. The tongue shall be freed to permit a detailed visual inspection of the mouth and the fauces;

(b) an inspection of the trachea and oesophagus; visual inspection and palpation of the lungs; incision and examination of the bronchial and mediastinal lymph nodes (*Lnn. bifurcationes, eparteriales* and *mediastinales*);

(c) a visual inspection of the pericardium and heart, the latter being incised lengthways so as to open the ventricles and cut through the interventricular septum;

(d) a visual inspection of the diaphragm;

(e) a visual inspection of the liver and the hepatic and pancreatic lymph nodes (*Lnn. portales*);

(f) a visual inspection of the gastro-intestinal tract, the mesentery, the gastric and mesenteric lymph nodes (*Lnn. gastrici, mesenterici, craniales* and *caudales*); palpation of the gastric and mesenteric lymph nodes;

(g) a visual inspection of the spleen;

(h) a visual inspection of the kidneys;

(i) a visual inspection of the pleura and the peritoneum;

(j) a visual inspection of the genital organs (except for the penis, if already discarded);

(k) a visual inspection of the udder and its lymph nodes (*Lnn. supramammarii*).

2. The official veterinarian shall proceed with the following post-mortem inspection procedures using incision and palpation of the carcase and offal, when there are indications of a possible risk to human health, animal health or animal welfare indicated in accordance with Article 24:

(a) an incision and examination of the sub-maxillary and parotid lymph nodes (*Lnn. mandibulares* and *parotidei*); palpation of the tongue and the fauces;

(b) an incision of the bronchial and mediastinal lymph nodes (*Lnn. bifurcationes, eparteriales* and *mediastinales*); lengthwise opening of the trachea and the main branches of the bronchi; the lungs shall be incised in their posterior third, perpendicular to their main axes; these incisions are not necessary where the lungs are excluded from human consumption;

(c) a palpation of the liver and the hepatic and pancreatic lymph nodes (*Lnn. portales*); incision of the gastric surface of the liver and at the base of the caudate lobe to examine the bile ducts;

(d) an incision of the gastric and mesenteric lymph nodes;

(e) a palpation of the spleen;

(f) an incision of the kidneys and the renal lymph nodes (*Lnn. renales*);

(g) a palpation and incision of the udder and its lymph nodes (*Lnn. supramammarii*) in cows. Each half of the udder shall be opened by a long, deep incision as far as the lactiferous sinuses (*sinus lactiferes*) and the lymph nodes of the udder shall be incised, except where the udder is excluded from human consumption.

Article 20

Young domestic sheep and goats and sheep with no eruption of permanent incisors

1. Carcases and offal of sheep not having any permanent incisor erupted or less than 12 months of age, and goats less than six months of age, shall undergo the following post-mortem inspection procedures:

(a) a visual inspection of the head, including the throat, mouth, tongue and parotid and retropharyngeal lymph nodes. These examinations are not necessary if the competent authorities are able to guarantee that the head, including the tongue and the brains, will be excluded from human consumption;

(b) a visual inspection of the lungs, trachea and oesophagus and the bronchial and mediastinal lymph nodes (*Lnn. bifurcationes, eparteriales* and *mediastinales*);

(c) a visual inspection of the pericardium and heart;

(d) a visual inspection of the diaphragm;

(e) a visual inspection of the liver and the hepatic and pancreatic lymph nodes (*Lnn. portales*);

(f) a visual inspection of the gastro-intestinal tract, the mesentery and the gastric and mesenteric lymph nodes (*Lnn. gastrici, mesenterici, craniales* and *caudales*);

(g) a visual inspection of the spleen;

(h) a visual inspection of the kidneys;

(i) a visual inspection of the pleura and peritoneum;

(j) a visual inspection of the umbilical region and joints.

2. The official veterinarian shall proceed with the following post-mortem inspection procedures using incision and palpation of the carcase and offal, when there are indications of a possible risk to human health, animal health or animal welfare indicated in accordance with Article 24:

(a) a palpation of the throat, mouth, tongue and parotid lymph nodes. Unless animal-health rules provide otherwise, these examinations are not necessary if the competent authorities are able to guarantee that the head, including the tongue and the brains, will be excluded from human consumption;

(b) a palpation of the lungs; incision of the lungs, trachea, oesophagus, bronchial and mediastinal lymph nodes;

(c) an incision of the heart;

(d) a palpation of the liver and its lymph nodes; incision of the gastric surface of the liver to examine the bile ducts;

(e) a palpation of the spleen;

(f) an incision of the kidneys and the renal lymph nodes (*Lnn. renales*);

(g) a palpation of the umbilical region and joints; the umbilical region shall be incised and the joints opened; the synovial fluid shall be examined.

Article 21

Other domestic sheep and goats

1. Carcases and offal of sheep having a permanent incisor erupted or 12 months of age or more, and goats six months of age or more, shall undergo the following post-mortem inspection procedures:

(a) a visual inspection of the head, including the throat, mouth, tongue and parotid lymph nodes and palpation of the retropharyngeal lymph nodes. These examinations are not necessary if the competent authorities are able to guarantee that the head, including the tongue and the brains, will be excluded from human consumption;

(b) a visual inspection of the lungs, trachea and oesophagus; palpation of the lungs, the bronchial and mediastinal lymph nodes (*Lnn. bifurcationes, eparteriales* and *mediastinales*);

(c) a visual inspection of the pericardium and heart;

(d) a visual inspection of the diaphragm;

(e) a visual inspection of the liver and the hepatic and pancreatic lymph nodes (*Lnn. portales*); palpation of the liver and its lymph nodes; incision of the gastric surface of the liver to examine the bile ducts;

(f) a visual inspection of the gastro-intestinal tract, the mesentery and the gastric and mesenteric lymph nodes (*Lnn. gastrici, mesenterici, craniales* and *caudales*);

(g) a visual inspection of the spleen;

(h) a visual inspection of the kidneys;

(i) a visual inspection of the pleura and peritoneum;

(j) a visual inspection of the genital organs (except for the penis, if already discarded);

(k) a visual inspection of the udder and its lymph nodes.

2. The official veterinarian shall proceed with the following post-mortem inspection procedures using incision and palpation of the carcase and offal when there are indications of a possible risk to human health, animal health or animal welfare indicated in accordance with Article 24:

(a) a palpation of the throat, mouth, tongue and parotid lymph nodes. Unless animal-health rules provide otherwise, these examinations are not necessary if the competent authorities are able to guarantee that the head, including the tongue and the brains, will be excluded from human consumption;

(b) an incision of the lungs, trachea, oesophagus and the bronchial and mediastinal lymph nodes;

(c) an incision of the heart;

(d) a palpation of the spleen;

(e) an incision of the kidneys and the renal lymph nodes (*Lnn. renales*).

Article 22

Domestic solipeds

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

(a) a visual inspection of the head and, after freeing the tongue, the throat; the tongue shall be freed to permit a detailed visual inspection of the mouth and the fauces and must itself be visually examined;

(b) a visual inspection of the lungs, trachea, oesophagus and the bronchial and mediastinal lymph nodes (*Lnn. bifurcationes, eparteriales* and *mediastinales*);

(c) a visual inspection of the pericardium and the heart;

(d) a visual inspection of the diaphragm;

(e) a visual inspection of the liver and the hepatic and pancreatic lymph nodes (*Lnn portales*);

(f) a visual inspection of the gastro-intestinal tract, the mesentery and the gastric and mesenteric lymph nodes (*Lnn. gastrici, mesenterici, craniales* and *caudales*);

(g) a visual inspection of the spleen;

(h) a visual inspection of the kidneys;

(i) a visual inspection of the pleura and peritoneum;

(j) a visual inspection of the genital organs of stallions (except for the penis, if already discarded) and mares;

(k) a visual inspection of the udder and its lymph nodes (*Lnn. supramammarii*);

(l) a visual inspection of the umbilical region and joints of young animals;

(m) examination of the muscles and lymph nodes (*Lnn. subrhomboidei*) of the shoulders beneath the scapular cartilage after loosening the attachment of one shoulder, in the case grey horses, in order to inspect for melanosis and melanomata. The kidneys shall be exposed.

2. The official veterinarian shall proceed with the following post-mortem inspection procedures using incision and palpation of the carcase and offal, when there are indications of a possible risk to human health, animal health or animal welfare indicated in accordance with Article 24:

(a) a palpation and incision of the sub-maxillary, retropharyngeal and parotid lymph nodes (*Lnn. retropharyngiales, mandibulares* and *parotidei*); palpation of the tongue;

(b) a palpation of the lungs; palpation and incision of the bronchial and mediastinal lymph nodes. The trachea and the main branches of the bronchi shall be opened lengthwise and the lungs shall be incised in their posterior third, perpendicular to their main axes; however, these incisions are not necessary where the lungs are excluded from human consumption;

(c) an incision of the heart lengthwise, so as to open the ventricles and cut through the interventricular septum;

(d) a palpation and incision of the liver and the hepatic and pancreatic lymph nodes, (*Lnn. portales*);

(e) an incision of the gastric and mesenteric lymph nodes;

(f) a palpation of the spleen;

(g) a palpation of the kidneys and incision of the kidneys and the renal lymph nodes (*Lnn. renales*);

(h) an incision of the supramammary lymph nodes;

(i) a palpation of the umbilical region and joints of young animals. In cases of doubt, the umbilical region shall be incised and the joints opened; the synovial fluid must be examined;

(j) an incision through the entire kidney in grey horses.

Article 23

Domestic swine

1. Carcases and offal of domestic swine shall undergo the following post-mortem inspection procedures:

(a) a visual inspection of the head and throat;

(b) a visual inspection of the mouth, fauces and tongue;

(c) a visual inspection of the lungs, trachea and oesophagus;

(d) a visual inspection of the pericardium and heart;

(e) a visual inspection of the diaphragm;

(f) a visual inspection of the liver and the hepatic and pancreatic lymph nodes (*Lnn. portales*); visual inspection of the gastro-intestinal tract, the mesentery, the gastric and mesenteric lymph nodes (*Lnn. gastrici, mesenterici, craniales* and *caudales*);

(g) a visual inspection of the spleen; visual inspection of the kidneys; visual inspection of the pleura and peritoneum;

(h) a visual inspection of the genital organs (except for the penis, if already discarded);

(i) a visual inspection of the udder and its lymph nodes (*Lnn. supramammarii*);

(j) a visual inspection of the umbilical region and joints of young animals.

