Proposal for a Regulation of the European Parliament and of the Council laying down specific hygiene rules for food of animal origin

(2000/C 365 E/03)

(Text with EEA relevance)

COM(2000) 438 final — 2000/0179(COD)

(Submitted by the Commission on 14 July 2000)

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

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

Having regard to the proposal from the Commission,

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

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

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

Whereas:

(1) European Parliament and Council Regulation . . . (on the hygiene of foodstuffs) lays down the basic hygiene rules to be respected by food operators in order to ensure food safety.

(2) Certain food may present specific hazards to human health requiring the setting of specific hygiene rules in order to ensure food safety.

(3) This is in particular the case for food of animal origin in which microbiological and chemical hazards have frequently been reported.

(4) In the context of the common agricultural policy, specific health rules affecting the production and placing on the market of products included in the list contained in Annex I to the Treaty have already been established.

(5) These health rules have ensured that barriers to trade for the products concerned were removed, thus contributing to the creation of the internal market, whilst ensuring a high level of protection of public health.

(6) These specific rules are contained in a large number of Directives and in particular in:

— Council Directive 64/433/EEC of 26 June 1964, on health conditions for the production and marketing of fresh meat [1], as last amended by Directive 95/23/EC [2],

— Council Directive 71/118/EEC of 15 February 1971, on health problems affecting the production and placing on the market of fresh poultry meat [3], as last amended by Directive 97/79/EC [4],

— Council Directive 77/96/EEC of 21 December 1976, on the examination for trichinae (*Trichinella spiralis*) upon importation from third countries of fresh meat derived from domestic swine [5], as last amended by Directive 94/59/EC [6],

— Council Directive 77/99/EEC of 21 December 1976, on health problems affecting the production and marketing of meat products and certain other products of animal origin [7], as last amended by Directive 97/76/EC [8],

— Council Directive 89/437/EEC of 20 June 1989, on hygiene and health problems affecting the production and the placing on the market of egg products [9], as last amended by Directive 96/23/EC,

— Council Directive 91/492/EEC of 15 July 1991, laying down the health conditions for the production and the placing on the market of live bivalve molluscs [10], as last amended by Directive 97/79/EC,

— Council Directive 91/493/EEC of 22 July 1991, laying down the health conditions for the production and the placing on the market of fishery products [11], as last amended by Directive 97/79/EC,

— Council Directive 91/495/EEC of 27 November 1990, concerning public health and animal health problems affecting the production and placing on the market of rabbit meat and farmed game meat [12], as last amended by the act of accession of Austria, Finland and Sweden,

[1] OJ 121, 29.7.1964, p. 2101/64.
[2] OJ L 243, 11.10.1995, p. 7.
[3] OJ L 55, 8.3.1971, p. 23.
[4] OJ L 24, 30.1.1998, p. 31.
[5] OJ L 26, 31.1.1977, p. 8.
[6] OJ L 315, 8.12.1994, p. 18.
[7] OJ L 26, 31.1.1977, p. 85.
[8] OJ L 10, 16.1.1998, p. 25.
[9] OJ L 212, 22.7.1989, p. 87.
[10] OJ L 168, 24.9.1991, p. 1.
[11] OJ L 268, 24.9.1991, p. 15.
[12] OJ L 268, 24.9.1991, p. 41.

— Council Directive 92/45/EEC of 16 June 1992, on public health and animal health problems relating to the killing of wild game and the placing on the market of wild-game meat [1], as last amended by Directive 97/79/EC,

— Council Directive 92/46/EEC of 16 June 1992, laying down the health rules for the production and placing on the market of raw milk, heat-treated milk and milk-based products [2], as last amended by Directive 96/23/EC,

— Council Directive 92/48/EEC of 16 June 1992, laying down the minimum hygiene rules applicable to fishery products caught on board certain vessels in accordance with Article 3(1)(a)(i) of Directive 91/493/EEC [3],

— Council Directive 92/118/EEC 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 [4], as last amended by Directive 97/79/EC,

— Council Directive 94/65/EC of 14 December 1994, laying down the requirements for the production and placing on the market of minced meat and meat preparations [5].

(7) With regard to public health, these Directives contain common principles such as those related to the responsibilities of manufacturers of products of animal origin, the obligations of the competent authorities, the technical requirements for the structure and operation of establishments handling products of animal origin, the hygiene requirements which must be complied with in these establishments, the procedures for the approval of establishments, the conditions for storage and transport, the health marking of the products, etc.

(8) Many of these principles are the same as the principles laid down in Regulation . . . (on the hygiene of foodstuffs) which serve as a common basis for all food.

(9) This common basis allows simplifying the Directives referred to above.

(10) These specific rules can be further simplified by eliminating possible inconsistencies which have arisen at the time of their adoption.

(11) With the introduction of the HACCP procedure, food operators must develop methods to control and reduce or eliminate biological, chemical or physical hazards.

(12) The above elements lead to a complete recasting of the specific hygiene rules and to more transparency.

(13) The principle objective of the recasting of the general and specific hygiene rules is to ensure a high level of consumer protection with regard to food safety.

(14) It is therefore necessary to maintain and, where required to ensure consumer protection, tighten detailed hygiene rules for products of animal origin.

(15) The primary production, the transport of animals, the slaughter and processing facilities up to the point of sale at the retailers level must be considered as interacting entities where animal health, animal welfare and public health are intertwined.

(16) This requires adequate communication between the different stakeholders along the food chain.

(17) Microbiological criteria, targets and/or performance standards may be laid down in accordance with the appropriate procedures foreseen for the purpose in Regulation . . . (on the hygiene of foodstuffs); awaiting the setting of new microbiological criteria, the criteria fixed in the Directives referred to above shall continue to apply.

(18) In the case of establishments with a limited production capacity for handling food of animal origin and which are the subject of particular constraints or serving the local market only, Member States must be given the tools necessary to define specific hygiene rules for such establishments provided that the objectives of food safety are not compromised and taking into account that in certain cases the local market may exceed national borders.

(19) Imported food of animal origin must be of at least the same or an equivalent health standard as that produced within the Community, and uniform procedures to ensure that this objective is attained must be introduced.

(20) The present recast means that the existing hygiene rules can be repealed; this is achieved through Council Directive . . ./. . ./EC repealing certain Directives on the hygiene of foodstuffs and on the health conditions for the production and placing on the market of certain products of animal origin intended for human consumption, and amending Directives 89/662/EEC and 91/67/EEC.

[1] OJ L 268, 14.9.1992, p. 35.
[2] OJ L 268, 14.9.1992, p. 1.
[3] OJ L 187, 7.7.1992, p. 41.
[4] OJ L 62, 15.3.1993, p. 49.
[5] OJ L 368, 31.12.1994, p. 10.

(21) The products covered by this Regulation are included in Annex I to the Treaty.

(22) Scientific advice underpins Community legislation on food hygiene; to this end, the scientific committees in the field of consumer protection and food safety set up by Commission Decision 97/579/EC of 23 July 1997 [1] and the Scientific Steering Committee set up by Commission Decision 97/404/EC of 10 June 1997 [2] should be consulted wherever necessary.

(23) In order to take account of technical and scientific progress, a procedure should be available to adopt certain requirements called for in the present Regulation; equally, a procedure should be available enabling, where necessary, a smooth transition to the required health level.

(24) Since the measures necessary for the implementation of this Regulation are measures of general scope within the meaning of Article 2 of Council Decision 1999/468/EC of 28 June 1999 laying down the procedures for the exercise of implementing powers conferred on the Commission [3], they should be adopted by use of the regulatory procedure provided for in Article 5 of that Decision,

HAVE ADOPTED THIS REGULATION:

Article 1

Scope

This Regulation lays down the specific hygiene rules to ensure the hygiene of food of animal origin.

Article 2

Definitions

For the purpose of this Regulation, the definitions laid down in Regulation . . . (on the hygiene of foodstuffs) shall apply. In addition, the definitions laid down in Annex I to the present Regulation shall apply.

Article 3

General obligation

In addition to the requirements laid down in Regulation . . . (on the hygiene of foodstuffs), food business operators shall ensure that food of animal origin is obtained and marketed in accordance with Annex II to the present Regulation.

Article 4

Imports from third countries

Food of animal origin imported from third countries shall comply with the requirements laid down in Annex III to the present Regulation.

Article 5

Amending of Annexes and implementing measures

In accordance with the procedure referred to in Article 6,

1. Provisions in the Annexes to this Regulation may be repealed, amended, adapted or supplemented in order to take account of the development of codes to good practice, the implementation of food safety programmes by food operators, new risk assessments and the possible setting of food safety targets and/or performance standards.

2. Implementing measures to ensure the uniform implementation of the Annexes may be taken.

Article 6

Standing Committee procedure

1. The Commission shall be assisted by the Standing Veterinary Committee, instituted by Council Decision 68/361/EEC [4].

2. Where reference is made to this paragraph, the Regulatory procedure laid down in Article 5 of Decision 1999/468/EC shall apply, in compliance with Article 7(3) and Article 8 thereof.

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

Article 7

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

It shall apply from 1 January 2004.

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

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[1] OJ L 237, 28.8.1997, p. 18.

[2] OJ L 169, 27.6.1997, p. 85.

[3] OJ L 184, 17.7.1999, p. 23.

[4] OJ L 225, 18.10.1968, p. 23.

ANNEX I

DEFINITIONS

1. **Meat**

1.1. *meat:* all parts of animals which are fit for human consumption;

1.1.1. *meat of domestic ungulates:* meat of domestic bovine (including Bubalus and Bison species), porcine, ovine and caprine animals, and domestic solipeds;

1.1.2. *poultry meat:* meat of farmed birds including birds which are not considered as domestic but which are farmed as domestic animals (farmed game birds);

1.1.3. *meat of lagomorphs:* meat of rabbits, hares and rodents farmed for human consumption;

1.1.4. *wild game meat:* meat of:

— wild land mammals which are hunted, including mammals living in enclosed territory under conditions of freedom similar to those of wild game,

— wild birds which are hunted;

1.1.5. *farmed game meat:* meat of farmed even-toed ungulate game mammals (including Cervidae and Suidae) and of farmed ratites;

1.2. *large wild game:* wild mammals of the Orders Artiodactyla, Perissodactyla and Marsupialia, as well as other mammal species classified under national hunting legislation as large game;

1.3. *small wild game:* wild game birds and wild game mammals not classified as large game;

1.4. *carcase (domestic ungulates):* the whole body of a slaughtered domestic ungulate after bleeding, evisceration and removal of the limbs at the carpus and the tarsus, removal of the head, tail and where appropriate the udder, and in addition, in the case of bovine animals, sheep, goats and solipeds, after flaying;

1.5. *carcase (poultry):* the whole body of a bird after bleeding, plucking and evisceration; however, removal of the heart, liver, lungs, gizzard, crop and kidneys, sectioning of the legs at the tarsus and removal of the head, oesophagus or trachea are optional;

1.6. *New-York dressed poultry:* poultry carcases for which the evisceration has been deferred;

1.7. *fresh meat:* meat, including meat which is vacuum-wrapped or wrapped in a controlled atmosphere, which has not undergone any preserving process other than chilling, freezing or quick-freezing to ensure preservation;

1.8. *offals:* meat other than that of the carcase even if it remains naturally connected to the carcase;

1.9. *viscera:* offal from the thoracic, abdominal and pelvic cavities, including the trachea and oesophagus, and in birds the crop;

1.10. *slaughterhouse:* an establishment for slaughtering animals, the meat of which is intended for sale for human consumption, including any place available in connection therewith for the confinement of animals while awaiting slaughter there;

1.11. *cutting plant:* an establishment used for boning and/or cutting up carcases, parts of carcases and other edible parts of animals including premises adjacent to sale points where these operations are carried out for supplying the consumer or other sale points;

1.12. *game collection centre:* an establishment where killed wild game is kept prior to being transported to a game handling establishment;

1.13. *game handling establishment:* an establishment for the skinning of game and the further handling of game meat obtained after hunting;

1.14. *minced meat:* boned meat which has been reduced into fragments or passed through a spiral screw mincer;

1.15. *mechanically separated meat:* product resulting from the mechanical separation of meat left on the bones after boning, so that the cellular structure of the meat is broken;

1.16. *meat preparations:* fresh meat including minced meat which has had foodstuffs, seasonings or additives added to it or which has undergone a treatment insufficient to modify the internal cellular structure of the meat and thus to eliminate the characteristics of the fresh meat.