2. The official veterinarian shall proceed with the following post-mortem inspection procedures using incision and palpation of the carcase and offal, when there are indications of a possible risk to human health, animal health or animal welfare indicated in accordance with Article 24:

(a) an incision and examination of the submaxillary lymph nodes (*Lnn. mandibulares*);

(b) a palpation of the lungs and the bronchial and mediastinal lymph nodes (*Lnn. bifurcationes, eparteriales* and *mediastinales*). The trachea and the main branches of the bronchi shall be opened lengthwise and the lungs shall be incised in their posterior third, perpendicular to their main axes; those incisions are not necessary where the lungs are excluded from human consumption;

(c) an incision of the heart lengthwise so as to open the ventricles and cut through the interventricular septum;

(d) a palpation of the liver and its lymph nodes;

(e) a palpation and, if necessary, incision of the gastric and mesenteric lymph nodes;

(f) a palpation of the spleen;

(g) an incision of the kidneys and the renal lymph nodes (*Lnn. renales*);

(h) an incision of the supramammary lymph nodes;

(i) a palpation of the umbilical region and joints of young animals and, if necessary, incision of the umbilical region and opening of the joints.

Article 24

Indications of a possible risks to human health, animal health or animal welfare in domestic bovine animals, domestic sheep and goats, domestic solipeds and domestic swine

The official veterinarian shall proceed with the additional post-mortem inspection procedures referred to in Articles 18(3), 19(2), 20(2), 21(2), 22(2) and 23(2) using incision and palpation of the carcase and offal, where, in his/her opinion, one of the following indicates a possible risk to human health, animal health or animal welfare:

(a) the checks and analysis of the checks of documents carried out in accordance with Articles 9 and 10;

(b) the findings of the ante-mortem inspection carried out in accordance with Article 11;

(c) the results of the verifications of compliance with animal welfare rules carried out in accordance with Article 38;

(d) the findings of post-mortem inspection carried out in accordance with Articles 12 to 24;

(e) additional epidemiological data or other data from the holding of provenance of the animals.

Article 25

Practical arrangements for post-mortem inspection of poultry

1. All poultry shall undergo post-mortem inspection which may include the assistance of slaughterhouse staff in accordance with Article 18(3) of Regulation (EU) 2017/625. The official veterinarian or official auxiliary, in accordance with Article 18(2)(c) of that Regulation shall personally carry out the following checks:

(a) daily inspection of the viscera and body cavities of a representative sample of each flock;

(b) a detailed inspection of a random sample of parts of birds or entire birds declared unfit for human consumption following post-mortem inspection from each flock;

(c) any further investigations necessary where there is reason to suspect that the meat from the birds concerned could be unfit for human consumption.

2. By way of derogation from paragraph 1, the competent authorities may decide that only a representative sample of poultry from each flock undergoes post-mortem inspection if:

(a) food business operators have a system in place to the satisfaction of the official veterinarian, that allows the detection and the separation of birds with abnormalities, contamination or defects;

(b) the slaughterhouse has a longstanding history of compliance with the requirements as regards:

(i) general and specific requirements in accordance with Article 4 of Regulation (EC) No 852/2004, including the microbiological criteria applicable to Point 1.28 and 2.1.5 of Annex I to Regulation (EC) No 2073/2005;

(ii) procedures based on the HACCP principles in accordance with Article 5 of Regulation (EC) No 852/2004; and

(iii) specific hygiene rules in accordance with Article 5 and Section II of Annex III to Regulation (EC) No 853/2004;

(c) no abnormalities that may indicate a serious problem for human or animal health that may indicate the need for measures laid down in Articles 40 to 44, have been found during ante-mortem inspection or verification of food chain information.

3. In case of poultry reared for the production of *foie gras* and delayed eviscerated poultry obtained at the holding of provenance in accordance with Points 8 and 9 of Chapter VI to Section II of Annex III to Regulation (EC) No 853/2004, post-mortem inspection shall take place at the cutting plant where such carcases are transported directly from the holding of provenance.

Article 26

Practical arrangements for post-mortem inspection of farmed lagomorphs

The practical arrangements for post-mortem inspection in poultry in accordance with Article 25, shall apply to farmed lagomorphs. The provisions applicable to a single poultry flock in Article 25 shall apply to farmed lagomorphs slaughtered the same day from a single holding of provenance.

Article 27

Practical arrangements for post-mortem inspection of farmed game

1. The following post-mortem inspection procedures shall apply to farmed game:

(a) in the case of small (< 100 kg) *Cervidae*, the post-mortem procedures for ovine animals laid down in Article 21, however in the case of reindeer the post-mortem procedures for ovine animals laid down in Article 20 shall be used and the tongue may be used for human consumption without inspection of the head;

(b) in the case of game of the family *Suidae*, the post-mortem procedures for domestic swine laid down in Article 23;

(c) in the case of large game of the family *Cervidae* and other large game, not covered by paragraph (a) and in the case of large game of the family *Suidae* not covered by paragraph (b), the post-mortem procedures for bovine animals laid down in Article 19;

(d) in the case of ratites, the post-mortem procedures for poultry laid down in Article 25(1).

2. Where the animals have been slaughtered outside the slaughterhouse, the official veterinarian at the slaughterhouse shall verify the certificate.

Article 28

Practical arrangements for post-mortem inspection of wild game

1. The official veterinarian shall verify that a health certificate conforming to the specimen set out in the Annex to Regulation (EU) No 636/2014, or the declaration(s) in accordance with point 8(b) of Chapter II of Section IV of Annex III to Regulation (EC) No 853/2004, accompanies unskinned large wild game transported to the game-handling establishment from the territory of another Member State. The official veterinarian shall take into account the content of that certificate or declaration(s).

2. During post-mortem inspection, the official veterinarian shall carry out:

(a) a visual inspection of the carcase, its cavities and, where appropriate, organs with a view to:

  (i) detecting any abnormalities not resulting from the hunting process. For this purpose, the diagnosis may be based on any information that the trained person has provided concerning the behaviour of the animal before killing;

  (ii) checking that death was not due to reasons other than hunting;

(b) an investigation of organoleptic abnormalities;

(c) palpation and incisions of organs, where appropriate;

(d) where there are serious grounds for suspecting the presence of residues or contaminants, an analysis by sampling of residues not resulting from the hunting process, including environmental contaminants. Where a more extensive inspection is made on the basis of such suspicions, the veterinarian shall wait until that inspection has been concluded before assessing all the wild game killed during a specific hunt, or those parts suspected of showing the same abnormalities;

(e) examination for characteristics indicating that the meat presents a health risk, including:

  (i) abnormal behaviour or disturbance of the general condition of the live animal, as reported by the hunter;

  (ii) the generalised presence of tumours or abscesses affecting different internal organs or muscles;

  (iii) arthritis, orchitis, pathological changes in the liver or the spleen, inflammation of the intestines or the umbilical region;

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

  (v) the presence of parasites;

  (vi) formation of a significant amount of gas in the gastro-intestinal tract with discolouring of the internal organs (when these viscera are present);

  (vii) significant abnormalities of colour, consistency or odour of muscle tissue or organs;

  (viii) aged open fractures;

  (ix) emaciation and/or general or localised oedema;

  (x) recent pleural or peritoneal adhesions;

  (xi) other obvious extensive changes, such as putrefaction.

3. Where the official veterinarian so requires, the vertebral column and the head shall be split lengthwise.

4. In the case of small wild game not eviscerated immediately after killing, the official veterinarian shall carry out a post-mortem inspection on a representative sample of animals from the same source. Where inspection reveals a disease transmissible to humans or any of the characteristics listed in point (e) in paragraph 2, the official veterinarian shall carry out more checks on the entire batch to determine whether it shall be declared unfit for human consumption or whether each carcase shall be inspected individually.

5. The official veterinarian may perform any further cuts and inspections of the relevant parts of the animals that are necessary to reach a final diagnosis. If an assessment cannot be made on the basis of the practical arrangements in paragraph 2, additional investigations shall be carried out in a laboratory.

6. In addition to the cases provided for in Article 45, meat presenting during post-mortem inspection any of the characteristics listed in point (e) in paragraph 2 shall be declared unfit for human consumption.

Section 4

Official controls on specific hazards and laboratory testing

Article 29

Practical arrangements for official controls for transmissible spongiform encephalopathies (TSEs)

1. In addition to the requirements of Regulation (EC) No 999/2001 concerning the official controls to be carried out in relation to TSEs, the official veterinarian shall check the removal, separation and, where appropriate, marking of specified risk material also in accordance with the rules laid down in Article 8(1) of that Regulation and in Article 12 of Regulation (EC) No 1069/2009 on animal by-products.

2. The official veterinarian shall ensure that the food business operator takes all necessary measures to avoid contaminating meat with specified risk material during slaughter, including stunning. This includes the removal of specified risk material.

Article 30

Practical arrangements for official controls for cysticercosis during post-mortem inspection in domestic bovine animals and *Suidae*

1. The post-mortem inspection procedures described in Articles 18, 19 and 23 shall be the minimum requirements for the examination for cysticercosis in bovine animals and *Suidae* (domestic swine, farmed game and wild game). In the case of bovine animals referred to in Article 19, the competent authorities may decide that incision of the masseters at post-mortem inspection is not compulsory if:

(a) a specific serological test is used;

(b) the animals have been raised on a holding of provenance officially certified to be free of cysticercosis; or,

(c) the prevalence of the source population or in a well-defined subpopulation is below one in a million, has been demonstrated with 95 % certainty or no cases have been detected in all slaughtered animals in the past five years (or two years where supported and justified by the competent authorities' risk analysis) based on data from reporting carried out in accordance with Article 9(1) of Directive 2003/99/EC.

2. Meat infected with cysticerci shall be declared unfit for human consumption. However, where the animal is not generally infected with cysticercus, the parts not infected may be declared fit for human consumption after having undergone a cold treatment.