2. **Live bivalve molluscs**

2.1. *bivalve molluscs:* filter-feeding lamellibranch molluscs, and by extension, echinoderms, tunicates and marine gastropods;

2.2. *marine biotoxins:* poisonous substances accumulated by bivalve molluscs feeding on plankton containing toxins;

2.3. *conditioning:* the storage of live bivalve molluscs coming from class A areas in tanks or any other installation containing clean sea water or in natural sites to remove sand, mud or slime and to improve organoleptic qualities;

2.4. *gatherer:* 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:* any sea, estuarine or lagoon area containing natural beds of bivalve molluscs or sites used for cultivation of bivalve molluscs from which live bivalve molluscs are taken;

2.6. *relaying area:* any sea, estuarine or lagoon area approved by the competent authority, 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:* any approved on-shore or off-shore installation for the reception, conditioning, washing, cleaning, grading and wrapping of live bivalve molluscs fit for human consumption;

2.8. *purification centre:* an approved establishment with tanks fed by clean sea water in which live bivalve molluscs are placed for the time necessary to remove microbiological contamination, so making them fit for human consumption;

2.9. *relaying:* an operation whereby live bivalve molluscs are transferred to approved sea, lagoon or estuarine areas under the supervision of the competent authority for the time necessary to remove contamination. This does not include the specific operation of transferring bivalve molluscs to areas more suitable for further growth or fattening;

2.10. *faecal coliform:* facultative aerobic, gram-negative, non-sporeforming, cytochrome oxidase negative, rod-shaped bacteria that are able to ferment lactose with gas production in the presence of bile salts, or other surface active agents with similar growth-inhibiting properties, at 44 °C ± 0,2 °C within 24 hours;

2.11. *E. coli:* faecal coliform which also forms indole from tryptophan at 44 °C ± 0.2 °C within 24 hours;

2.12. *clean seawater:* sea water, brackish water or seawater preparations made from fresh water, free from microbiological contamination, objectionable substances and/or toxic marine plankton in such quantities likely to adversely affect the health quality of bivalve molluscs and fishery products.

3. **Fishery products**

3.1. *fishery products:* all seawater or freshwater animals, wild or farmed, other than live bivalve molluscs, aquatic mammals and frogs, or parts of these animals including their roes and livers;

3.2. *aquaculture products:* all fishery products born and raised in controlled conditions until placed on the market as a foodstuff as well as seawater or freshwater fish or crustaceans caught in their natural environment when juvenile and kept until they reach the desired commercial size for human consumption. Fish and crustaceans of commercial size caught in their natural environment and kept alive to be sold at a later date are not considered to be aquaculture products if they are merely kept alive without any attempt being made to increase their size or weight;

3.3. *factory vessel:* any vessel, fishing or not, on which fishery products undergo one or more of the following operations followed by wrapping: filleting, slicing, skinning, mincing, or processing; fishing vessels in which only crustaceans and molluscs are cooked on board are not deemed to be factory-vessels;

3.4. *freezer vessel:* any vessel, fishing or not, on board which freezing of fishery products is carried out, where appropriate after preparatory work such as bleeding, heading, gutting and removal of fins. Where necessary, these operations are followed by wrapping and/or packaging;

3.5. *mechanically recovered fish flesh:* flesh obtained by mechanical means from gutted whole fish or bones after filleting;

3.6. *clean seawater:* see definition at point 2.12;

3.7. *clean river or lake water:* river or lake water free from microbiological contamination or any objectionable substances in quantities likely to adversely affect the health quality of fishery products.

4. **Eggs**

4.1. *eggs:* eggs of birds in shell, fit for direct consumption or for the preparation of egg products, other than broken, incubated or cooked eggs;

4.2. *liquid egg:* untreated egg contents after removal of the shell;

4.3. *egg production farm:* farm for the production of eggs intended for human consumption;

4.4. *cracked eggs:* eggs with a damaged but unbroken shell, with intact membranes.

5. **Milk**

5.1. *milk:* the lactic secretion of the mammary gland free of colostrum;

5.2. *raw milk:* milk which has not been heated beyond 40 °C; treatments such as homogenisation and standardisation which have an effect on the quality of the milk may be carried out;

5.3. *milk production holding:* a holding in which one or more cows, ewes, goats, buffaloes or females of other species are kept to supply milk;

5.4. *dairy establishment:* an establishment for the processing of milk, or for the further processing of already processed milk.

6. **Frogs' legs and snails**

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

6.2. *snails:* terrestrial gastropods of the species Helix pomatia Linné, Helix aspersa Muller, Helix lucorum and species of the family Achatinidae.

7. **Processed products**

7.1. *processed product:* foodstuff resulting from the application to unprocessed products of a treatment such as heating, smoking, curing, maturing, drying, marinating, etc., or a combination of these processes and/or products; substances necessary for their manufacture or for giving specific characteristics to the products may be added;

7.2. *meat products:* products resulting from the application of a treatment to meat;

7.3. *processed fish products:* fishery products to which a treatment has been applied;

7.4. *egg products:* products resulting from the application of a treatment to eggs or to the various components or mixtures thereof after removal of the shell and membranes. They may be partially supplemented by other foodstuffs or additives. They may be liquid, concentrated, dried, crystallised, frozen, quick-frozen or coagulated.

7.5. *milk products:* products resulting from the application to raw milk of a treatment, such as heat-treated drinking milk, milk powder, whey, butter, cheese, yoghurt (whether or not with acid, salt, spices or fruits added) and reconstituted drinking milk;

7.6. *rendered animal fat:* fat derived from rendering meat, including bones, and intended for human consumption;

7.7. *greaves:* the protein-containing residue of rendering, after partial separation of fat and water;

7.8. *gelatine:* 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 (including fish and poultry);

7.9. *treated stomachs, bladders and intestines:* stomachs, bladders and intestines which 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. *composite product:* a foodstuff containing products, whether unprocessed or processed, of animal and plant origin;

8.2. *re-wrapping:* the removal of the original wrapping from the product for replacing it by a new wrapping, possibly after having applied to the unwrapped product physical operations such as cutting or slicing;

8.3. *wholesale market:* means a food business which includes several separate units which share common installations and sections where foodstuffs are sold to food businesses and not to the final consumer.

ANNEX II

SPECIFIC REQUIREMENTS

Preface

1. This Annex applies to unprocessed and processed products of animal origin. Composite products are not subject to the requirements of the present Annex. However, it must be ensured that possible hazards resulting from the use of ingredients of animal origin are identified and controlled, and where necessary eliminated or reduced to acceptable levels.

2. Unless specified otherwise, the requirements laid down in this Annex shall not apply to the point of retail trade.

3. Where approval of establishments is required under the present Annex, the following shall apply:

   (a) approved establishments shall be given an approval number to which codes shall be added to indicate the types of products of animal origin manufactured. For wholesale markets, the approval number may be completed with a secondary number indicating units or groups of units selling or manufacturing products of animal origin;

   (b) Member States shall maintain up-to-date lists of approved establishments with their respective approval numbers.

   In addition to the above, the approval is also required for wholesale markets where unprocessed or processed products of animal origin are handled.

4. Where required under the present Annex, products of animal origin shall carry an oval health mark in accordance with the following rules:

   (a) the health mark shall be applied during or immediately after manufacture in the establishment in such a way that it cannot be re-used;

   (b) the health mark must be legible, indelible and the characters must be easily decipherable; it must be clearly displayed for the controlling authorities;

   (c) the health mark shall carry the following information:

      — the name of the country of dispatch, which may be written out in full or shown as an abbreviation as follows:

        A, B, DK, D, EL, E, F, FIN, IRL, I, L, NL, P, S, UK,

      — the approval number of the establishment;

   (d) the health 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 health mark may also be an irremovable tag made of a resistant material.

      For products of animal origin which are placed in transport containers or large packages and intended for further handling, processing or wrapping in another establishment, the health mark may be applied to the external surface of the container or packaging. In this event, the recipient food operator must maintain a record of the quantities, type, origin and the destination of the products of animal origin;

   (e) the health marking of individual products of animal origin contained in a retail sale unit is not necessary if the health mark is applied to the external surface of that retail sales unit;

   (f) when the health mark is applied directly to products of animal origin, the colours used shall be authorised in accordance with Community rules on the use of colouring substances in foodstuffs;

   (g) if products of animal origin are unwrapped and subsequently re-wrapped, handled or further processed in another establishment, the latter establishment must be approved and apply its own health mark to the product.

   Products to which the above health mark must not be applied shall carry a mark that allows the origin of the products to be traced and that is distinctly different from the oval health mark.

5. Any substance other than potable water applied to products for hazard reduction, as well as their conditions for use, must be approved in accordance with the procedure referred to in Article 6, after the opinion of the Scientific Committee. The implementation of this paragraph shall be without prejudice to the correct implementation of the requirements of the present Regulation.

6. Where necessary, special conditions may be granted by the competent authority in particular in order to take account of traditional production methods.

7. The present Annex shall apply without prejudice to the relevant animal health rules and without prejudice to more stringent rules laid down for the prevention and control of certain transmissible spongiform encephalopathies.

SECTION I

Meat of domestic ungulates

The animals, or where appropriate each batch of animals sent for slaughter must be identified so that its origin can be traced.

Animals may not come from a holding or an area subject to a movement prohibition for reasons of animal health unless permitted by the competent authority.

CHAPTER I

CONDITIONS FOR SLAUGHTERHOUSES

Slaughterhouses must be constructed and equipped in accordance with the following conditions:

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

   Where considered necessary by the competent authority, they must also have separate lockable premises 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.

   The size of the lairage facilities must enable to ensure the respect of the welfare of the animals. Their lay-out must facilitate ante-mortem inspections including the identification of the animals or groups of animals.

2. Have a slaughter room and where appropriate a sufficient number of rooms appropriate to the operations being carried out and be constructed in such a way as to avoid contamination of the meat by ensuring that:

   (a) there is a distinctly separated area for stunning and bleeding;

   (b) in the case of pig slaughtering, there is a separation of scalding, depilation, scraping and singeing operations of pigs from other operations;

   (c) there are installations ensuring that there is no contact between the meat and the floors, walls or equipment;

   (d) where slaughter lines are operated, these are designed to allow a constant progress of the slaughter process and avoid cross-contamination between the different parts of the slaughter line;

   where different slaughter lines are operated in the same premises, adequate separation of these lines is ensured in order to prevent cross-contamination;

   (e) the following operations are carried out separately from the operations during which meat is obtained:

   — emptying stomachs and intestines; in slaughterhouses with a limited throughput, the competent authority may allow the cleaning of stomachs and intestines in the slaughter room at times when no slaughtering is taking place,

   — further handling of guts and tripe, if this is carried out in the slaughterhouse,

   — preparation and cleaning of other offal; skinned heads must be handled at a sufficient distance from meat and other offal, if these operations are carried out in the slaughterhouse and do not take place at the slaughter line;

   (f) there is a separate place for packaging offal if this is done in the slaughterhouse;

   (g) there is an appropriate area, sufficiently protected, for dispatching meat.

3. They must have facilities for disinfecting tools with hot water supplied at not less than 82 °C, or an alternative system having an equivalent effect.

4. The equipment for washing hands used by the staff engaged in handling exposed meat shall be provided with taps that are non-hand operable.

5. Lockable premises must be provided for the refrigerated storage of detained meat and for the storage of meat declared unfit for human consumption.

6. There must be a separate place with appropriate facilities for the cleaning and disinfection of means of transport of livestock. These places and facilities are not compulsory if officially authorised places and facilities exist nearby.

7. They must have lockable premises 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. The premises must be cleaned and disinfected under official supervision before slaughter is resumed.

8. If manure and stomach or gut content is stored in the slaughterhouse precincts, they must have a special area or place for that purpose.

CHAPTER II

CONDITIONS FOR CUTTING PLANTS

Cutting plants must:

1. Be constructed so as to allow constant progress of the operations or ensure separation between the different production batches.