Article 31

Practical arrangements for official controls for *Trichinella* during post-mortem inspection

1. Carcases of *Suidae*, solipeds and other species susceptible to *Trichinella* shall be examined for *Trichinella* in accordance with Regulation (EU) 2015/1375 unless one of the derogations set out in Article 3 of that Regulation applies.

2. Meat from animals infected with trichinae shall be declared unfit for human consumption.

Article 32

Practical arrangements for official controls for glanders during post-mortem inspection of solipeds

1. Fresh meat of solipeds shall be placed on the market only if it was produced from solipeds kept for at least 90 days prior to the date of slaughter in a Member State or in a third country or region thereof from which it is authorised to bring solipeds into the Union.

2. In the case of solipeds originating from a Member State or third country or region thereof not meeting the World Organisation for Animal Health criteria for a glanders-free country, solipeds shall be inspected for glanders by a careful examination of the mucous membranes of the trachea, larynx, nasal cavities and sinuses and their ramifications, after splitting the head in the median plane and excising the nasal septum.

3. Meat produced from solipeds in which glanders has been diagnosed shall be declared unfit for human consumption.

Article 33

Practical arrangements for official controls for tuberculosis during post-mortem inspection

1. Where animals have reacted positively or inconclusively to tuberculin, or there are other grounds for suspecting infection, they shall be slaughtered separately from other animals, taking precautions to avoid the risk of contamination of other carcases, the slaughter line and staff present in the slaughterhouse.

2. All meat from animals in which post-mortem inspection has revealed localised lesions similar to tuberculoid lesions in a number of organs or a number of areas of the carcase shall be declared unfit for human consumption. However, where a tuberculoid lesion has been found in the lymph nodes of only one organ or part of the carcase, only the affected organ or part of the carcase and the associated lymph nodes shall be declared unfit for human consumption.

Article 34

Practical arrangements for official controls for brucellosis during post-mortem inspection

1. Where animals have reacted positively or inconclusively to a brucellosis test, or there are other grounds for suspecting infection, they shall be slaughtered separately from other animals, taking precautions to avoid the risk of contamination of other carcases, the slaughter line and staff present in the slaughterhouse.

2. Meat from animals in which post-mortem inspection has revealed lesions indicating acute brucellosis shall be declared unfit for human consumption. In the case of animals reacting positively or inconclusively to a brucellosis test, the udder, genital tract and blood shall be declared unfit for human consumption even if no such lesion is found.

Article 35

Practical arrangements for official controls for *Salmonella*

1. The competent authorities shall verify the correct implementation by food business operators of points 2.1.3, 2.1.4 and 2.1.5 of Chapter 2 of Annex I of Regulation (EC) No 2073/2005 by applying one or more of the following measures:

(a) official sampling using the same method and sampling area as food business operators. At least 49 random samples ([40]) shall be taken in each slaughterhouse each year. This number of samples may be reduced in small slaughterhouses based on a risk evaluation;

(b) collecting all information on the total number and the number of *Salmonella*-positive samples taken by food business operators in accordance with Article 5 of Regulation (EC) No 2073/2005, in the framework of points 2.1.3, 2.1.4 and 2.1.5 of Chapter 2 of Annex I thereto;

(c) collecting all information on the total number and the number of *Salmonella*-positive samples taken in the framework of national control programmes in Member States or regions of Member States for which special guarantees have been approved in accordance with Article 8 of Regulation (EC) No 853/2004 as regards ruminant, equine, swine and poultry production.

2. Where the food business operator fails on several occasions to comply with the process hygiene criterion, the competent authorities shall require it to submit an action plan and shall strictly supervise its outcome.

([40]) If all are negative, 95 % statistical certainty is provided that the prevalence is below 6 %.

3. The total number and the number of *Salmonella*-positive samples, differentiating between samples taken under points (a), (b) and (c) in paragraph 1, when applied, shall be reported in accordance with Article 9(1) of Directive 2003/99/EC.

Article 36

Practical arrangements for official controls for *Campylobacter*

1. The competent authorities shall verify the correct implementation by food business operators of point 2.1.9 (process hygiene criterion for *Campylobacter* on carcases of broilers) of Chapter 2 of Annex I of Regulation (EC) No 2073/2005 by applying the following measures:

(a) official sampling using the same method and sampling area as food business operators. At least 49 random samples shall be taken in each slaughterhouse each year. This number of samples may be reduced in small slaughterhouses based on a risk evaluation; or

(b) collecting all information on the total number and the number of *Campylobacter* samples with more than 1 000 cfu/g taken by food business operators in accordance with Article 5 of Regulation (EC) No 2073/2005, in the framework of point 2.1.9 of Chapter 2 of Annex I thereto.

2. Where the food business operator fails on several occasions to comply with the process hygiene criterion, the competent authorities shall require it to submit an action plan and shall strictly supervise its outcome.

3. The total number and the number of *Campylobacter* samples with more than 1 000 cfu/g, differentiating between samples taken under points (a) and (b) in paragraph 1, when applied, shall be reported in accordance with Article 9(1) of Directive 2003/99/EC.

Article 37

Specific requirements as regards laboratory tests

1. When performing laboratory tests in accordance with Article 18(2)(d)(ii) and (iv) of Regulation (EU) 2017/625, the official veterinarian shall ensure that, when sampling takes place, samples are appropriately identified and handled and sent to the appropriate laboratory in the framework of:

(a) the monitoring and control of zoonoses and zoonotic agents;

(b) the annual programme for the monitoring of TSEs in accordance with Article 6 of Regulation (EC) No 999/2001;

(c) the detection of pharmacologically active substances or products either prohibited or unauthorised, and controls for regulated pharmacologically active substances, pesticides, feed additives and contaminants exceeding applicable maximum Union limits, in particular in the framework of the national plans for the detection of residues or substances referred to in Article 110(2) of Regulation (EU) 2017/625 and in Article 5 of Directive 96/23/EC;

(d) the detection of animal diseases for which animal health rules are laid down in Regulation (EU) 2016/429.

2. The official veterinarian shall ensure that any additional laboratory testing deemed necessary for the fulfilment the obligations under Article 18(2) of Regulation (EU) 2017/625 takes place as required.

Section 5

Official controls on animal welfare

Article 38

Official controls on animal welfare at transport and slaughter

The official veterinarian shall verify compliance with the rules concerning the protection of animals during transport in accordance with Regulation (EC) No 1/2005 and at the time of slaughter in accordance with Regulation (EC) No 1099/2009 and national rules on animal welfare.

CHAPTER III

Communication of inspection results and measures to be taken by competent authorities in cases of specific non-compliance with requirements for fresh meat and for animal welfare

Article 39

Measures concerning the communication of the results of official controls

1. The official veterinarian shall record and evaluate the results of official controls carried out in accordance with Articles 7 to Article 38.

2. The following actions shall be taken by the official veterinarian where inspections reveal the presence of any disease or condition that might affect human or animal health, or compromise animal welfare:

(a) the official veterinarian shall inform the slaughterhouse operator;

(b) where the problem referred to in this paragraph arose during primary production and relates to human health, animal health, animal welfare or residues of veterinary medicinal products, unauthorised or prohibited substances, pesticide residues, feed additives or contaminants, the official veterinarian shall inform:

  (i) the veterinarian attending the holding of provenance;

  (ii) the official veterinarian who carried out any ante-mortem inspection at the holding of provenance, where different from (i);

  (iii) the food business operator responsible for the holding of provenance (provided that such information would not prejudice subsequent legal proceedings); and,

  (iv) the competent authorities responsible for supervising the holding of provenance or the hunting area;

(c) where the animals concerned were raised in another country, the official veterinarian shall ensure that the country's competent authorities are informed.

3. The competent authorities shall enter the results of official controls in relevant databases, at least where the collection of such information is required under Article 4 of Directive 2003/99/EC, Article 8 of Council Directive 64/432/EEC ([41]) and Annex III to Directive 2007/43/EC.

4. Where the official veterinarian, while carrying out ante-mortem or post-mortem inspection or any other official control, suspects the presence of an animal disease for which animal health rules are laid down in Regulation (EU) 2016/429, he/she shall notify the competent authorities. The official veterinarian and competent authorities, within their respective areas of competence, shall take all necessary measures and precautions to prevent the possible spread of the disease agent.

5. The official veterinarian may use the model document in Annex I for the purpose of communicating the relevant results of ante-mortem and post-mortem inspections to the holding of provenance where the animals were kept before slaughter.

6. Where the animals were kept on a holding of provenance in another Member State, the competent authorities of the Member State in which they were slaughtered shall communicate the relevant results of ante-mortem and post-mortem inspections to the competent authorities in the Member State of provenance. They shall use the model document in Annex I in the official languages of both Member States involved or in a language agreed between both Member States.

Article 40

Measures in cases of non-compliance with requirements for food chain information

1. The official veterinarian shall ensure that animals are not slaughtered unless the slaughterhouse operator has been provided with, checked and evaluated relevant food chain information in accordance with Article 9(2)(a) and (b).

([41]) 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).

2. By way of derogation from paragraph 1, the official veterinarian may allow animals to undergo slaughter in the slaughterhouse if the relevant food chain information is not available. In such cases, the information shall be supplied before the meat is declared fit for human consumption and carcases and related offal shall be stored separately from other meat pending that declaration.

3. Where relevant food chain information is not available within 24 hours of an animal's arrival at the slaughterhouse, the official veterinarian shall declare all meat from the animal unfit for human consumption. If the animal has not yet been slaughtered, it shall be killed separately from other animals taking all necessary precautions to safeguard animal and human health.

Article 41

Measures in cases of non-compliance recorded in food chain information

1. The official veterinarian shall verify that the slaughterhouse operator does not accept animals for slaughter when the food chain information or any other accompanying records, documentation or information shows that:

(a) the animals come from a holding of provenance or an area subject to a movement prohibition or other restriction for reasons of animal or human health;

(b) rules on the use of veterinary medicinal products have not been complied with, animals have been treated with prohibited or unauthorised substances, or the legal limits for chemical residues or contaminants have not been complied with; or

(c) any other condition which might adversely affect human or animal health is present.

2. If the animals are already present at the slaughterhouse, they shall be killed separately and declared unfit for human consumption, taking precautions to safeguard animal and human health. Where the official veterinarian considers it necessary, official controls shall be carried out on the holding of provenance.

Article 42

Measures in cases of misleading food chain information

1. The competent authorities shall take appropriate action if they discover that the accompanying records, documentation or other information do not correspond to the true situation of the holding of provenance or the true condition of the animals, or aim deliberately to mislead the official veterinarian.

2. They shall take action against the food business operator responsible for the holding of provenance of the animals, or any other person involved, including the slaughterhouse operator. In particular, this action may consist of extra controls. The food business operator responsible for the holding of provenance or any other person involved shall bear the costs of such extra controls.

Article 43

Measures in cases of non-compliance with requirements for live animals

1. The official veterinarian shall verify the food business operator's compliance with its duty under point 3 in Chapter IV of Section I of Annex III to Regulation (EC) No 853/2004 to ensure that animals accepted for slaughter for human consumption are properly identified. The official veterinarian shall ensure that animals whose identity is not ascertainable are killed separately and declared unfit for human consumption. Where the official veterinarian considers it necessary, official controls shall be carried out on the holding of provenance.

2. The official veterinarian shall ensure that animals subject to an unacceptable risk of contamination of the meat during slaughter, as laid down in Article 11(4), are not slaughtered for human consumption unless they are cleaned beforehand.

3. The official veterinarian shall ensure that animals with a disease or condition that may be transmitted to animals or humans handling or eating the meat and, in general, animals showing clinical signs of systemic disease or emaciation, or any other condition rendering meat unfit for human consumption, are not slaughtered for human consumption. Such animals shall be killed separately under such conditions that other animals or carcases cannot be contaminated, and declared unfit for human consumption.

4. The official veterinarian shall defer the slaughter of animals suspected of having a disease or condition that may adversely affect human or animal health. Such animals shall undergo detailed ante-mortem examination by the official veterinarian in order to make a diagnosis. In addition, the official veterinarian may decide that sampling and laboratory examinations must take place to supplement post-mortem inspection. If necessary to avoid contamination of other meat, the animals shall be slaughtered separately or at the end of normal slaughtering, taking all other necessary precautions.

5. The official veterinarian shall ensure that animals that might contain residues of prohibited or unauthorised pharmacologically active substances or residues of authorised pharmacologically active substances, pesticides or contaminants in excess of the levels laid down in accordance with Union legislation, are dealt with in accordance with Articles 16 to 19 of Directive 96/23/EC.

6. The official veterinarian shall impose the conditions under which animals shall be dealt with under a specific scheme for the eradication or control of a specific disease, such as brucellosis or tuberculosis, or zoonotic agents such as salmonella, under his/her direct supervision. The competent authorities shall determine the conditions under which such animals may be slaughtered. These conditions shall be designed to minimise the contamination of other animals and the meat of other animals.

As a rule, animals that are presented to a slaughterhouse for slaughter shall be slaughtered there. However, in exceptional circumstances, such as a serious breakdown of the slaughter facilities, the official veterinarian may allow direct movements to another slaughterhouse.

Where non-compliance which results in a risk to animal or human health, or animal welfare, is detected during ante-mortem inspection at the holding of provenance, the official veterinarian shall not allow the animals to be transported to the slaughterhouse and the relevant measures regarding the communication of inspection results in accordance with Article 39(2)(b)(i) and (iii) shall apply.

Article 44

Measures in cases of non-compliance with requirements for animal welfare

1. In cases of non-compliance with the rules concerning the protection of animals at the time of slaughter or killing laid down in Articles 3 to 9 and Articles 14 to 17, 19 and 22 of Council Regulation (EC) No 1099/2009, the official veterinarian shall verify that the food business operator immediately takes the necessary corrective measures and prevents recurrence.

2. The official veterinarian shall take a proportionate and stepped approach to enforcement action, ranging from issuing directions to slowing down and stopping production, depending on the nature and gravity of the problem.

3. Where appropriate, the official veterinarian shall inform other competent authorities of welfare problems.

4. Where the official veterinarian discovers non-compliance with the rules concerning the protection of animals during transport laid down in Regulation (EC) No 1/2005, he/she shall take the requisite measures in accordance with the relevant Union legislation.

5. Where an official auxiliary carries out checks on animal welfare and those checks identify non-compliance with the rules on the protection of animals, he/she shall immediately inform the official veterinarian. If necessary in urgent cases, he/she shall take the necessary measures referred to in paragraphs 1 to 4 pending the arrival of the official veterinarian.

Article 45

Measures in cases of non-compliance with requirements for fresh meat

The official veterinarian shall declare fresh meat unfit for human consumption if it:

(a) derives from animals that have not undergone ante-mortem inspection in accordance with Article 18(2)(a) or (b) of Regulation (EU) 2017/625, except for wild game and stray reindeer referred to in Article 12(1)(b) of Delegated Regulation (EU) 2019/624;

(b) derives from animals whose offal has not undergone post-mortem inspection in accordance with Article 18(2)(c) of Regulation (EU) 2017/625, except in case of viscera of large wild game that do not need to accompany the body to a game-handling establishment in accordance with point 4 of Chapter II of Section IV in Annex III of Regulation (EC) No 853/2004;

(c) derives from animals that are dead before slaughter, stillborn, unborn or slaughtered under the age of seven days;

(d) results from the trimming of sticking points;

(e) derives from animals affected by animal diseases for which animal health rules are laid down in the Union legislation listed in Annex I to Directive 2002/99/EC, except if it is obtained in conformity with the specific requirements provided for in that Directive; this exception shall not apply if otherwise provided for in the requirements on the official controls of tuberculosis and brucellosis provided for in Articles 33 and 34 of this Regulation;

(f) derives from animals affected by a generalised disease, such as generalised septicaemia, pyaemia, toxaemia or viraemia;

(g) is not in conformity with the food safety criteria laid down in Chapter I of Annex I to Regulation (EC) No 2073/2005 for determining whether food may be placed on the market;

(h) exhibits parasitic infestation, unless otherwise provided for in the requirements on the official controls for cysticercosis provided for in Article 30;

(i) contains chemical residues or contaminants in excess of the levels laid down in Regulations (EU) No 37/2010, (EC) No 396/2005, (EC) No 1881/2006 and (EC) No 124/2009 or residues of substances that are prohibited or unauthorised under Regulation (EU) No 37/2010 or Directive 96/22/EC;

(j) consists of the liver and kidneys of animals more than two years old from regions where implementation of plans approved in accordance with Article 5 of Directive 96/23/EC has revealed the generalised presence of heavy metals in the environment;

(k) has been treated illegally with decontaminating substances;

(l) has been treated illegally with ionising radiation, including UV-radiation;

(m) contains foreign bodies, except, in the case of wild game, material used to hunt the animal;

(n) exceeds maximum permitted radioactivity levels laid down under Union legislation or, in the absence of Union legislation, under national rules;

(o) indicates pathological or organoleptic changes, in particular a pronounced sexual odour or insufficient bleeding (except for wild game);

(p) derives from emaciated animals;

(q) contains specified risk material unless removal is allowed in another establishment in accordance with Point 4.3 of Annex V to Regulation (EC) No 999/2001 and the fresh meat remains under the control of the competent authorities;

(r) shows soiling, faecal or other contamination;

(s) consists of blood that may constitute a risk to human or animal health owing to the health status of any animal from which it derives or contamination arising during the slaughter process;

(t) in the opinion of the official veterinarian, after examination of all the relevant information, may constitute a risk to human or animal health or is for any other reason not suitable for human consumption;

(u) gives rise to specific hazards in accordance with Articles 29 to 36.

Article 46

Measures in cases of non-compliance with requirements on good hygiene practices

1. The competent authorities may instruct the food business operator to take immediate corrective action, including a reduction in the speed of slaughter, where this is considered necessary by the official present in the following cases:

(a) where contamination is detected on external surfaces of a carcase or its cavities and the food business operator does not take appropriate action to rectify the situation; or

(b) if the competent authorities consider that good hygiene practices are jeopardised.

2. In such cases, the competent authorities shall increase the intensity of inspection until such time as they are satisfied that the food business operator has regained control of the process.

CHAPTER IV

Restrictions

Article 47

Restrictions for certain fresh meat

The official veterinarian may impose requirements concerning the use of fresh meat derived from animals:

(a) that have undergone emergency slaughter outside the slaughterhouse; or

(b) from flocks where a treatment of the meat is applied in accordance with Part E of Annex II to Regulation (EC) No 2160/2003 before the meat is placed on the market.

CHAPTER V

Health marking of meat fit for human consumption after ante-mortem and post-mortem inspection

Article 48

Technical requirements of the health mark and practical arrangements for its application

1. The official veterinarian shall supervise health marking and the marks used.

2. The official veterinarian shall ensure, in particular, that:

(a) the health mark is applied only to domestic ungulates and farmed game mammals other than lagomorphs, having undergone ante-mortem and post-mortem inspection, and large wild game having undergone post mortem inspection, in accordance with Article 18(2)(a), (b) and (c) of Regulation (EU) 2017/625, where there are no grounds for declaring the meat unfit for human consumption. However, the mark may be applied before the results of any examination for *Trichinella* and/or TSE testing are available, provided that the competent authorities introduced a system in place in the slaughterhouse or game-handling establishment ensuring that all parts of the animal can be traced, and no parts of the examined animals bearing the mark leave the slaughterhouse or game-handling establishment until a negative result has been obtained except when provided for in accordance with Article 2(3) of Regulation (EU) 2015/1375;

(b) the health mark is applied on the external surface of the carcase, by stamping in ink or hot branding, in such a manner that, if carcases are cut in the slaughterhouse into half carcases or quarters, or half carcases are cut into three pieces, each piece bears a health mark.

3. The competent authorities shall ensure that the practical arrangements for the health mark are applied in accordance with Annex II.

4. The competent authorities shall ensure that meat from unskinned wild game does not bear a health mark until, after skinning in a game-handling establishment, it has undergone post-mortem inspection and been declared fit for human consumption.