2. Have rooms for the separate storage of packed and exposed meat, unless stored at different times.

3. Have cutting rooms equipped to ensure that the cold chain is not interrupted during cutting operations.

4. Have equipment for washing hands provided with taps that are non-hand operable to be used by the staff engaged in handling exposed meat.

5. They must have facilities for disinfecting tools with hot water supplied at not less than 82 °C, or an alternative system having an equivalent effect.

CHAPTER III

SLAUGHTER HYGIENE

1. After arrival in the slaughterhouse, the slaughter of the animals shall not be unduly delayed. However, where required for welfare reasons, animals must be given a resting period before slaughter. Only live animals intended for slaughter may be brought into the slaughter premises, with the exception of animals that have undergone emergency slaughter outside the slaughterhouse, farmed game slaughtered at the place of production and wild game.

   Animals which have died during transport or in the lairages shall not be used for human consumption.

2. The state of cleanliness of the animals must be such as not to present an unnecessary risk of contaminating the meat during slaughter operations.

3. Before slaughter, animals must be presented to the competent authority in order to be submitted to an ante-mortem inspection. Slaughterhouse operators shall follow the instructions of the competent authority in order to ensure that the ante-mortem inspection is carried out under suitable conditions.

4. Slaughter animals brought into the slaughter hall must be slaughtered without undue delay.

5. Stunning, bleeding, skinning, dressing and evisceration must be carried out without undue delay in such a way that contamination of the meat is avoided. It must in particular be ensured that:

   — the trachea and oesophagus remain intact during bleeding, except in the case of ritual slaughter,

   — during the removal of hides and fleece, contact between the outside of the skin and the carcase is prevented, and that operators and equipment coming into contact with the outer surface of hides and fleece do not touch the meat,

   — measures are taken to prevent the spillage of digestive tract contents during evisceration and that evisceration is completed as soon as possible after stunning,

   — removal of the udder does not result in contamination of the carcase with milk.

6. Skinning must be complete; however, the skinning of the head is not required:

   — in the case of heads of calves and ovines, provided that such heads are handled so as to avoid contamination of meat,

— if such heads, including tongues and brains, are not intended for human consumption.

When not skinned, pigs 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 provided that pigs are thoroughly rinsed afterwards with potable water.

7. The carcases must not contain visible faecal contamination. Any visible contamination must be removed by trimming.

8. Carcases and offal shall not come into contact with floors, walls or work stands.

9. Slaughtered animals must be presented to the competent authority in order to be submitted to a post-mortem inspection. Slaughterhouse operators shall follow the instructions of the competent authority in order to ensure that the post-mortem inspection is carried out under suitable conditions.

Parts of the slaughtered animals that have been removed before the post-mortem inspection is performed, must remain identifiable as belonging to a given carcase. However, provided it shows no pathological symptom or lesion, the penis may be discarded immediately.

Both kidneys must be removed from their fatty covering and peri-renal capsule.

If the blood or offals of several animals are collected in the same container before completion of the 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.

Carcases and offal shall not come into contact with each other before post-mortem inspection is finalised.

10. After post-mortem inspection:

— the tonsils of bovine animals under six weeks and pigs must be removed hygienically,

— the parts unfit for human consumption must be removed at once from the clean sector of the establishment,

— meat detained or declared unfit for human consumption and inedible by-products must not come into contact with meat declared fit for human consumption,

— viscera or parts of viscera which have not been removed from the carcase before post-mortem inspection, except for the kidneys or unless specified elsewhere, must be removed entirely if possible and as quickly as possible.

11. After completion of slaughter and post-mortem inspection procedures, the meat must be stored in accordance with the requirements laid down in Chapter IX of the present Section.

12. 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 the operations carried out on the different species. Separate facilities for the reception and storage of carcases of farmed game slaughtered at the farm and for wild game must be available.

CHAPTER IV

HYGIENE DURING CUTTING AND BONING

1. Carcases of domestic ungulates may be cut into half-carcases, and half-carcases into quarters or a maximum of three pieces in approved 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 the growth of pathogenic micro-organisms or the formation of toxins or other pathogenic substances, and in particular:

(a) Meat intended for cutting must be brought into the work rooms progressively as needed.

(b) During cutting, boning, slicing, dicing, wrapping and packaging, the cooling of the meat must not be interrupted.

Where meat is boned and cut prior to reaching the temperatures for storage and transport provided for in Chapter IX of the present Section, such meat must be transferred directly from the slaughter premises to the cutting room, or after a waiting period in the cold store. As soon as it is cut and where appropriate packaged, the meat must be chilled to 7 °C for carcase meat and 3 °C for offals.

(c) Where the premises are approved for the cutting of meat of different species, precautions must be taken to avoid cross-contamination, where necessary by separation of the operations of the different species in either space or time.

CHAPTER V

SPECIAL CONDITIONS

Member States may adapt the requirements laid down in Chapters I and II with a view to accommodate the needs of establishments situated in regions suffering from special geographical constraints or affected by supply difficulties, or those serving the local market. Hygiene shall not be compromised. The Member States shall inform the Commission of the details of such special conditions.

Establishments serving the local market shall mean slaughterhouses and cutting plants marketing their meat in the vicinity of the place where such slaughterhouses and cutting plants are situated.

CHAPTER VI

CASUALTY AND EMERGENCY SLAUGHTER

1. Meat from animals that have undergone emergency slaughter following serious physiological or functional problems is not authorised for human consumption.

2. Meat from animals that have undergone emergency slaughter outside the slaughterhouse following an accident is authorised for human consumption on the local market if the following requirements are fulfilled:

   — the animal is examined by a veterinarian before slaughter; however, the animal may be slaughtered before examination by a veterinarian when required for welfare reasons,

   — the animal is slaughtered after stunning, bled and possibly eviscerated on the spot; the veterinarian may authorise shooting in special cases,

   — the slaughtered and bled animal is transported as quickly as possible after slaughter under satisfactory hygiene conditions to a slaughterhouse approved for that purpose. Where the slaughtered animal cannot be brought to such a slaughterhouse within an hour, it must be transported in a container or means of transport in which the ambient temperature is maintained between 0 °C and 4 °C. Evisceration must be carried out as soon as possible. If an excessively long period elapses between slaughter and evisceration, the official veterinarian may require that special checks are carried out at post-mortem inspection. If evisceration is carried out on the spot, the viscera must accompany the carcase to the slaughterhouse,

   — during transport to the slaughterhouse, the slaughtered animal and where appropriate the viscera are transported hygienically and are accompanied by a certificate issued by the veterinary surgeon who has ordered slaughter attesting to the outcome of the ante-mortem inspection, the time of slaughter and the nature of any treatment administered to the animal and, if appropriate, the result of the inspection of the viscera,

   — the slaughtered animal is declared wholly or partly fit for human consumption after having been submitted to a detailed post-mortem examination, where necessary supplemented by a bacteriological and residue examination,

   — the meat is not provided with the health mark but with an identification mark approved by the competent authority.

3. Meat from animals that have undergone emergency slaughter following an accident in a slaughterhouse may be marketed if the animals have been submitted to an examination before slaughter, if no other serious lesions than those which occurred immediately before slaughter have been found and if it has been declared wholly or partly fit for human consumption after having been submitted to a detailed post-mortem examination.

CHAPTER VII

APPROVAL AND REGISTRATION OF ESTABLISHMENTS

Slaughterhouses, cutting plants and cold stores must be approved by the competent authority and be given an approval number. However, low capacity establishments distributing their products on the local market only may be registered. Such establishments shall not apply the health mark referred to in Chapter VIII.

CHAPTER VIII

HEALTH MARKING

1. Marking of meat must be carried out under the responsibility of an official veterinarian, who for this purpose, must supervise the marking and keep under his control the health stamp to be applied to the meat which must be handed over to auxiliaries or designated plant employees at the time of marking and for the length of time required for this purpose.

Health marks may not be removed unless the meat is further worked upon in another separate approved establishment where the original mark must be replaced by that establishment's own number.

2. After completion of the post-mortem inspection, carcases, half carcases, quarters and carcases cut into three pieces must be stamped in ink or hot-branded on their external surface so as to ensure that the slaughterhouse of origin is easily identifiable.

3. Livers must be hot-branded, unless wrapped or packaged.

4. In the case of cut meat and packaged cut offal obtained in a cutting plant the mark must be applied to a label fixed to the packaging, or printed on the packaging. However, when cut meat or offal is wrapped, the label may be affixed to the wrapping in such a way that the label is destroyed when the wrapping is opened.

5. The health mark may include an indication of the official veterinarian who carried out the health inspection of the meat.

CHAPTER IX

STORAGE, TRANSPORT AND MATURATION

1. Except where warm cutting and boning is practised, meat must be chilled after post-mortem inspection to an internal temperature of not more than 7 °C for carcase meat and 3 °C for offals along a chilling curve which ensures a constant decrease of the temperature. During the chilling operations, there must be adequate ventilation in order to prevent condensation on the surface of the meat.

   For technical reasons relating to maturation of the meat, a derogation may be granted on a case-by-case basis for the transportation of meat to cutting plants or butcher shops located in the immediate vicinity of a slaughterhouse, provided that such transport takes not more than one hour.

2. Meat intended for freezing must be frozen without undue delay, taking into account where necessary a stabilisation period before freezing.

3. Exposed meat must be stored in a separate room from packaged meat, unless stored at different times.

4. Carcases, half-carcases, half-carcases cut into no more than three wholesale cuts, and quarters may be transported at temperatures higher than those referred to in point 1, under conditions to be set in accordance with the procedure referred to in Article 6 after consultation of the Scientific Committee.

5. Meat must not come into contact with the floor. Containers must not be placed directly on the floor.

6. Packaged meat must not be transported with unpacked meat unless adequate physical separation is provided. Stomachs may not be transported unless scalded or cleaned, nor may heads and feet unless they are skinned or scalded and depilated.

CHAPTER X

ADDITIONAL GUARANTEES

In respect of salmonella, the following rules shall apply to beef and veal meat and meat of porcine animals intended for Sweden and Finland:

(a) The consignments must have been subjected to a microbiological test by sampling in the establishment of origin.

(b) With regard to meat of bovine and porcine animals, the test provided for in (a) must not be carried out for consignments intended for an establishment for the purposes of pasteurisation, sterilisation or treatment having a similar effect.

(c) The test provided for in (a) must not be carried out for meat originating in an establishment which is subject to an operational programme recognised by the Commission, in accordance with the procedure referred to in Article 6, as equivalent to that approved for Sweden and Finland.

The operational programmes of the Member States may be amended and updated by the Commission in accordance with the procedure referred to in Article 6.

SECTION II

Poultrymeat

The requirements of this section apply, by analogy, to meat from lagomorphs.

Ratites must be handled in accordance with the requirements set out below but with appropriate accommodation adapted to the size of the animals to ensure the respect of hygiene.

CHAPTER I

TRANSPORT OF BIRDS TO THE SLAUGHTERHOUSE

1. During the collection of birds at the farm and during transport, birds must be handled carefully without causing unnecessary distress. Only birds which do not show symptoms of disease or other deficiencies may be transported. Where appropriate, birds showing symptoms of disease or originating in flocks that are known to be contaminated with agents of public health importance must be transported under the control of the competent authority.

2. Equipment used for collecting live birds must be cleaned and disinfected before re-use. Crates for delivering poultry to the slaughterhouse must be made of non-corrodible material and be easy to clean and disinfect.

3. Upon arrival at the slaughterhouse, birds must be rested before slaughter.

CHAPTER II

CONDITIONS FOR SLAUGHTERHOUSES

Slaughterhouses must:

1. Have a room or covered space for the reception of the animals and for their inspection before slaughter.

2. Be constructed in such a way as to avoid the contamination of the meat, ensuring in particular that:

   — there is a slaughter room for stunning and bleeding on the one hand, and plucking and any scalding on the other, to be carried out in separate places,

   — there is a room for evisceration and further dressing which is large enough for evisceration to be carried out in a place sufficiently far from the other work stations, or separated from them by a partition, to prevent contamination,

   — slaughter lines are designed to allow a constant progress of the slaughter process and to avoid cross contamination between different parts of the slaughter line as well as contact between carcases and walls, equipment, etc.,

   — there is an appropriate area, sufficiently protected, for dispatching meat.

3. Have refrigeration facilities of sufficient capacity in relation to the volume of production.

4. Have lockable premises for the refrigerated storage of detained meat.

5. Have facilities for disinfecting tools with hot water supplied at not less than 82 °C, or an alternative system having an equivalent effect.

6. Have equipment for washing hands used by the staff engaged in handling exposed meat provided with taps that are non-hand operable.

7. There must be a separate place with appropriate facilities for the cleaning and disinfection of means of transport and, where appropriate, transport equipment such as crates. These places and facilities are not compulsory if officially authorised places and facilities exist nearby.

CHAPTER III

CONDITIONS FOR CUTTING PLANTS

Cutting plants must:

1. Be constructed so as to allow constant progress of the operations or ensure separation between the different batches.

2. Have rooms for the separate storage of packed and exposed meat, unless stored at different times.

3. Have cutting rooms equipped to ensure that the cold chain is not interrupted during cutting operations.

4. The equipment for washing hands used by staff handling exposed meat shall be provided with taps that are non-hand operable.

5. Have facilities for disinfecting tools with hot water supplied at not less than 82 °C, or an alternative system having an equivalent effect.

If the following operations are undertaken in a cutting plant:

— the evisceration of geese and ducks reared for the production of 'foie gras', which have been stunned, bled and plucked on the fattening farm,

— the evisceration of 'New York dressed' poultry,

separate rooms must be available for that purpose unless these operations are separated in time from the cutting operations and proper cleaning and infection procedures are in place.

CHAPTER IV

SLAUGHTER HYGIENE

1. Crates for delivering live poultry must be cleaned and disinfected each time they are emptied.

2. Only live animals intended for slaughter may be brought into the slaughter premises with the exemption of farmed ratites slaughtered at the place of production, 'New York dressed' poultry slaughtered at the farm, small wild game and geese and ducks reared for the production of 'foie gras' which have been stunned, bled and plucked on the fattening farm.

   Animals that have died during transport or before slaughter shall not be used for human consumption.

3. Where provided for in Community legislation, animals must before slaughter be presented to the competent authority in order to be submitted to an ante-mortem inspection. Slaughterhouse operators shall follow the instructions of the competent authority in order to ensure that the ante-mortem inspection is carried out under suitable conditions.

4. 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.

5. Animals brought into the slaughter room must be immediately slaughtered after stunning, save in case of slaughter according to religious rite.

6. Stunning, bleeding, skinning or plucking, dressing and evisceration must be carried out without delay in such a way that contamination of the meat is avoided. It must in particular be ensured that measures are taken to prevent the spillage of digestive tract contents during evisceration.

7. Slaughtered animals must be submitted to a post-mortem inspection under the supervision of the competent authority. Slaughterhouse operators shall follow the instructions of the competent authority in order to ensure that the post-mortem inspection is carried out under suitable conditions ensuring in particular that slaughtered poultry can be inspected properly.

8. Viscera or parts of viscera which have not been removed from the carcase before post-mortem inspection must, except for the kidneys, be removed entirely, if possible, and as quick as possible after inspection has been completed.

9. After inspection and evisceration, slaughtered birds must be cleaned and chilled to a temperature of not more than 4 °C as soon as possible, unless the meat is cut while warm.

   'New York dressed' poultry obtained at the farm of production may be kept for up to 15 days at a temperature which must not exceed 4 °C; they must, at the latest at the end of this period, be eviscerated in a slaughterhouse or in a cutting plant. Such poultry must be accompanied by a certificate signed by the competent authority stating that the uneviscerated carcases are of birds which were examined before slaughter on the farm of origin and were found to be healthy at the time of examination.

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

    (a) every precaution must be taken to avoid cross-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;

    (c) calibrated control equipment must continuously record the following:

    — the water consumption during spray-washing before immersion,

    — the temperature of the water of the tank or tanks at the points of entry and exit of the carcases,

    — the water consumption during immersion,

    — the total weight of the immersed carcases.

11. Sick or suspect birds or birds 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 CUTTING AND BONING

The work on meat must be organised in such a way as to prevent the growth of pathogenic micro-organisms or the formation of toxins or other pathogenic substances, and in particular:

1. Meat intended for cutting must be brought into the work rooms progressively as needed.

2. During cutting, boning, slicing, dicing, wrapping and packaging, the cooling of the meat must not be interrupted.

   Where meat is boned and cut prior to reaching 4 °C, such meat must be transferred directly from the slaughter premises to the cutting room in a single operation, or after a waiting period in the cold store. Cutting must be carried out immediately after transfer.

3. As soon as it is cut, and where appropriate wrapped and packaged, the meat must be chilled to 4 °C.

4. Where the premises are approved for the cutting of meat of different species or for handling 'New York dressed' poultry and small wild game, precautions must be taken to avoid cross-contamination, where necessary by separation of the operations of the different species in either space or time.

CHAPTER VI

SPECIAL CONDITIONS

1. Member States may adapt the requirements laid down in Chapters II and III with a view to accommodate the needs of establishments situated in regions suffering from special geographical constraints or affected by supply difficulties, or those serving the local market. Hygiene shall not be compromised. The Member States shall inform the Commission of the details of such special conditions.

   Establishments serving the local market shall mean farms with an annual production of under 10 000 birds supplying fresh poultry meat coming from their holdings in small quantities:

   — either directly to the final consumer at the holding or at the weekly markets in the vicinity of their holdings or

   — to retailers with a view to direct sale to the final consumer, provided that such retailers pursue their activities in the same or neighbouring locality as that of the producer.

2. Member States may:

   — allow the further handling in establishments approved for that purpose of farmed game birds and small farmed game animals which are slaughtered and bled at the farm,

   — grant a derogation from the slaughter and evisceration provisions in the case of the production of partially eviscerated or non-eviscerated farmed game birds.

3. Slaughter, bleeding and plucking of poultry reared and slaughtered for the production of 'foie gras' may be carried out at the farm, provided these operations are carried out in a separate room fully complying with hygiene rules. The uneviscerated carcases must be transported immediately, under respect of the cold chain principles, to a slaughterhouse or cutting plant with a special room where the carcases must be eviscerated within 24 hours under the supervision of the competent authority. During transport, such poultry carcases must be accompanied by a certificate signed by the official veterinarian giving information about the health status of the flock of origin and the hygiene at the farm of production.

4. Where the competent authority authorises the slaughter of animals at the farm in accordance with point 3, the following conditions shall apply:

— the farm must undergo regular veterinary inspection and not be placed under any animal- or public-health restriction,

— the competent authority must be informed in advance of the date of slaughter of birds,

— the holding must have facilities for concentrating the birds to allow an ante-mortem inspection of the group to be made,

— the holding must have premises suitable for the hygienic slaughter and further handling of the birds,

— animal welfare requirements must be complied with.

CHAPTER VII

APPROVAL AND REGISTRATION OF ESTABLISHMENTS

Slaughterhouses, cutting plants and cold stores must be approved by the competent authority and be given an approval number. However, low capacity establishments referred to in Chapter VI distributing their products on the local market only may be registered.

CHAPTER VIII

ADDITIONAL GUARANTEES

In respect of salmonella, the following rules shall apply to meat of domestic fowl, turkey, guinea fowl, ducks and geese intended for Sweden and Finland:

(a) The consignments must have been subjected to a microbiological test by sampling in the establishment of origin.

(b) The test provided for in (a) must not be carried out for meat originating in an establishment which is subject to an operational programme recognised by the Commission, in accordance with the procedure referred to in Article 6, as equivalent to that approved for Sweden and Finland.

The operational programmes of the Member States may be amended and updated by the Commission in accordance with the procedure referred to in Article 6.

SECTION III

Meat of farmed game

1. The provisions for meat of domestic ungulates shall apply to the production and marketing of meat of farmed even-toed game mammals (Cervidae and Suidae).

2. The provisions for poultry meat shall apply to the production and marketing of meat from ratites.

3. Notwithstanding paragraphs 1 and 2, the competent authority may authorise the slaughter of farmed game at the place of origin where it cannot be transported, in order to avoid any risk for the handler or to protect the welfare of the animals. This authorisation may be granted if:

— the herd undergoes regular veterinary inspection and is not under any animal- or public-health restriction,

— a request is submitted by the owner of the animals,

— the competent authority is informed in advance of the date of slaughter of the animals,

— the holding has facilities for concentrating the animals to allow an ante-mortem inspection of the group to be made,

— the holding has premises suitable for the slaughter, sticking and bleeding, and where ratites are to be plucked, plucking of the animals,

— slaughter by sticking and bleeding is preceded by stunning in accordance with Directive 93/119/EC; slaughter by shooting may be allowed,

— slaughtered and bled animals are transported suspended, under satisfactory conditions of hygiene, to an approved establishment as soon as possible after slaughter. Where animals slaughtered at the place of rearing cannot be brought within one hour to an approved establishment, they must be transported in a container or means of transport in which the ambient temperature is maintained at between 0 °C and 4 °C. Evisceration must be carried out as soon as possible after stunning and bleeding,

— during transport to the approved establishment, slaughtered animals are accompanied by a certificate issued and signed by the official veterinarian attesting to a favourable result of the ante-mortem inspection, correct slaughter and bleeding and the time of slaughter.

4. All operations for the slaughter of reindeer destined for intra-Community trade may be carried out in mobile slaughter units in accordance with the provisions for meat of domestic ungulates. In accordance with the procedure referred to in Article 6, and after the opinion of the Scientific Committee, the conditions under which mobile slaughterhouses can be used for the slaughter of other species shall be laid down.

SECTION IV

Wild game meat

This Section does not apply to trophies or killed wild game transported by travellers, in so far as this involves a small quantity of small wild game or only one whole item of large wild game and where the circumstances indicate that the game is not intended for commercial purposes, and provided that it does not come from an area or region subject to animal health restrictions or restrictions because of the presence of residues.

CHAPTER I

TRAINING OF HUNTERS IN HEALTH AND HYGIENE

1. Persons responsible for hunting wild game and for placing it on the market for human consumption must have sufficient knowledge of wild game hygiene and pathology in order to undertake an initial examination of wild game on the spot.

   For that purpose, Member States shall organise training and education schemes for hunters, game managers, game keepers, etc. which must cover at least the following subjects:

   — normal anatomy, physiology and behaviour of wild game animals,

   — abnormal behaviour and pathological changes in wild game due to diseases, environmental contamination or other factors which may affect human health after consumption,

   — the hygiene rules and proper techniques for handling, transportation, evisceration, etc. of wild game animals after killing,

   — legislation, regulations and administrative provisions on the health and hygiene conditions governing the placing on the market of wild game.

   Such schemes shall if possible be set up and run in collaboration with officially recognised hunters' organisations in order to guarantee that there is a permanent effort of instructing and educating hunters about possible public-health risks due to meat from wild game.

2. Hunters, or in a hunting team at least one person shall have the qualifications referred to above for performing a health check on hunted animals

CHAPTER II

KILLING, EVISCERATION AND TRANSPORT OF WILD GAME TO AN APPROVED ESTABLISHMENT

1. After killing, large wild game must be drawn and have their stomachs and intestines removed; small wild game may be totally or partially eviscerated on the spot or in a game handling establishment.

2. Hunted animals must be examined by the hunter, a qualified person as referred to in Chapter I point 2 or where appropriate a veterinarian as soon as possible after killing and opening in order to detect characteristics which may indicate that the meat presents a health risk.

(a) Where no such characteristics are found or where there is no suspicion of environmental contamination, the game may be either released for direct private consumption or else be transported as soon as possible to a game collecting centre or game handling establishment. In a game collection centre, any intervention on the game is forbidden. In the game handling establishment, the game shall be presented for inspection to the competent authority. Unless the game carcase is accompanied by a certificate from a qualified hunter or person as referred to in Chapter I point 2, stating that the game did not show abnormal characteristics and that there is no suspicion of environmental contamination, the thoracic viscera of large wild game, even if detached from the carcase, the kidneys and, where appropriate, the liver and the spleen, must accompany the carcase and be identified in such a way that the inspection of the viscera can be carried out together with the rest of the carcase; the head may have been removed as a trophy.