TITLE IV

SPECIFIC REQUIREMENTS AND UNIFORM MINIMUM FREQUENCY OF OFFICIAL CONTROLS WITH RESPECT TO RAW MILK, COLOSTRUM, DAIRY PRODUCTS AND COLOSTRUM-BASED PRODUCTS, AS NECESSARY TO RESPOND TO RECOGNISED UNIFORM HAZARDS AND RISKS

Article 49

Control of milk and colostrum production holdings

1. The official veterinarian shall verify that the health requirements for raw milk and colostrum production as laid down in Part I of Chapter I of Section IX of Annex III to Regulation (EC) No 853/2004 are complied with. In particular, the official veterinarian shall verify:

(a) the health status of the animals;

(b) the absence of the use of prohibited or unauthorised pharmacologically active substances; and

(c) that the possible presence of residues of authorised pharmacologically active substances, pesticides or contaminants does not exceed the levels laid down in Regulations (EU) No 37/2010, (EC) No 396/2005 or (EC) No 1881/2006.

2. The official controls referred to in paragraph 1 may take place at the occasion of veterinary checks carried out pursuant to Union provisions on animal or human health or animal welfare.

3. If there are grounds for suspecting that the health requirements referred to in paragraph 1 are not being complied with, the official veterinarian shall check the general health status of the animals.

4. Milk and colostrum production holdings shall undergo official controls by the competent authorities to verify that hygiene requirements laid down in Part II of Chapter I of Section IX of Annex III to Regulation (EC) No 853/2004 are being complied with. These controls may involve inspections and the monitoring of controls carried out by professional organisations. If it is demonstrated that the hygiene is inadequate, the competent authorities shall verify that appropriate steps are taken to correct the situation.

Article 50

Control of milk and colostrum

1. In the case of raw milk and colostrum, the competent authorities shall monitor the checks carried out in accordance with Part III of Chapter I, Section IX of Annex III to Regulation (EC) No 853/2004. When testing is used, the competent authorities shall use the analytical methods set out in Annex III to this Regulation to check compliance with the limits laid down for raw milk and colostrum in Part III of Chapter I, Section IX of Annex III to Regulation (EC) No 853/2004.

2. If the food business operator of the production holding has not corrected the situation within three months of the first notification to the competent authorities of non-compliance with the plate count and/or somatic cell count criteria for raw milk and colostrum, the competent authorities shall verify that:

(a) delivery of raw milk and colostrum from the production holding is suspended, or

(b) the raw milk and colostrum is subjected to requirements concerning its treatment and use necessary to protect human health in accordance with a specific authorisation of, or general instructions from the competent authorities.

This suspension or these requirements shall remain in place by the competent authorities until the food business operator has proved that the raw milk and colostrum again comply with the criteria.

3. The competent authorities shall use the analytical methods set out in Annex III of this Regulation to verify appropriate application of a pasteurisation process to dairy products as referred to in Part II of Chapter II, Section IX of Annex III to Regulation (EC) No 853/2004.

TITLE V

SPECIFIC REQUIREMENTS FOR OFFICIAL CONTROLS CONCERNING LIVE BIVALVE MOLLUSCS FROM CLASSIFIED PRODUCTION AND RELAYING AREAS

Article 51

Exclusion

This Title applies to live bivalve molluscs. It also applies to live echinoderms, live tunicates and live marine gastropods. This Title does not apply to live marine gastropods and live *Holothuroidea* that are not filter feeders.

Article 52

Classification of production and relaying areas for live bivalve molluscs

1. The competent authorities shall fix the location and boundaries of the production and relaying areas that they classify in accordance with Article 18(6) of Regulation (EU) 2017/625. They may, where appropriate, do so in cooperation with the food business operator.

2. The competent authorities shall classify production and relaying areas from which they authorise the harvesting of live bivalve molluscs as Class A, Class B and Class C areas according to the level of faecal contamination. They may, where appropriate, do so in cooperation with the food business operator.

3. In order to classify production and relaying areas, the competent authorities shall fix a review period for sampling data from each production and relaying area in order to determine compliance with the standards referred to in Articles 53, 54 and 55.

CHAPTER I

Specific requirements for the classification of production and relaying areas for live bivalve molluscs

Article 53

Requirements for Class A areas

1. The competent authorities may classify as Class A areas those from which live bivalve molluscs may be collected for direct human consumption.

2. Live bivalve molluscs placed on the market from such areas shall meet the health standards for live bivalve molluscs set out in Chapter V of Section VII of Annex III to Regulation (EC) No 853/2004.

3. Samples of live bivalve molluscs from Class A areas shall not exceed, in 80 % of samples collected during the review period, 230 *E. coli* per 100 g of flesh and intravalvular liquid.

4. The remaining 20 % of samples shall not exceed 700 *E. coli* per 100 g of flesh and intravalvular liquid.

5. When evaluating the results for the fixed review period for maintenance of a Class A area, the competent authorities may, on the basis of a risk assessment based on an investigation, decide to disregard an anomalous result exceeding the level of 700 *E. coli* per 100 g of flesh and intravalvular liquid.

Article 54

Requirements for Class B areas

1. The competent authorities may classify as Class B areas those from which live bivalve molluscs may be collected and placed on the market for human consumption only after treatment in a purification centre or after relaying so as to meet the health standards referred to in Article 53.

2. Live bivalve molluscs from Class B areas shall not exceed, in 90 % of the samples, 4 600 *E. coli* per 100 g of flesh and intravalvular liquid.

3. The remaining 10 % of samples shall not exceed 46 000 *E. coli* per 100 g of flesh and intravalvular liquid.

Article 55

Requirements for Class C areas

1. The competent authorities may classify as Class C areas those from which live bivalve molluscs may be collected and placed on the market only after relaying over a long period so as to meet the health standards referred to in Article 53.

2. Live bivalve molluscs from Class C areas shall not exceed 46 000 *E. coli* per 100 g of flesh and intravalvular liquid.

Article 56

Sanitary survey requirements

1. Before classifying a production or relaying area, the competent authorities shall carry out a sanitary survey that includes:

(a) an inventory of the sources of pollution of human or animal origin likely to be a source of contamination for the production area;

(b) an examination of the quantities of organic pollutants released during the different periods of the year, according to the seasonal variations of human and animal populations in the catchment area, rainfall readings, waste-water treatment, etc.;

(c) determination of the characteristics of the circulation of pollutants by virtue of current patterns, bathymetry and the tidal cycle in the production area.

2. The competent authorities shall carry out a sanitary survey fulfilling the requirements set out in paragraph 1 in all classified production and relaying areas, unless carried out previously.

3. The competent authorities may be assisted by other official bodies or food business operators under conditions established by the competent authorities in relation to the performance of this survey.

Article 57

Monitoring programme

The competent authorities shall establish a monitoring programme for live bivalve mollusc production areas that is based on an examination of the sanitary survey referred to in Article 56. The number of samples, geographical distribution of sampling points and sampling frequency for the programme shall ensure that the results of the analysis are representative of the area in question.

Article 58

The competent authorities shall establish a procedure to ensure that the sanitary survey referred to in Article 56 and the monitoring programme referred to in Article 57 are representative of the area considered.

CHAPTER II

Conditions for the monitoring of classified production and relaying areas for live bivalve molluscs

Article 59

Monitoring of classified production and relaying areas

The competent authorities shall periodically monitor production and relaying areas classified in accordance with Article 18(6) of Regulation (EU) 2017/625 in order to check:

(a) that there is no malpractice with regard to the origin, provenance and destination of live bivalve molluscs;

(b) the microbiological quality of live bivalve molluscs in relation to the classified production and relaying areas;

(c) for the presence of toxin-producing plankton in production and relaying waters and marine biotoxins in live bivalve molluscs;

(d) for the presence of chemical contaminants in live bivalve molluscs.

Article 60

Recognised methods for the detection of marine biotoxins in live bivalve molluscs

1. The competent authorities shall use the analytical methods laid down in Annex V to check compliance with the limits laid down in point 2 of Chapter V of Section VII of Annex III to Regulation (EC) No 853/2004 and, where appropriate, to verify compliance by food business operators. Food business operators shall use these methods where appropriate.

2. In accordance with Article 4 of Directive 2010/63/EU, a scientifically satisfactory method or testing strategy, not entailing the use of live animals, shall be used where possible, instead of a procedure as defined in Article 3(1) of that Directive.

3. In accordance with Article 4 of Directive 2010/63/EU, elements of replacement, refinement and reduction must be taken into account when biological methods are used.

Article 61

Sampling plans

1. For the purposes of the checks provided for in points (b), (c) and (d) of Article 59, the competent authorities shall draw up sampling plans providing for such checks to take place at regular intervals, or on a case-by-case basis if harvesting periods are irregular. The geographical distribution of the sampling points and the sampling frequency shall ensure that the results of the analysis are representative of the classified production and relaying area concerned.

2. Sampling plans to check the microbiological quality of live bivalve molluscs shall take particular account of:

(a) the likely variation in faecal contamination;

(b) the parameters referred to in Article 56(1).

3. Sampling plans to check for the presence of toxin-producing plankton in the water in classified production and relaying areas and for marine biotoxins in live bivalve molluscs shall take particular account of possible variations in the presence of plankton containing marine biotoxins. Sampling shall comprise:

(a) periodic sampling to detect changes in the composition of plankton containing toxins and their geographical distribution. Results suggesting an accumulation of toxins in live bivalve mollusc flesh shall be followed by intensive sampling;

(b) periodic toxicity tests using live bivalve molluscs from the affected area most susceptible to contamination.

4. The sampling frequency for toxin analysis in live bivalve molluscs shall be weekly during harvesting periods, except when:

(a) the sampling frequency may be reduced in specific classified relaying or production areas, or for specific types of live bivalve mollusc, if a risk assessment of toxins or phytoplankton occurrence suggests a very low risk of toxic episodes;

(b) the sampling frequency shall be increased where such an assessment suggests that weekly sampling would not be sufficient.

5. The risk assessment referred to in paragraph 4 shall be reviewed periodically in order to assess the risk of toxins occurring in the live bivalve molluscs from these areas.

6. Where knowledge of toxin accumulation rates is available for a group of species growing in the same classified production or relaying area, the species with the highest rate may be used as an indicator species. This will allow the exploitation of all species in the group if toxin levels in the indicator species are below the regulatory limits. Where toxin levels in the indicator species are above the regulatory limits, the harvesting of the other species may be allowed only if further analysis of the other species shows toxin levels below the limits.

7. With regard to the monitoring of plankton, the samples shall be representative of the water column in the classified production or relaying area and provide information on the presence of toxic species and on population trends. If any changes in toxic populations that may lead to toxin accumulation are detected, the sampling frequency for live bivalve molluscs shall be increased or precautionary closures of the areas established until results of toxin analysis are obtained.

8. Sampling plans to check for the presence of chemical contaminants shall enable the detection of any overshooting of the levels laid down in Regulation (EC) No 1881/2006.

CHAPTER III

Management of classified production and relaying areas after monitoring

Article 62

Decisions following monitoring

1. Where the results of the monitoring provided for in Article 59 indicate that the health standards for live bivalve molluscs are not met or that there may otherwise be a risk to human health, the competent authorities shall close the classified production or relaying area concerned, preventing the harvesting of live bivalve molluscs. However, they may reclassify a production or relaying area as being of Class B or C if it meets the relevant criteria set out in Articles 54 and 55 and presents no other risk to human health.

2. Where the results of microbiological monitoring show that the health standards for live bivalve molluscs referred to in Article 53 not met, competent authorities may, on the basis of a risk assessment, and only on a temporary and non-recurring basis, permit continued harvesting without closure or reclassification subject to the following conditions:

(a) the classified production area concerned and all approved establishments receiving live bivalve molluscs from it are under the official control of the same competent authorities;

(b) the live bivalve molluscs concerned are subjected to appropriate restrictive measures such as purification, relaying or processing.

3. The accompanying registration document, as referred to in Chapter I of Section VII of Annex III to Regulation (EC) No 853/2004, shall include all the information concerning the application of paragraph 2.

4. The competent authorities shall establish the conditions under which paragraph 2 can be availed of in order to ensure, for the production area concerned, maintenance of the compliance with the criteria established in Article 53.

Article 63

Re-opening of production areas

1. The competent authorities may re-open a closed production or relaying area only if the health standards for live bivalve molluscs comply once again with the relevant requirements of Chapter V of Section VII of Annex III to Regulation (EC) No 853/2004 and present no other risk to human health.

2. Where the competent authorities have closed a production or relaying area because of the presence of plankton or levels of toxins in live bivalve molluscs that exceed the regulatory limit for marine biotoxins laid down in point 2 of Chapter V of Section VII of Annex III to Regulation (EC) No 853/2004, they may re-open it only if at least two consecutive analytical results separated by at least 48 hours are below the regulatory limit.

3. When deciding whether to re-open a production or relaying area, the competent authorities may take account of information on phytoplankton trends.

4. Where there are robust data on the dynamic of the toxicity for a given area, and provided that recent data on decreasing trends of toxicity are available, the competent authorities may decide to re-open an area with results below the regulatory limit in point 2 of Chapter V of Section VII of Annex III to Regulation (EC) No 853/2004 obtained from a single sampling.

Article 64

Control system

1. The competent authorities shall set up a control system to ensure that products of animal origin harmful to human health are not placed on the market. The control system shall comprise laboratory tests to verify food business operators' compliance with the requirements for the end product, including live bivalve molluscs and any products derived from them, at all stages of production, processing and distribution.

2. This control system shall verify, where applicable, that the levels of marine biotoxins and contaminants do not exceed safety limits and that the microbiological quality of the molluscs does not constitute a hazard to human health.

Article 65

Decision by the competent authorities

1. The competent authorities shall act promptly where a production area must be closed or reclassified, or may be re-opened, or where live bivalve molluscs are subject to the application of measures as referred to in Article 62(2).

2. When deciding on the classification, reclassification, opening or closure of production areas in accordance with Articles 52, 62 and 63, competent authorities may take into account the results of checks carried out by food business operators or organisations representing food business operators, only if the laboratory carrying out the analysis is designated by the competent authorities, and the sampling and analysis are performed in accordance with a protocol agreed upon jointly by the competent authorities and food business operators or organisation concerned.

CHAPTER IV

Other requirements

Article 66

Recording and exchange of information

The competent authorities shall:

(a) establish and keep up to date a list of classified production and relaying areas, with details of their location, and boundaries, as well as the Class in which the area is classified, from which live bivalve molluscs may be taken in accordance with the requirements of Article 52. This list shall be communicated to interested parties affected by this Regulation, such as producers, gatherers and operators of purification centres and dispatch centres;

(b) immediately inform the interested parties such as producers, gatherers and operators of purification centres and dispatch centres, of any change to the location, boundaries or Class of a production area, of its temporary or final closure, or of the application of measures as referred to in Article 60(2).

TITLE VI

SPECIFIC REQUIREMENTS AND UNIFORM MINIMUM FREQUENCY OF OFFICIAL CONTROLS WITH RESPECT TO FISHERY PRODUCTS

Article 67

Official controls on production and placing on the market

Official controls on the production and placing on the market of fishery products shall include verification of compliance with the requirements set out in Section VIII of Annex III to Regulation (EC) No 853/2004, in particular:

(a) a regular check on the hygiene conditions of landing and first sale;

(b) regular inspections of vessels and establishments on land, including fish auctions and wholesale markets, in particular to check:

(i) whether the conditions for approval are still fulfilled;

(ii) whether the fishery products are handled correctly;

(iii) compliance with hygiene and temperature requirements;

(iv) the cleanliness of establishments, including vessels, and their facilities and equipment, and staff hygiene;

(c) checks on storage and transport conditions.

Article 68

Site of official controls

1. The competent authorities shall carry out official controls on vessels when these call at a port in a Member State. These controls shall concern all vessels landing fishery products at EU ports, irrespective of flag.

2. Flag state competent authorities may carry out official controls on vessels under their flag while the vessel is at sea or in a port in another Member State or a third country.

Article 69

Approval of factory, freezer or reefer vessels

1. Where a factory, freezer or reefer vessel flying the flag of a Member State is inspected with a view to granting approval of the vessel, the competent authorities of the flag Member State shall carry out official controls in accordance with Article 148 of Regulation (EU) 2017/625, particularly the time limits referred to in Article 148(4). If necessary, they may inspect the vessel while it is at sea or in a port in another Member State or a third country.

2. Where the competent authorities of the flag Member State have granted the vessel conditional approval in accordance with Article 148 of Regulation (EU) 2017/625, they may authorise the competent authorities of another Member State, or of a third country to carry out follow-up controls with a view to granting full approval, prolonging conditional approval or keeping approval under review, provided that, in the case of a third country, such country appears on a list of third countries from which imports of fishery products are permitted pursuant to Article 127 of Regulation (EU) 2017/625. If necessary, these competent authorities may inspect the vessel while it is at sea or in a port in another Member State or third country.

3. Where the competent authorities of a Member State authorise the competent authorities of another Member State or of a third country to carry out controls on their behalf in accordance with this Article, the two competent authorities shall agree on the conditions governing such controls. These conditions shall ensure, in particular, that the competent authorities of the flag Member State receive reports on the results of the controls and on any suspected non-compliance without delay, so as to enable them to take the necessary measures.

Article 70

Official controls of fishery products

Official controls of fishery products shall include at least the practical arrangements laid down in Annex VI as regards:

(a) organoleptic examinations;

(b) freshness indicators;

(c) histamine;

(d) residues and contaminants;

(e) microbiological checks;

(f) parasites;

(g) poisonous fishery products.

Article 71

Decisions after controls

The competent authorities shall declare fishery products unfit for human consumption if:

(a) official controls carried out in accordance with Article 70 reveal they are not in compliance with organoleptic, chemical, physical or microbiological requirements or requirements for parasites as established in Section VII of Annex III of Regulation (EC) No 853/2004 and/or Regulation (EC) No 2073/2005;

(b) they contain in their edible parts chemical residues or contaminants in excess of the levels laid down in Regulations (EU) No 37/2010, (EC) No 396/2005, (EC) No 1881/2006, or residues of substances that are prohibited or unauthorised in accordance with Regulation (EU) No 37/2010 or Directive 96/22/EC, or are not in compliance with any other relevant Union legislation on pharmacologically active substances;

(c) they derive from:

  (i) poisonous fish;

  (ii) fishery products not complying with the requirements on marine biotoxins;

  (iii) live bivalve molluscs, echinoderms, tunicates or marine gastropods containing marine biotoxins in total quantities exceeding the limits referred to in Regulation (EC) No 853/2004; or

(d) the competent authorities consider that they may constitute a risk to human or animal health or are for any other reason not suitable for human consumption.

Article 72

Requirements concerning the official controls on fishery products caught by vessels flying the flag of Member States entering the Union after being transferred in third countries with or without storage

1. Fishery products intended for human consumption caught by vessels flying the flag of a Member State, unloaded, with or without storage, in third countries listed as provided for in Article 126(2)(a) of Regulation (EU) 2017/625 before entering the Union by a different means of transportation, shall be accompanied by a health certificate issued by the competent authorities of that third country and completed in accordance with the model health certificate set out in Chapter B of Part II to Annex III to Implementing Regulation (EU) 2019/628.

2. If the fishery products referred to in paragraph 1 are unloaded and transported to a storage facility located in the third country referred to in that paragraph, that storage facility shall appear in a list as provided for in Article 5 of Delegated Regulation (EU) 2019/625.

3. If the fishery products referred to in paragraph 1 are loaded in a vessel flying the flag of a third country, that third country shall be listed as provided for in Article 3 of Delegated Regulation (EU) 2019/625 and the vessel shall appear in a list as provided for in Article 5 of Delegated Regulation (EU) 2019/625.

4. Container vessels used to transport containerised fishery products are excluded from this requirement.

TITLE VII

SPECIFIC REQUIREMENTS FOR THE PERFORMANCE OF OFFICIAL CONTROLS AND UNIFORM MINIMUM FREQUENCY FOR OFFICIAL CONTROLS ON REPTILE MEAT

Article 73

Ante-mortem and post-mortem inspection of reptiles

Article 11 shall apply to the ante-mortem inspection of reptiles.

Articles 12, 13 and 14 shall apply to the post-mortem inspection of reptiles. For the purpose of Article 13 (a)(i), a reptile will be considered as 0,5 livestock units.