(b) If any abnormal behaviour before killing or pathological changes are detected during the examination or when environmental contamination is suspected, the carcase together with the viscera must be transported to the game handling establishment to be submitted to a complete post-mortem inspection and the competent authority must ensure that the hunter informs the official veterinarian thereof. The official veterinarian must submit the carcase to the tests necessary in order to make a diagnosis about the nature of the defect. After making a diagnosis, the official veterinarian determines if the carcase is fit for human consumption.

It must be ensured that species that may be contaminated by *trichinella spiralis* are submitted in an officially recognised laboratory to an examination to detect the possible presence of that parasite before release for human consumption. Hunters or the qualified person referred to in Chapter I point 2 shall be held responsible for any decision taken by them with regard to the examination of wild game for the possible presence of a health risk.

Where a hunter is not qualified or when in a hunting team there is no qualified person as referred to in Chapter I point 2, the hunted animal together with its viscera shall be presented for inspection by the competent authority in a game handling establishment.

3. Carcases and viscera must be moved within 12 hours after killing to a game handling establishment or a collection centre, where they must be chilled to the required temperature. If the game is brought to a collection centre first, it must be transported within 12 hours after arrival in the collection centre to a game handling establishment or in remote regions where climatological conditions so permit, within a period to be fixed by the competent authority. During transport to the game collection centre and the game handling establishment, heaping and stacking shall be prohibited.

4. Wild game carcases must be chilled to a temperature of not more than 7 °C for large game and not more than 4 °C for small game.

5. Where unskinned large game is marketed:

(a) their viscera must have undergone post-mortem inspection in a wild game handling establishment;

(b) it must be accompanied by a health certificate signed by the official veterinarian to certify that the result of the post-mortem inspection was satisfactory;

(c) it must have been cooled to a temperature not exceeding:

— + 7 °C and be kept below this temperature for a maximum period of 7 days from the post-mortem inspection, or

— + 1 °C and kept below this temperature for a maximum period of 15 days from the post-mortem inspection;

(d) it must be stored and handled separately from other food.

Meat from such unskinned wild game cannot bear the health mark unless, after skinning in a game handling establishment, it has undergone post-mortem inspection and has been declared fit for human consumption.

CHAPTER III

HYGIENE PROVISIONS IN GAME HANDLING ESTABLISHMENTS

1. Wild game meat must be prepared in an approved game handling establishment.

2. Evisceration must be carried out without undue delay, upon arrival at the wild game handling establishment, if it has not been carried out on the spot. The lungs, heart, kidneys, mediastinum and where appropriate the liver and spleen may either be detached or left attached to the carcase by their natural connections.

3. During cutting, boning, wrapping and packaging the internal temperature of the wild game must be kept at a temperature of + 7 °C or lower in the case of large wild game, or 4 °C or lower in the case of small wild game.

CHAPTER IV

REGISTRATION AND APPROVAL OF ESTABLISHMENTS

1. Game collection centres shall be registered.

2. Game handling establishments shall be approved.

SECTION V

Minced meat, meat preparations and mechanically separated/recovered meat

This Section does not apply to the production and marketing of minced meat intended for the processing industry; such meat remains subject to the requirements for fresh meat.

CHAPTER I

ESTABLISHMENTS OF PRODUCTION

1. Production rooms must be equipped to ensure that the cold chain is not interrupted during the operations.

2. It must be ensured that the products are microbiologically safe.

3. Establishments shall be approved by the competent authority.

CHAPTER II

MINCED MEAT

1. Requirements for the raw materials:

   (a) minced meat must have been prepared from skeletal muscle (including the adherent fatty tissues);

   (b) frozen or deep-frozen meat used for the preparation of minced meat must have been boned before freezing and have been stored for a limited period after boning;

   (c) the competent authority may authorise the boning of meat on the spot immediately before mincing where this operation is carried out in satisfactory conditions of hygiene and quality;

   (d) where it has been prepared from chilled meat, such meat must be used:

      — within no more than 6 days after slaughter of the animals, or

      — within no more than 15 days after slaughter of the animals in the case of boned, vacuum-packed beef and veal;

   (e) in all cases, meat with organoleptic deficiencies shall be excluded from the production of minced meat;

   (f) minced meat shall not be obtained from:

      — scrap cuttings and scrap trimmings (other than whole muscle cuttings) or from mechanically separated meat,

— meat from the following parts of bovine animals, pigs, sheep or goats: 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, and bone scrapings. The muscles of the diaphragm — after removal of the serosa – and of the masseters may be used only after being examined for cysticercosis,

— meat containing bone fragments or skin.

Pig meat or horse meat used for minced meat production must have been obtained in accordance with the requirements regarding trichina examination.

2. The mincing operations must be performed within one hour from the time when the meat enters the preparation room. A longer time limit may be granted in individual cases where the addition of salt justifies this on technical grounds, or where hazard analysis demonstrates that there is no increased hazard to human health.

When the duration of these operations exceeds the time limit referred to above, the fresh meat may not be used until the internal temperature of the meat has been reduced to a maximum of 4 °C.

3. Immediately after production, minced meat must be hygienically wrapped and/or packaged and after that be cooled to and stored at a temperature not exceeding 2 °C.

4. Minced meat may be deep-frozen only once.

5. Minced meat to which not more than 1 % of salt has been added shall be subject to the same requirements. If more than 1 % salt is added, the product is considered to be a meat preparation.

6. In order to take account of particular habits of consumption, and on condition that the products of animal origin do not present a hazard to human health, Member States may grant derogations from points 1 to 5. In this case, the minced meat must not be given the Community health mark.

CHAPTER III

MEAT PREPARATIONS

1. Meat preparations obtained from minced meat must fulfil the conditions laid down for minced meat.

2. The addition of seasonings to whole poultry carcases may be authorised in a specific room that is clearly separate from the slaughter room.

3. Where the meat has been frozen or deep-frozen, it must be used within a time period sufficiently short after slaughter.

4. Boning of meat on the spot immediately before preparation may be authorised, provided this operation is carried out in satisfactory conditions of hygiene.

5. Meat preparations may be deep-frozen only once.

6. After their production, wrapping and packaging, meat preparations must be cooled as quickly as possible to an internal temperature of maximum 4 °C.

In the deep-frozen form, an internal temperature below - 18 °C must be reached, in accordance with Article 1(2) of Directive 89/108/EEC.

CHAPTER IV

MECHANICALLY SEPARATED MEAT (MSM)

MSM must have been obtained under the following conditions:

1. Raw materials

(a) The raw materials used for the production of MSM must comply with the requirements for fresh meat.

(b) The use of the following is not allowed for the production of MSM:

— for poultry: feet, neckskin, neckbones and head,

— for other animals: the bones of the head, feet, tails (except bovine tails), femur, tibia, fibula, humerus, radius and ulna, the vertebral column of bovine, ovine and caprine animals.

(c) Chilled raw material for deboning from an on-site slaughterhouse must not be older than 7 days.

Chilled raw material for deboning from another slaughterhouse must not be older than 5 days.

Flesh-bearing bones from frozen carcases may be used.

2. Conditions for the production of MSM:

(a) Mechanical separation must take place without undue delay after deboning. Otherwise, the flesh-bearing bones obtained after boning must:

— either be chilled at 2 °C and stored at a room temperature not exceeding 2 °C,

— or be frozen after boning so as to reach a temperature of - 18 °C within 24 hours. Such bones must be used within three months after freezing. However, refreezing of flesh-bearing bones obtained from frozen carcases is not allowed.

(b) During mechanical separation, the room temperature may not exceed 12 °C.

(c) If not used within one hour after it has been obtained, the MSM must be chilled immediately to a temperature of not more than 2 °C.

After chilling, it can be processed within 24 hours, or else it must be frozen within 12 hours after production.

If the MSM is frozen, the freezing layers must reach a core temperature of - 18 °C or less within six hours. Frozen MSM shall not be stored for more than three months. Frozen MSM must be kept below - 18 °C during transport and storage.

MSM may be transported from the separation unit to a processing establishment. The cold chain may not be interrupted during transport, the product remaining at 2 °C or below.

3. Use of MSM

MSM may only be used in heat-treated meat products in which the temperature increases to + 70 °C during 30 minutes or any other time/temperature combination providing the same security.

SECTION VI

Meat products

CHAPTER I

REQUIREMENTS FOR RAW MATERIALS

The following items may not be used in the preparation of processed meat products:

(a) genital organs of both female and 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) corneal tissue;

(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.

CHAPTER II

APPROVAL OF ESTABLISHMENTS

Establishments for the manufacture of meat products must be approved by the competent authority. However, low capacity establishments distributing their products on the local market only may be registered.

SECTION VII

Live bivalve molluscs

The provisions on purification shall not apply to echinoderms, tunicates and marine gasteropods.

It shall be ensured that live bivalve molluscs harvested from the wild and destined for direct human consumption, comply with the standards set out in Chapter IV of this Section.

CHAPTER I

SPECIAL HYGIENE CONDITIONS FOR THE PRODUCTION AND HARVESTING OF LIVE BIVALVE MOLLUSCS

A. *Conditions for production areas*

1. Live bivalve molluscs shall only be harvested from areas the location and boundaries of which are fixed and classified by the competent authority as follows:

   (a) *Class A areas:* areas from which live bivalve molluscs may be collected for direct human consumption. Live bivalve molluscs taken from these areas must meet the requirements of Chapter IV of this Section.

   (b) *Class B areas:* areas from which live bivalve molluscs may be collected, but only placed on the market for human consumption after treatment in a purification centre or after relaying.

   (c) *Class C areas:* areas from which live bivalve molluscs may be collected but placed on the market only after relaying over a long period (at least two months).

   The criteria for the classification of class B or C areas will be laid down by the Commission in accordance with the procedure referred to in Article 6, after obtaining the opinion of the appropriate Scientific Committee.

   After purification or relaying, molluscs from class B or C areas must meet all of the requirements of Chapter IV of this Section.

   However, live bivalve molluscs from such areas which have not been submitted to purification or relaying may be sent to a processing establishment where they must be subjected to a treatment intended to inhibit the development of pathogenic micro-organisms. Such treatment must be approved by the Commission in accordance with the procedure referred to in Article 6, after obtaining the opinion of the appropriate Scientific Committee.

2. Any production and harvesting of bivalve molluscs in areas considered unsuitable for these activities for health reasons or in areas not classified in one of the categories referred to in point 3 shall be prohibited. Operators shall inform themselves with the competent authority about the areas that are suitable for production and harvesting.

3. The provisions laid down in point 1 apply, with regard to pectinids, only to products of aquaculture, or, where data are available permitting the classification of fishing grounds, to wild pectinids. However, if no classification of fishing grounds is possible, the requirements of Chapter IV apply to pectinids harvested from the wild.

B. *Conditions for harvesting and transporting live bivalve molluscs to a dispatch or purification centre, relaying area or processing plant*

1. Harvesting techniques and further handling must not cause additional contamination and excessive damage to the shells or tissues of live bivalve molluscs and must not result in changes significantly affecting their suitability for treatment by purification, processing or relaying. They must in particular:

   — be adequately protected from crushing, abrasion or vibration,

   — not be exposed to extremes of hot or cold temperatures,

   — not be re-immersed in water which could cause additional contamination.

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

3. A registration document for the identification of batches of live bivalve molluscs during transport from the production area to a dispatch centre, purification centre, relaying area or processing establishment is to be issued by the competent authority at the request of the gatherer. For each batch, the gatherer must complete legibly and indelibly the relevant sections of the registration document, the form for which is laid down in accordance with the procedure referred to in Article 6. This document must be produced in at least one of the languages of the country of destination.

The registration documents must be sequentially numbered. The competent authority must keep a register containing the numbers of registration documents together with the names of the persons collecting live bivalve molluscs to whom the documents have been issued. The registration document for each batch of live bivalve molluscs must be date-stamped upon delivery of a batch to a dispatch centre, purification centre, relaying area or processing establishment. It must be kept by operators of such centres, areas or establishments for at least twelve months, or, upon request of the competent authority, for a longer period. In addition, the gatherer is also obliged to keep it for the same period.

However, if gathering is carried out by the same staff operating the dispatch centre, purification centre, relaying area or processing establishment of destination, the registration document may be replaced by a standing transport authorisation granted by the competent authority.

4. If a production or relaying area is closed temporarily, the competent authority must refrain from issuing registration documents for that area and immediately suspend the validity of all registration documents already issued.

C. *Conditions for relaying live bivalve molluscs*

For relaying live bivalve molluscs, the following conditions must be met:

1. Only areas approved by the competent authority for relaying live bivalve molluscs may be used. The boundaries of the sites must be clearly identified by buoys, poles or other fixed means; there must be a minimum distance between relaying areas, and also between relaying areas and production areas, so as to ensure that the quality of the waters is not adversely affected.

2. Conditions for relaying must ensure optimal conditions for purification. It must in particular be ensured that:

   — techniques for handling live bivalve molluscs intended for relaying permit the resumption of filter-feeding activity after immersion in natural waters,

   — live bivalve molluscs are not be relayed at a density which prevents purification,

   — live bivalve molluscs are immersed in sea water at the relaying area for an appropriate period which is fixed depending on the water temperature. This period must exceed the time taken for levels of faecal bacteria to become reduced to the levels permitted under Chapter IV of this Section,

   — the minimum water temperature for effective relaying is, where necessary, determined and publicised by the competent authority for each species of live bivalve molluscs and each approved relaying area,

   — to prevent mixing of batches, sites within a relaying area are well separated.

3. Permanent records of the source of live bivalve molluscs, relaying periods, relaying areas and subsequent destination of the batch after relaying must be kept by the operators of relaying areas for inspection by the competent authority.

4. After harvesting from a relaying area, batches must be accompanied by a registration document during transport from the relaying area to the approved dispatch centre, purification centre or processing establishment, the form for which is to be laid down in accordance with the procedure referred to in Article 6, except where the same staff operates both the relaying area and the dispatch centre, purification centre or processing establishment. This document must be produced in at least one of the languages of the country of destination.

CHAPTER II

DISPATCH AND PURIFICATION CENTRES

A. *Premises*

1. The location of premises must not be subject to flooding by ordinary high tides or run-off from surrounding areas.

2. When sea water is used, facilities for the supply of clean sea water must be available.

B. *Special conditions for purification centres*

In addition to the conditions laid down under A, purification centres must meet the following conditions:

— the internal surfaces of the purification tanks and any water storage containers must be smooth, durable and impermeable, easy to clean by scrubbing or the use of pressurised water,

— the purification tanks must be constructed so as to allow complete draining of water,

— the purification tanks must be supplied with a sufficient flow of clean sea water and sufficient water outlet capacity for the volume of products to be purified,

— if the purification centre does not have a directly pumped clean water supply, it must have equipment making it possible to purify the sea water.

CHAPTER III

HYGIENE CONDITIONS IN DISPATCH AND PURIFICATION CENTRES

A. *Hygiene conditions to be met in purification centres*

1. Before purification commences, live bivalve molluscs must be washed free of mud and accumulated debris using pressurised clean sea water or potable water.

2. The purification tanks must be supplied with a sufficient flow of sea water per hour and per tonne of live bivalve molluscs treated; the distance between the sea water intake point and the waste water outlets must be sufficient to avoid contamination.

3. Operation of the purification system must allow live bivalve molluscs to rapidly resume filter-feeding activity, eliminate sewage contamination, not become re-contaminated and be able to remain alive in a suitable condition after purification for wrapping, storage and transport before being placed on the market.

4. 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 allow the microbiological standards of Chapter IV of this Section to be met.

5. Should a purification tank contain several species of bivalve molluscs, the length of the treatment must be based on the time required by the species needing the longest period of purification.

6. Containers used to hold live bivalve molluscs in purification systems must have a construction which allows sea water to flow through; the depth of layers of live bivalve molluscs must not impede the opening of shells during purification.

7. After completion of purification, the shells of live bivalve molluscs must be washed thoroughly by hosing with potable water or clean sea water.

8. No crustaceans, fish or other marine species may be kept in a purification tank in which live bivalve molluscs are undergoing purification.

9. Purification centres must accept only batches of live bivalve molluscs which are accompanied by a registration document, the form for which is to be drawn up in accordance with the procedure referred to in Article 6.

10. Purification centres sending batches of live bivalve molluscs to dispatch centres must provide a registration document, the form for which is to be drawn up in accordance with the procedure referred to in Article 6.

11. 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. *Hygiene conditions to be met in dispatch centres*

1. Handling of molluscs such as packing or calibration procedures must not cause contamination of the product or affect the viability of the molluscs.

2. Any washing or cleaning of live bivalve molluscs must be carried out using pressurised clean sea water or potable water; cleaning water may not be recycled.

3. Dispatch centres must accept only batches of live bivalve molluscs which are accompanied by the registration document referred to under point I.B(4) and come from an approved production area (class A), relaying area or purification centre.

4. Molluscs must be kept away from places to which domestic animals have access.

5. Dispatch centres situated aboard vessels are subject to the conditions laid down in points 1, 2 and 4. The molluscs must come from an approved production area (class A). The conditions laid down in Chapter II(A) apply *mutatis mutandis* to such dispatch centres, although special conditions may be laid down by the Commission in accordance with the procedure referred to in Article 6.

CHAPTER IV

HEALTH STANDARDS FOR LIVE BIVALVE MOLLUSCS

Live bivalve molluscs placed on the market for human consumption must comply with the following requirements:

1. They must have organoleptic characteristics associated with freshness and viability, including shells free of dirt, an adequate response to percussion, and, except for Pectinidae, normal amounts of intravalvular liquid.

2. They must respect microbiological criteria or be produced in conformity with microbiological guidelines to be established in accordance with the procedure referred to in Article 6 of the present Regulation.

3. They must not contain toxic or objectionable compounds occurring naturally or added to the environment in such quantities that the calculated dietary intake exceeds the permissible daily intake (PDI).

4. The upper limits for radionuclide levels must not exceed the limits for foodstuffs as laid down by the Community.

5. Limits for marine biotoxines:

   (a) the total Paralytic Shellfish Poison (PSP) content in the edible parts of the molluscs (the whole body or any part edible separately) must not exceed 80 micrograms per 100 g of mollusc flesh in accordance with a method recognised by the Commission deciding in accordance with the procedure referred to in Article 6;

   (b) the total Amnesic Shellfish Poison (ASP) content in edible parts of molluscs (the entire body or any edible part edible separately) must not exceed 20 micrograms of domoic acid per gram using the HPLC method;

   (c) the customary biological testing methods must not give a positive result to the presence of Diarrheic Shellfish Poison (DSP) in the edible parts of the molluscs (the whole body or any part edible separately).

The Commission is to lay down, in cooperation with the relevant Community Reference Laboratory and in accordance with the procedure referred to in Article 6, and after obtaining the opinion of the Scientific Committee:

— limit values and analysis methods for other marine biotoxins, where the need occurs,

— virus testing procedures and virological standards,

— sampling plans as well as the methods and analytical tolerances to be applied in order to check compliance with the health standards. Pending decisions thereon, methods for checking compliance with the health standards must be scientifically recognised,

— other health standards or checks are to be introduced where there is scientific evidence indicating that this should be done in order to protect public health.

CHAPTER V

WRAPPING OF LIVE BIVALVE MOLLUSCS

1. Oysters must be wrapped with the concave shell downwards.

2. All wrappings of live molluscs, including vacuum wrapping in sea water, must be closed and remain closed from the dispatch centre until delivery to the consumer or retailer. However, wrappings may be opened and the molluscs be re-wrapped in an approved dispatch or purification centre.

CHAPTER VI

APPROVAL OF ESTABLISHMENTS

Dispatch and purification centres shall be approved by the competent authority.

CHAPTER VII

HEALTH MARKING AND LABELING

1. The health marking must be waterproof.

2. In addition to the health marking requirements, the following information must be present on the label:

   — the species of bivalve mollusc (common name and scientific name),

— the date of wrapping, comprising at least the day and the month.

By way of derogation from Directive 79/112/EEC, the date of durability may be replaced by the entry 'these animals must be alive when sold'.

3. The label attached to the wrapping of live bivalve molluscs which are not wrapped in individual consumer-size parcels must be kept for at least 60 days by the retailer after splitting up the contents.

CHAPTER VIII

STORAGE AND TRANSPORT OF LIVE BIVALVE MOLLUSCS

1. In storage rooms, live bivalve molluscs must be kept at a temperature which does not adversely affect their safety and viability.

2. Re-immersion in or spraying with water of live bivalve molluscs must not take place after they have been wrapped and have left the dispatch centre, except in the case of retail sale at the dispatch centre.

SECTION VIII

Fishery products

CHAPTER I

CONDITIONS FOR FISHERIES VESSELS

Fishery products caught in their natural environment must have been caught and, where appropriate, handled for bleeding, heading, gutting and the removal of fins, chilled, frozen or processed and/or wrapped/packaged on board vessels in accordance with the rules laid down in this Chapter.

I. **Conditions for the equipment of fisheries vessels**

A. *Conditions applicable to all vessels*

1. Fisheries 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 the fish comes into contact must be of suitable corrosion-resistant material which is smooth and easy to clean. Surface coatings must be durable and non-toxic.

3. Equipment and material used for working on fish must be made of corrosion-resistant material which is easy to clean.

B. *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 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 pumping 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) equipment providing a supply of potable water within the meaning of Council Directive 98/83/EC, or pressurised clean sea water or clean river or lake water. The sea water intake must be situated in a position where it is not possible for the water being taken in to be affected by discharges into the sea of waste water, waste and engine coolant;

(h) appliances for cleaning and disinfecting hands with taps that must not be manually operated unless a procedure of equal guarantee can be demonstrated, and hygienic means of drying hands.

2. Factory vessels which freeze fishery products must have:

(a) freezing equipment with sufficient capacity to lower the temperature rapidly so as to achieve a core temperature of - 18 °C or lower;

(b) refrigeration equipment with sufficient capacity to maintain fishery products in the storage holds at - 18 °C or lower. 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.

Whole frozen fish in brine intended for the manufacture of canned food may be kept at a temperature of - 9 °C or lower.

C. *Freezer vessels and vessels designed and equipped to preserve fishery products for more than 24 hours*

1. Such vessels must be equipped with holds, tanks or containers for the storage of refrigerated or frozen fishery products at the temperatures laid down in this Section. The 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. The freezing and refrigeration equipment is subject to the same conditions as laid down for factory vessels under B(3).

2. The holds shall be designed to ensure that melt water cannot remain in contact with fishery products.

3. Containers used for the storage of products must ensure their preservation under satisfactory conditions of hygiene and, in particular, be clean and allow the drainage of melt water.

4. In vessels equipped for chilling fishery products in cooled sea water, tanks must incorporate devices for achieving a uniform temperature throughout the tanks; a chilling rate must be achieved which ensures that the mix of fish and sea water reaches 3 °C at the most 6 hours after loading and 0 °C at the most after 16 hours.

II. **Hygiene on board fishing vessels**

The following hygiene conditions apply to fishery products on board fishing vessels:

1. When in use, the parts of fishing vessels or containers set aside for the storage of fishery products must be clean and, in particular, must not be capable of being 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 fresh water complying with the parameters set out in Directive 98/83/EC, or where appropriate, clean sea water or clean river or lake water.

3. Fishery products must be handled and stored so as to prevent bruising. The use of spiked instruments is allowed for moving large fish or fish which might injure the handler, provided the flesh of these products is not damaged.

4. Fishery products other than those kept alive must undergo cold treatment as soon as possible after loading. However, when cooling is not possible, fishery products must be landed as soon as possible.

5. When ice is used for chilling products, it must be made from potable water or clean sea water or clean river or lake water. Before use, it must be stored under conditions which prevent its contamination.

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, clean sea water or clean river or lake water. In that event, the viscera and parts which 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 the temperature of melting ice or be frozen.