TITLE VIII

FINAL PROVISIONS

Article 74

Amendments to Regulation (EC) No 2074/2005

Regulation (EC) No 2074/2005 is amended as follows:

1. Articles 5, 6b and 6c are deleted.

2. In Annex I, Section II and the Appendix are deleted.

3. In Annex II, Section II is deleted.

4. Annexes III and V are deleted.

5. Annex VIa is deleted.

6. Annex VIb and its Appendix are deleted.

Article 75

Entry in force and application

This Regulation shall enter into force on the 20th day following that of its publication in the *Official Journal of the European Union*.

It shall apply from 14 December 2019.

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

Done at Brussels, 15 March 2019.

For the Commission
The President
Jean-Claude JUNCKER

ANNEX I

MODEL DOCUMENT FOR COMMUNICATION WITH THE HOLDING OF PROVENANCE IN ACCORDANCE WITH ARTICLE 39(5)

1.	**Identification details**
1.1.	Holding of provenance (owner or manager) Name/number Full address Telephone number Electronic address if available
1.2.	Identification numbers of ..... [please specify] or attach list Total number of animals (by species) Identification problems (if any)
1.3.	Herd/flock/cage identification number (if applicable)
1.4.	Animal species
1.5.	Reference number of health certificate (if applicable)
2.	**Ante-mortem findings**
2.1.	Welfare Number of animals affected Type/class/age Observations
2.2.	Animals were delivered dirty
2.3.	Clinical findings of disease Number of animals affected Type/class/age Observations Date of inspection
2.4.	Laboratory results ([1])

([1]) Microbiological, chemical, serological, etc. (include results as attached).

3. **Post-mortem findings**	
3.1. Macroscopic findings	
Number of animals affected	
Type/class/age	
Organ or site of animal(s) affected	
Date of slaughter	
3.2. Disease (codes may be used ([2]))	
Number of animals affected	
Type/class/age	
Organ or site of the animal(s) affected	
Partially or totally condemned carcase (give reason)	
Date of slaughter	
3.3. Laboratory results ([3])	
3.4. Other results	
3.5. Welfare findings	
4. **Additional information**	
5. **Contact details of slaughterhouse (approval number)**	
Name	
Full address	
Telephone number	
Electronic address if available	
6. **Official veterinarian (print name)**	
Signature and stamp	
7. **Date**	
8. **Number of pages attached to this form:**	

([2]) The competent authorities may introduce the following codes: code A for OIE-listed diseases; codes B100 and B200 for welfare issues and C100 to C290 for decisions concerning meat. The coding system can, if necessary, include further subdivisions (e.g. C141 for a mild generalised disease, C142 for a more severe disease, etc.). If codes are used, they must be readily available to the food business operator with a suitable explanation of their meaning.

([3]) Microbiological, chemical, serological, etc. (include results as attached).

ANNEX II

PRACTICAL ARRANGEMENTS FOR THE HEALTH MARK IN ACCORDANCE WITH ARTICLE 48

1. The health mark must be an oval mark at least 6,5 cm wide by 4,5 cm high bearing the following information in perfectly legible characters:

   (a) the name of the country in which the establishment is located, which may be written out in full in capitals or shown as a two-letter code in accordance with the relevant ISO code. In the case of Member States, however, these codes are BE, BG, CZ, DK, DE, EE, IE, GR, ES, FR, HR, IT, CY, LV, LT, LU, HU, MT, NL, AT, PL, PT, RO, SI, SK, FI, SE and UK;

   (b) the approval number of the slaughterhouse; and

   (c) (when the mark is applied in an establishment located in the Union) the abbreviation CE, EC, EF, EG, EK, EO, EY, ES, EÜ, EB, EZ, KE or WE. Those abbreviations must not appear on marks applied on meat imported into the Union from slaughterhouses located outside the Union.

2. Letters must be at least 0,8 cm high and figures at least 1 cm high. The dimensions of the characters and the mark may be reduced for the health marking of lamb, kids and piglets.

3. The ink used for health marking must be authorised in accordance with Union rules on the use of colouring substances in foodstuffs.

4. The health mark may also include an indication of the official veterinarian who carried out the health inspection of the meat.

ANNEX III

TESTING METHODS FOR RAW MILK AND HEAT-TREATED COW'S MILK IN ACCORDANCE WITH ARTICLE 50

CHAPTER I

DETERMINATION OF PLATE COUNT AND SOMATIC CELL COUNT

A. When verifying compliance with the criteria laid down in Part III of Section IX, Chapter I of Annex III to Regulation (EC) No 853/2004, the following standards must be applied as reference methods:

1. EN ISO 4833-1 for the plate count at 30 °C;

2. EN ISO 13366-1 for the somatic cell count.

B. The use of alternative analytical methods is acceptable:

1. for the plate count at 30 °C, where the methods are validated against the reference method mentioned in point 1 of Part A in accordance with the protocol set out in standard EN ISO 16140-2, supplemented by standard EN ISO 16297 for the specific case of plate count in raw milk.

   In particular, the conversion relationship between an alternative method and the reference method mentioned in point 1 of Part A is established according to standard EN ISO 21187.

2. for the somatic cell count, where the methods are validated against the reference method mentioned in point 2 of Part A in accordance with the protocol set out in standard ISO 8196-3 and operated in accordance with standard EN ISO 13366-2 or other similar internationally accepted protocols.

CHAPTER II

DETERMINATION OF ALKALINE PHOSPHATASE ACTIVITY IN COW'S MILK

A. To determine alkaline phosphatase activity in pasteurised cow's milk, standard EN ISO 11816-1 must be applied as the reference method.

B. The alkaline phosphatase activity in pasteurised cow's milk is expressed as milli units of enzyme activity per litre (mU/l). A unit of alkaline phosphatase activity is the amount of alkaline phosphatase enzyme that catalyses the transformation of 1 micromole of substrate per minute.

C. An alkaline phosphatase test is considered to give a negative result if the measured activity in cow's milk is not higher than 350 mU/l.

D. The use of alternative analytical methods is acceptable where they are validated against the reference methods mentioned in Part A in accordance with internationally accepted protocols and rules of good laboratory practices.

ANNEX IV

REFERENCE TESTING METHOD FOR ANALYSIS OF E. COLI IN LIVE BIVALVE MOLLUSCS FOR CLASSIFICATION OF PRODUCTION AND RELAYING AREAS IN ACCORDANCE WITH ARTICLE 52(2)

The reference method for analysis of E. coli in live bivalve molluscs shall be the detection and 'most probable number' (MPN) technique specified in ISO 16649-3. Alternative methods may be used if they are validated against this reference method in accordance with the criteria in ISO 16140.

ANNEX V

RECOGNISED METHODS FOR THE DETECTION OF MARINE BIOTOXINS IN ACCORDANCE WITH ARTICLE 60

CHAPTER I

PARALYTIC SHELLFISH POISON DETECTION METHOD

A. The paralytic shellfish poisoning (PSP) toxins content of the whole body or any part edible separately of bivalve molluscs shall be determined using AOAC official method OMA 2005.06, as published in *AOAC International Journal* 88(6), 1714-1732 (Lawrence method), the mouse bioassay or any other internationally recognised validated method.

B. If the results are challenged, the reference method shall be AOAC official method OMA 2005.06 as referred in Part A.

CHAPTER II

AMNESIC SHELLFISH POISON DETECTION METHOD

A. The amnesic shellfish poisoning (ASP) toxins content of the entire body or any part edible separately of bivalve molluscs shall be determined using the high-performance liquid chromatography with ultraviolet detection (HPLC/UV) method or any other internationally recognised validated method.

B. However, for screening purposes, AOAC official method 2006.02, as published in *AOAC International Journal* 90, 1011-1027 (ASP enzyme-linked immunosorbent assay (ELISA) method), or any other internationally recognised validated method may also be used.

C. If the results are challenged, the reference method shall be the HPLC/UV method.

CHAPTER III

LIPOPHILIC TOXIN DETECTION METHODS

A. The reference method for the detection of marine toxins as referred to in points (c), (d) and (e) in Chapter V(2) of Section VII of Annex III to Regulation (EC) No 853/2004 shall be the EU reference laboratory liquid chromatography-mass spectrometry/mass spectrometry (EURL LC-MS/MS) method. This method shall determine at least the following compounds:

(a) okadaic acid group toxins: OA, DTX1 and DTX2, including their esters (DTX3);

(b) pectenotoxins group toxins: PTX1 and PTX2;

(c) yessotoxins group toxins: YTX, 45 OH YTX, homo YTX and 45 OH homo YTX;

(d) azaspiracids group toxins: AZA 1, AZA 2 and AZA 3.

If new analogues of the above toxins appear, for which a toxicity equivalent factor (TEF) has been established, they shall be included in the analysis.

Total toxicity equivalence shall be calculated using TEFs as recommended by the European Food Safety Authority (EFSA) in Journal (2008) 589, 1-62 or any updated EFSA advice.

B. Methods other than those referred to in Part A, such as the LC-MS method, HPLC with appropriate detection, immunoassays and functional assays, such as the phosphatase inhibition assay, may be used as alternatives to, or as well as, the EURL LC-MS/MS method, provided that:

(a) either alone or combined they can detect at least the analogues identified in Part A; more appropriate criteria shall be defined where necessary;

(b) they meet the method performance criteria stipulated by the EURL LC-MS/MS method. Such methods must be intra-laboratory validated and successfully tested under a recognised proficiency test scheme. The European Reference Laboratory for marine biotoxins shall support activities toward inter-laboratory validation of the technique to allow for formal standardisation;

(c) their implementation provides an equivalent level of public health protection.

CHAPTER IV

DETECTION OF NEW OR EMERGING MARINE TOXINS

Chemical methods, alternative methods with appropriate detection, or the mouse bioassay can be used during the periodic monitoring of production areas and relaying areas for detecting new or emerging marine toxins on the basis of the national control programmes elaborated by the Member States.

ANNEX VI

PRACTICAL ARRANGEMENTS FOR OFFICIAL CONTROLS ON FISHERY PRODUCTS IN ACCORDANCE WITH ARTICLE 70

CHAPTER I

GENERAL PROVISIONS

A. **Organoleptic examinations**

Random organoleptic controls shall be carried out at all stages of production, processing and distribution. One aim of the controls is to verify compliance with the freshness criteria established in accordance with this Regulation. In particular, this includes verifying, at all stages of production, processing and distribution, that fishery products at least meet the baselines of freshness criteria established in accordance with Council Regulation (EC) No 2406/96 ([1]).

B. **Freshness indicators**

When the organoleptic examination gives rise to any doubt as to the freshness of the fishery products, samples may be taken and subjected to laboratory tests to determine the levels of total volatile basic nitrogen (TVB-N) and trimethylamine nitrogen (TMA-N) in accordance with the technical arrangements in Chapter II.

The competent authorities shall use the criteria laid down in this Regulation.

When the organoleptic examination gives cause to suspect the presence of other conditions that may affect human health, appropriate samples shall be taken for verification purposes.

C. **Histamine**

Random testing for histamine shall be carried out to verify compliance with the permitted levels laid down in Regulation (EC) No 2073/2005.

D. **Residues and contaminants**

Monitoring arrangements shall be established in accordance with Directive 96/23/EC and Decision 97/747/EC to control compliance with the EU legislation on:

— maximum residue limits for pharmacologically active substances, in accordance with Regulations (EU) No 37/2010 and (EU) No 2018/470;

— prohibited and non-authorised substances, in accordance with Regulation (EU) No 37/2010, Directive 96/22/EC and Decision 2005/34/EC;

— contaminants, in accordance with Regulation (EC) No 1881/2006 setting maximum levels for certain contaminants in food; and

— pesticide residues, in accordance with Regulation (EC) No 396/2005.

E. **Microbiological checks**

Where necessary, microbiological controls shall be performed in accordance with the relevant rules and criteria laid down in Regulation (EC) No 2073/2005.

F. **Parasites**

Risk-based testing shall take place to verify compliance with Part D of Chapter III of Section VIII of Annex III to Regulation (EC) No 853/2004 and Section I of Annex II to Regulation (EC) No 2074/2005.

([1]) Council Regulation (EC) No 2406/96 of 26 November 1996 laying down common marketing standards for certain fishery products (OJ L 334, 23.12.1996, p. 1).

G. **Poisonous fishery products**

Controls shall take place to ensure that:

1. fishery products derived from poisonous fish of the following families are not placed on the market: *Tetraodontidae*, *Molidae*, *Diodontidae* and *Canthigasteridae*;

2. fresh, prepared, frozen and processed fishery products belonging to the family *Gempylidae*, in particular *Ruvettus pretiosus* and *Lepidocybium flavobrunneum*, may be placed on the market only in wrapped/packaged form and are appropriately labelled to inform the consumer about preparation/cooking methods and the risk related to the presence of substances with adverse gastrointestinal effects. The scientific names of the fishery products and the common names shall appear on the label;

3. fishery products containing biotoxins such as ciguatera or other toxins dangerous to human health are not placed on the market. However, fishery products derived from live bivalve molluscs, echinoderms, tunicates and marine gastropods may be placed on the market if they have been produced in accordance with Section VII of Annex III to Regulation (EC) No 853/2004 and comply with the standards laid down in point 2 of Chapter V of that Section.

CHAPTER II

CONTROLS ON TOTAL VOLATILE BASIC NITROGEN (TVB-N)

A. **TVB-N limit values for certain categories of fishery products and analysis methods to be used**

1. Unprocessed fishery products shall be regarded as unfit for human consumption where organoleptic assessment has raised doubts as to their freshness and chemical checks reveal that the following TVB-N limits are exceeded:

   (a) 25 mg of nitrogen/100 g of flesh for the species referred to in point 1 of Part B of this Chapter;

   (b) 30 mg of nitrogen/100 g of flesh for the species referred to in point 2 of Part B of this Chapter;

   (c) 35 mg of nitrogen/100 g of flesh for the species referred to in point 3 of Part B of this Chapter;

   (d) 60 mg of nitrogen/100 g of whole fishery product used directly for the preparation of fish oil for human consumption, as referred to in the second paragraph of point 1 of Chapter IV.B of Section VIII of Annex III to Regulation (EC) No 853/2004; however, where the raw material complies with points (a), (b) and (c) of the first paragraph of that point, Member States may set limits at a higher level for certain species pending the establishment of specific Union legislation.

   The reference method to be used for checking the TVB-N limits involves distilling an extract deproteinised by perchloric acid as set out in Part C below.

2. Distillation as referred to in point 1 shall be performed using apparatus which complies with the diagram in Part D below.

3. The routine methods that may be used to check the TVB-N limit are as follows:

   (a) microdiffusion method described by Conway and Byrne (1933);

   (b) direct distillation method described by Antonacopoulos (1968);

   (c) distillation of an extract deproteinised by trichloracetic acid (Codex Alimentarius Committee on Fish and Fishery Products, 1968).

4. The sample shall consist of about 100 g of flesh, taken from at least three different points and mixed together by grinding.

Member States shall recommend that official laboratories use, as a matter of routine, the methods referred to above. Where the results are dubious or in the event of dispute regarding the results of analysis performed by one of the routine methods, only the reference method may be used to check the results.

B. **Species categories for which TVB-N limit values are fixed**

TVB-N limit values are fixed for the following species categories:

1. *Sebastes spp.*, *Helicolenus dactylopterus*, *Sebastichthys capensis*;

2. species belonging to the *Pleuronectidae* family (with the exception of halibut: *Hippoglossus spp.*);

3. *Salmo salar*, species belonging to the *Merlucciidae* family, species belonging to the *Gadidae* family.

C. **Reference procedure for determining the concentration of TVB-N in fish and fishery products**

1. Purpose and area of application

This method describes a reference procedure for identifying the nitrogen concentration of TVB-N in fish and fishery products. The procedure is applicable at TVB-N concentrations of 5 mg/100 g to at least 100 mg/100 g.

2. Definitions

'TVB-N concentration' means the nitrogen content of volatile nitrogenous bases as determined by the reference procedure described.

'Solution' means an aqueous solution as follows:

(a) perchloric acid solution = 6 g/100 ml;

(b) sodium hydroxide solution = 20 g/100 ml;

(c) hydrochloric acid standard solution 0,05 mol/l (0,05 N). When using an automatic distillation apparatus, titration must take place with a hydrochloric acid standard solution of 0,01 mol/l (0,01 N);

(d) boric acid solution = 3 g/100 ml;

(e) silicone anti-foaming agent;

(f) phenolphtalein solution = 1 g/100 ml 95 % ethanol;

(g) indicator solution (Tashiro mixed indicator) = 2 g methyl-red and 1 g methylene-blue dissolved in 1 000 ml 95 % ethanol.

3. Brief description

The volatile nitrogenous bases are extracted from a sample using a solution of 0,6 mol/l perchloric acid. After alkalinisation, the extract undergoes steam distillation and the volatile base components are absorbed by an acid receiver. The TVB-N concentration is determined by titration of the absorbed bases. The concentration is expressed in mg/100 g.

4. Chemicals

Unless otherwise indicated, reagent-grade chemicals shall be used. The water used shall be either distilled or demineralised and of at least the same purity.

5. The following instruments and accessories shall be used:

(a) a meat grinder to produce a sufficiently homogenous fish mince;

(b) high-speed blender with a speed of 8 000 to 45 000 revolutions/min;

(c) fluted filter, diameter 150 mm, quick-filtering;

(d) burette, 5 ml, graduated to 0,01 ml;

(e) apparatus for steam distillation. The apparatus must be able to regulate various amounts of steam and produce a constant amount of steam over a given period of time. It must ensure that, during the addition of alkalising substances, the resulting free bases cannot escape.

6. Execution of the reference procedure

When working with perchloric acid, which is strongly corrosive, necessary caution and preventive measures shall be taken. The samples shall be prepared as soon as possible after their arrival, in accordance with the following instructions:

(a) Preparing the sample

The sample to be analysed is ground carefully using a meat grinder as described in point 5(a). An amount of 10 g ± 0,1 g of the ground sample is weighed out into a suitable container. This is mixed with 90,0 ml perchloric acid solution, homogenised for two minutes with a blender as described in point 5(b), and then filtered.

The extract thereby obtained can be kept for at least seven days at a temperature of between approximately 2 °C and 6 °C;

(b) Steam distillation

50,0 ml of the extract obtained in accordance with point (a) is put into an apparatus for steam distillation as described in point 5(e). For a later check on the extract's alkalinisation, several drops of phenolphtalein solution are added. After adding a few drops of silicone anti-foaming agent, 6,5 ml of sodium hydroxide solution is added to the extract and steam distillation begins immediately.

The steam distillation is regulated so that around 100 ml of distillate is produced in 10 minutes. The distillation outflow tube is submerged in a receiver with 100 ml boric acid solution, to which three to five drops of the indicator solution have been added. After exactly 10 minutes, distillation is ended. The distillation outflow tube is removed from the receiver and washed out with water. The volatile bases contained in the receiver solution are determined by titration with hydrochloric acid standard solution.

The pH of the end point must be 5,0 ± 0,1;

(c) Titration

Duplicate analyses are required. The applied method is correct if the difference between the duplicates is not greater than 2 mg/100 g;

(d) Blank

A blind test is carried out as described in point (b). Instead of the extract, 50,0 ml perchloric acid solution is used.

7. Calculation of TVB-N concentration

By titration of the receiver solution with hydrochloric acid standard solution, the TVB-N concentration is calculated using the following equation:

$$\text{TVB-N (expressed in mg/100 g sample)} = \frac{(V_1 - V_0) \times 0{,}14 \times 2 \times 100}{M}$$

where:

V1 = volume of 0,01 mol hydrochloric acid standard solution in ml for sample;

V0 = volume of 0,01 mol hydrochloric acid standard solution in ml for blank;

M = mass of sample in g.

In addition, the following is required:

(a) duplicate analyses. The applied method is correct if the difference between duplicates is not greater than 2 mg/100 g;

(b) equipment check. The equipment is checked by distilling solutions of NH_4Cl equivalent to 50 mg TVB-N/100 g;

(c) standard deviations. The standard deviation for repeatability Sr = 1,20 mg/100 g and the standard deviation for reproducibility SR = 2,50 mg/100 g are calculated.

D. **TVB-N steam distillation apparatus**