7. Where freezing in brine of whole fish intended for canning is practised, a temperature of - 9 °C must be achieved for the product. The brine must not be a source of contamination for the fish.

8. The cooking of crustaceans and molluscs on board must be carried out under the conditions laid down in Chapter III point VI.

CHAPTER II

CONDITIONS OF HYGIENE DURING AND AFTER LANDING

1. Unloading and landing equipment must be constructed of material which is easy to clean and disinfect and must be maintained in a good state of repair and cleanliness.

2. During unloading and landing, contamination of fishery products must be avoided. It must in particular be ensured that:

   — unloading and landing operations proceed rapidly,

   — fishery products are placed without delay in a protected environment at the temperature required,

   — equipment and practices that cause unnecessary damage to the edible parts of the fishery products are not authorised.

3. Auction and wholesale markets or parts thereof where fishery products are displayed for sale must:

   (a) at the time of display or storage of fishery products, not be used for other purposes. Vehicles emitting exhaust fumes likely to impair the quality of the fishery products must not be admitted to markets. Persons having access to the premises are not allowed to introduce animals therein;

   (b) when sea water is used, have facilities for the supply of clean sea water.

4. After landing or, where appropriate, after first sale, fishery products must be conveyed without delay to their place of destination, or else stored in cold rooms before being displayed for sale or after being sold and pending transport to their place of destination. In such cases, fishery products must be stored at the temperature approaching that of melting ice.

CHAPTER III

SPECIAL CONDITIONS

I. **Conditions for fresh products**

1. Where chilled, unpacked products are not distributed, dispatched, prepared or processed immediately after reaching an establishment, they must be stored under ice in a cold room. Re-icing must be carried out as often as necessary; the ice used, with or without salt, must be made from potable water or clean sea, river or lake water and be stored hygienically in receptacles provided for the purpose. Wrapped fresh products must be chilled with ice or with a mechanical refrigeration appliance giving similar temperature conditions.

2. Operations such as heading and gutting must be carried out hygienically; the products must be washed thoroughly with potable water or clean sea, river or lake 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, and in a place other than used for heading and gutting. Fillets and slices must not remain on the work tables beyond the time necessary for their preparation and must be protected from contamination by suitable wrapping. Fillets and slices must be chilled as quickly as possible after their preparation.

4. Containers used for the dispatch or storage of fresh fishery products must provide adequate drainage of melt water.

II. **Conditions for frozen products**

Establishments where fishery products are frozen must have equipment which satisfies the same requirements for freezing and storage as set out for factory vessels which freeze fishery products.

III. **Conditions for mechanically separated fish flesh**

1. Mechanical separation of gutted fish must take place without undue delay after filleting, using raw materials free from guts. If whole fish are used, they must be gutted and washed beforehand.

2. After production, mechanically recovered flesh must be frozen as quickly as possible or incorporated in a product intended for freezing or a stabilising treatment.

IV. **Conditions concerning endo-parasites harmful to human health**

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) Fish to be consumed raw or almost raw, e.g. raw herring (maatjes).

   (b) The following species if they are to undergo a cold smoking process in which the internal temperature of the fish is less than 60 °C:

   — herring,

   — mackerel,

   — sprat,

   — (wild) Atlantic and Pacific salmon.

   (c) Marinated and/or salted herring where this process is insufficient to destroy nematode larvae.

2. Where epidemiological data are available indicating that the fishing grounds of origin do not present a health hazard with regard to the presence of parasites, a derogation from the above treatment may be granted by the Member States. Member States implementing this derogation must inform the Commission and the other Member States thereof.

3. When placed on the market, the fishery products referred to above must be accompanied by a document from the manufacturer stating the type of process they have undergone.

4. Before marketing, fish and fish products must be given a visual examination for the purpose of detecting endo-parasites that are visible. Fish or parts of fish which are obviously contaminated with parasites must be removed and not be used for human consumption.

V. **Cooked crustaceans and molluscs**

Crustaceans and molluscs must be cooked as follows:

(a) any cooking must be followed by rapid cooling. Water used for this purpose must be potable water within the meaning of Directive 98/83/EC or clean sea, river or lake water. If no other method of preservation is used, cooling must continue until a temperature approaching that of melting ice is reached;

(b) 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 and all working surfaces must be cleaned thoroughly. If machines are used, they must be cleaned at frequent intervals and disinfected according to a schedule drawn up under the HACCP procedures;

(c) after shelling or shucking, cooked products must be frozen immediately, or kept chilled at a temperature which will preclude the growth of pathogens and be stored in appropriate rooms allowing maintenance of the temperatures required.

CHAPTER IV

HEALTH STANDARDS FOR FISHERY PRODUCTS

1. Organoleptic properties of fishery products

Organoleptic examinations of fishery products must be carried out so as to ensure their hygienic quality. Where necessary, freshness criteria are to be issued by the Commission in accordance with the procedure referred to in Article 6, after obtaining the opinion of the Scientific Committee.

2. Histamine

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

— the mean value must not exceed 100 ppm,

— two samples may have a value exceeding 100 ppm but not more than 200 ppm,

— no sample may have a value exceeding 200 ppm.

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

3. Total Volatile Nitrogen (TVB-N)

Unprocessed fishery products shall be regarded as unfit for human consumption where, organoleptic assessment having raised doubts as to their freshness, chemical tests reveal that the limits with regard to TVB-N to be fixed in accordance with the procedure referred to in Article 6 have been exceeded.

4. Toxins harmful to human health

The placing on the market of the following products is prohibited:

— poisonous fish of the following families: Tetraodontidae, Molidae, Diodontidae, Canthigasteridae,

— fishery products containing biotoxins such as ciguatoxin or muscle-paralysing toxins.

CHAPTER V

WRAPPING AND PACKAGING OF FISHERY PRODUCTS

Containers in which fresh fishery products are kept under ice must be water-resistant and provide adequate drainage for melt water.

Frozen blocks prepared on board fisheries vessels must be adequately wrapped before landing.

CHAPTER VI

STORAGE OF FISHERY PRODUCTS

1. Fresh or thawed fishery products, and cooked and chilled products from crustaceans and molluscs must be maintained at the temperature of melting ice.

2. Frozen fishery products must be kept at a temperature of - 18 °C or below 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 - 9 °C or less.

CHAPTER VII

TRANSPORT OF FISHERY PRODUCTS

1. During transport, fishery products must be maintained at the required temperature. In particular:

   (a) fresh or thawed fishery products, and cooked and chilled products from crustaceans and molluscs, must be maintained at the temperature 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 - 18 °C or below in all parts of the product, with possibly short upward fluctuations of not more than 3 °C.

2. 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, and where the journey is short, the competent authority may grant a derogation from the conditions laid down in point 1(b).

3. If ice is used to chill the products, adequate drainage must be provided in order to ensure that melting water does not remain in contact with the products.

4. Fishery products to be placed on the market live must be transported in such a way that the hygiene of the product is preserved.

CHAPTER VIII

APPROVAL AND REGISTRATION OF ESTABLISHMENTS

Factory vessels, freezer vessels and establishments on land shall be approved by the competent authority. However, establishments on land marketing their products on the local market only may be registered.

Wholesale markets where fishery products are not worked upon but are only displayed for sale and auction halls shall be registered.

SECTION IX

Milk and milk products

CHAPTER I

RAW MILK — PRIMARY PRODUCTION

I. **Health conditions for milk production**

1. Raw milk must come:

(a) from cows or buffaloes:

(i) belonging to a herd which, under points I and II of Annex A of Directive 64/432/EEC, is officially free of tuberculosis and free or officially free of brucellosis,

(ii) which do not show any symptoms of infectious diseases communicable to humans through milk,

(iii) in a good general state of health and presenting no obvious sign of disease,

(iv) which are not suffering from any infection of the genital tract with discharge, enteritis with diarrhoea and fever, or a recognisable inflammation of the udder,

(v) which do not have any udder wound likely to affect the milk,

(vi) which have not been treated with substances dangerous or likely to be dangerous to human health that are transmissible to milk, unless the milking has complied with an official withdrawal period laid down in Community rules or, if absent, in national rules;

(b) from sheep or goats:

(i) belonging to a holding officially free or free of brucellosis (Brucella melitensis) within the meaning of Article 2(4) and (5) of Directive 91/68/EEC,

(ii) satisfying the requirements of point (a), except point (a)(i);

(c) from females of other species:

(i) belonging, for species susceptible to brucellosis or tuberculosis, to herds regularly checked for these diseases under a control plan approved by the competent authorities,

(ii) satisfying the requirements of point (a) except point (a)(i).

2. Raw milk:

   (a) from animals which do not show a positive reaction to tests for tuberculosis or brucellosis nor any symptoms of these diseases, but belong to a herd which does not meet the requirements of point 1(a)(i) must only be used after having undergone a heat treatment such as to show a negative reaction to the phosphatase test under the supervision of the competent authority;

   (b) from animals which do not show a positive reaction to tests for brucellosis nor any symptom of that disease, but belong to a herd which does not meet the requirements of point 1(b)(i) must be used:

      (i) only for the manufacture of cheese with a maturation period of at least two months, or

      (ii) after having undergone a heat treatment on the spot such as to show a negative reaction to the phosphatase test under the supervision of the competent authority;

   (c) from animals which 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 required in point 1(c)(i) must be treated to ensure its safety under the supervision of the competent authority;

   (d) from animals 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 cannot be used for human consumption.

3. If goats are kept together with cows, they must be inspected and tested for tuberculosis.

4. The isolation of animals which are infected, or suspected of being infected, with any of the diseases referred to in point 1 must be effective to avoid any adverse effect on the other animals' milk.

II. **Hygiene on milk-production holdings**

A. *Hygiene on milk-production holdings*

1. Movable milking equipment, and premises where milk is stored, handled or cooled must be so located and constructed as to limit the risk of contamination of milk.

2. Where appropriate, premises for the storage of milk must have suitable refrigeration equipment, be protected against vermin and have adequate separation from premises where animals are housed.

B. *Hygiene during milking, collection of raw milk and its transport*

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

   — before milking is started, the teats, udder and if necessary adjacent parts are clean,

   — the milk is checked; abnormal milk must be withheld,

   — milk from animals showing clinical signs of udder disease is withheld,

   — animals which have been submitted to a treatment likely to transfer residues of medicinal products to the milk can be identified and their milk is withheld,

   — components in teat dips or sprays do not produce residues in the milk.

2. Immediately after milking, milk must be held in a clean place designed to avoid adverse effects on the milk. If the milk is not processed or collected within 2 hours of milking, it must be cooled to a temperature of 8 °C or lower in the case of daily collection, or 6 °C or lower if collection is not daily.

3. During transport to a dairy establishment, the cold chain must be maintained and at arrival in the dairy establishment the temperature of the milk must not exceed + 10 °C, unless the milk has been collected within 2 hours of milking.

4. For technological reasons concerning the manufacture of certain milk products, Member States may grant derogations from the temperatures laid down in subparagraphs 2 and 3 provided the end-product meets the standards provided for in this Regulation.

C. *Hygiene of premises, equipment and tools*

1. Equipment and instruments or their surfaces which are intended to come into contact with milk (utensils, containers, tanks, etc. intended for milking, collection or transport) must be easy to clean and disinfect and be maintained in a sound condition. This will require the use of smooth, washable and non-toxic materials.

2. After use, utensils used for milking, mechanical milking equipment and containers which have been in contact with milk must be cleaned and 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 per day, the containers and tanks used for the transport of raw milk to a dairy establishment must be cleaned and disinfected before re-use.

D. *Staff hygiene*

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

2. Persons performing milking must wash their hands immediately before milking and keep them as clean as possible throughout milking. For this purpose, 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. **Standards for raw milk**

Awaiting the establishment of standards in the context of a more specific legislation on the quality of milk and milk products, the following standards shall apply and their compliance checked on a representative number of samples taken by random sampling:

Plate count and somatic cell count.

Raw cows' milk must meet the following standards:

Plate count 30 °C (per ml)	≤ 100 000 (1)
Somatic cell count (per ml)	≤ 400 000 (2)

(1) Rolling geometric average over a two-month period, with at least one sample per month.

(2) Rolling geometric average over a three-month period, with at least one sample per month. Where production levels vary considerably according to season, a Member State may be authorised by the Commission in accordance with the procedure referred to in Article 6 to apply another method of calculating the results for a low lactation period.

Other scientifically validated methods may be used.

For the manufacture of cheese with a period of ageing or ripening of at least 60 days, Member States may grant individual or general derogations.

When the standards to be met by raw milk are exceeded, measures must be taken to correct the situation. When these standards are repeatedly or excessively exceeded, the competent authority must be informed and it shall ensure that appropriate measures are taken.

IV. **Microbiological criteria for raw milk**

Member States shall ensure that raw milk intended for direct consumption or for the manufacture of products whose manufacturing process does not include any treatment capable of eliminating pathogenic micro-organisms, is tested in order to ensure the microbiological safety of the products.

CHAPTER II

MILK PRODUCTS

I. **Conditions for establishments**

Where necessary, special conditions may be granted by the competent authority in particular in order to take account of traditional production methods.

II. **Requirements for heat-treated drinking milk**

1. Upon acceptance at a dairy establishment, milk must be cooled to and/or maintained at a temperature not higher than + 6 °C until heat-treated, unless treated within 4 hours of acceptance.

2. Awaiting the establishment of standards in the context of a more specific legislation on the quality of milk and milk products, the following standards shall apply:

   (a) Pasteurised milk must:

   — have been prepared by a treatment involving a high temperature for a short time (at least 71,7 °C for fifteen seconds) or by a pasteurisation process using different time and temperature combinations to obtain an equivalent effect,

— show a negative reaction to the phosphatase test,

— be cooled immediately after pasteurisation to a temperature not exceeding 6 °C as soon as possible,

— be prepared from raw milk which, prior to heat treatment, has a plate count at 30 °C below 300 000 per ml, where cows' milk is concerned; or from thermised milk as referred to under III(2)(a) which, prior to heat treatment, has a plate count at 30 °C below 100 000 per ml, where cows' milk is concerned.

(b) Ultra high temperature (UHT) milk must:

— be prepared by applying to the raw milk a continuous flow of heat entailing the application of a high temperature for a short time (at least 135 °C for at least one second or a process using different time and temperature combinations to obtain an equivalent effect) — the aim being to destroy all residual spoilage micro-organisms and their spores — and be wrapped using aseptic wrapping in opaque containers or containers made opaque by their packaging, of a type such that chemical, physical and sensoric changes are reduced to a minimum,

— be preserved such that no deterioration can be observed after it has spent 15 days in a closed container at a temperature of 30 °C; where necessary, provision can also be made for a period of 7 days in a closed container at a temperature of 55 °C,

— be prepared from raw milk which, prior to heat treatment, has a plate count at 30 °C below 300 000 per ml, where cows' milk is concerned, or from thermised or pasteurised milk which, prior to heat treatment, has a plate count at 30 °C below 100 000 per ml, where cows' milk is concerned.

— Where the UHT milk treatment is applied by direct contact between milk and steam, the steam must be obtained from potable water and must not leave deposits of foreign substances in the milk or affect it adversely.

(c) Sterilised milk must:

— be heated and sterilised in hermetically sealed containers, the seals of which must remain intact,

— be preserved such that no deterioration can be observed after it has spent 15 days in a closed container at a temperature of 30 °C; where necessary, provision can also be made for a period of 7 days in a closed container at a temperature of 55 °C,

— be prepared from raw milk which, prior to heat treatment, has a plate count at 30 °C below 300 000 per ml, where cows' milk is concerned, or from thermised or pasteurised milk which, prior to heat treatment, has a plate count at 30 °C below 100 000 per ml, where cows' milk is concerned.

III. **Requirements for other milk products**

1. Upon acceptance at a dairy establishment, milk must be cooled to and/or maintained at a temperature not higher than + 6 °C until processed. For the manufacture of milk products with raw milk, the operator or manager of the dairy establishment must take all necessary measures to ensure that raw milk is kept at a temperature below + 6 °C awaiting its processing, or is processed immediately after milking is finished. However, for technological reasons concerning the manufacture of certain milk products, the competent authority may authorise the above temperature to be exceeded.

2. Awaiting the establishment of standards in the context of a more specific legislation on the quality of milk and milk products, milk subject to a treatment involving heating and intended for the manufacture of milk products must satisfy the following conditions:

(a) Thermised milk must:

— be obtained from raw milk which, prior to heat treatment, has a plate count at 30 °C below 300 000 per ml, where cows' milk is concerned,

— be prepared from raw milk which has been heated for at least 15 seconds at a temperature between 57 °C and 68 °C such that after treatment the milk shows a positive reaction to the phosphatase test,

— if it is used for the production of pasteurised, UHT or sterilised milk intended for the manufacture of milk products, comply before treatment with the following standards: plate count at 30 °C below 100 000 per ml;

(b) Pasteurised milk must:

— be prepared by means of a treatment involving a high temperature for a short time (at least 71,7 °C for 15 seconds) or by a pasteurisation process using different time and temperature combinations to obtain an equivalent effect,

— show a negative reaction to the phosphatase test;

(c) UHT milk must be prepared by applying to the raw milk a continuous flow of heat entailing the application of a high temperature for a short time (at least 135 °C for at least one second or by a process using different time/temperature combinations to obtain an equivalent effect) – the aim being to destroy all micro-organisms and their spores – be wrapped using aseptic wrapping in opaque containers or containers made opaque by their packaging, of a type such that chemical, physical and organoleptic changes are reduced to a minimum.

CHAPTER III

WRAPPING AND PACKAGING

Sealing must be carried out immediately after filling in the establishment where the last heat treatment of the drinking milk and/or liquid-milk products has taken place, by means of sealing devices which ensure the protection of milk against any harmful effects of external origin on its characteristics. 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

Without prejudice to the provisions of Directive 79/112/EEC, labelling must clearly show for inspection purposes:

1. The words 'raw milk' for raw milk intended for direct human consumption.

2. In the case of heat-treated milk and heat-treated liquid milk products:

— the nature of the heat treatment to which the milk has been submitted, e.g. thermised, pasteurised, UHT or sterilised,

— any indication, whether coded or not, making it possible to identify the date of the last heat treatment,

— for pasteurised milk, the temperature at which the product must be stored.

3. In the case of milk products:

— the words 'made with raw milk' or 'made with thermised milk' on milk products manufactured from non-heat-treated milk or from thermised milk and where the manufacturing process does not include any heat treatment,

— on milk products heat-treated at the end of the manufacturing process, the nature of this treatment,

— on pasteurised liquid-milk products, the temperature at which the product must be stored.

CHAPTER V

HEALTH MARKING

By way of derogation from the health marking requirements laid down in the preface to the present Annex, the approval number in the health mark may be replaced by a reference to where the approval number of the establishment is shown.

CHAPTER VI

APPROVAL AND REGISTRATION OF ESTABLISHMENTS

Dairy establishments shall be approved by the competent authority in accordance with the preface to the present Annex.

Dairy establishments serving the local market may be registered.

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. They must be stored and transported at a temperature which is best suited to assure optimal conservation of their hygiene properties.

2. Eggs must be delivered to the consumer within a maximum time limit of 21 days of laying.

3. In respect of salmonella, the following rules shall apply for eggs intended for Sweden and Finland:

   (a) consignments of eggs must originate from flocks which have been subjected to microbiological sampling defined in accordance with the procedure referred to in Article 6;

   (b) the test provided for in (a) is not required for consignments of eggs intended for the manufacture of egg products in an egg product establishment;

   (c) the guarantees provided in (a) are not required for eggs originating in an establishment subject to an operational programme recognised by the Commission in accordance with the procedure referred to in Article 6 as equivalent to that approved for Sweden and Finland. The operational programmes of the Member States may be amended and updated by the Commission in accordance with the same procedure.

CHAPTER II

EGG PRODUCTS

I. **Conditions for establishments**

Establishments for the manufacture of egg products must have at least:

1. Suitable rooms with appropriate equipment for

   (a) washing and disinfecting dirty eggs, if necessary;

   (b) breaking eggs and collecting their contents and removing the parts of shells and membranes.

2. A separate room for operations other than those referred to in point 1.

Where egg products are pasteurised, this may be done in the room referred to in point 1(b), when the establishment has a closed pasteurisation system. All measures must be taken to prevent contamination of egg products after their pasteurisation.

II. **Raw materials for the manufacture of egg products**

Only non-incubated eggs fit for human consumption may be used in the manufacture of egg products; their shells must be fully developed and contain no breaks. However, cracked eggs may be used for the manufacture of egg products provided they are delivered directly by the packaging centre or production farm to an approved establishment, where they must be broken as soon as possible.

Liquid egg obtained in an establishment approved for that purpose may be used as raw material. Liquid egg must be obtained under the following conditions:

1. The conditions referred to under III points 1 to 4 must be observed.

2. Immediately after production, the products must have been either deep-frozen or chilled to a temperature of not more than 4 °C; in the latter case they must be treated at their place of destination within the 48 hours from the time of breaking of the eggs from which they were obtained, except in the case of ingredients to be de-sugared.

3. The nature of the goods must be indicated as follows: 'non-pasteurised egg products — to be treated at place of destination — date and hour of breaking —'.

III. **Special hygiene requirements for the manufacture of egg products**

All operations must be carried out in such a way as to avoid any contamination during production, handling and storage of egg products, and in particular:

1. Dirty eggs must be washed before breaking.

2. Eggs must be broken in the room provided for that purpose; cracked eggs must be processed without delay.

3. Eggs other than those of hens, turkeys or guinea fowl must be handled and processed separately. All equipment must be cleaned and disinfected when 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 egg product must undergo a treatment as quickly as possible to eliminate micro-biological hazards or to reduce them to an acceptable level. A batch which has been insufficiently treated may immediately undergo treatment again in the same establishment, provided that this treatment renders it fit for human consumption; where a batch is found to be unfit for human consumption, it must be denatured.

   A treatment is not required for egg white intended for the manufacture of dried or crystallised albumin intended to undergo a later pasteurisation treatment.

6. If treatment is not carried out immediately after breaking, the egg contents must be stored either frozen or at a temperature not exceeding 4 °C; the storage period at 4 °C must not exceed 48 hours, except for stabilised products (e.g. with salt or sugar) and egg products to be de-sugared.

7. Products which have not been stabilised so as to be kept at room temperature must be cooled to a temperature not exceeding 4 °C; products for freezing must be frozen immediately after treatment.

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 must not exceed 1 000 mg/kg of egg product dry matter (applicable only to the untreated product).

   However, for fermented products, this value should be the one recorded before the fermentation process.

3. The quantity of eggshell remains, egg membranes and any other particles in the egg product must not exceed 100 mg/kg of egg product.

V. **Labelling of egg products**

Every consignment of egg products leaving an establishment must carry, in addition to the general requirements for health marking, a label giving the temperature at which the egg products must be maintained and the period during which conservation may thus be assured.

VI. **Approval and registration of establishments**

The premises of collectors and egg packaging centres shall be registered. Establishments manufacturing egg products shall be approved and given an approval number in accordance with the preface to this Annex

SECTION XI

Frogs' legs

1. Frogs may only be killed using humane slaughter techniques in an establishment approved for that purpose. Frogs which are found to be dead prior to slaughter must not be prepared for human consumption.

2. A special room must be 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. Immediately following preparation, the frogs' legs must be washed fully with running potable water within the meaning of Council Directive 98/83/EC, and immediately chilled to the temperature of melting ice or frozen to a temperature of at least - 18 °C or processed.

4. The frogs' legs must not contain, in their edible parts, contaminants such as heavy metals or organo-halogen substances at such a level that the calculated dietary intake exceeds the acceptable daily or weekly human intake.

SECTION XII

Snails

1. Snails may only be killed using humane methods in an establishment approved for that purpose. Snails that are found to be dead before being killed must not be used for human consumption.

2. The hepato-pancreas must be removed and must not be used for human consumption.

3. Snails must not contain, in their edible parts, contaminants such as heavy metals or organo-halogen substances at such a level that the calculated dietary intake exceeds the acceptable daily or weekly human intake.

SECTION XIII

Rendered animal fats and greaves

A. *Standards applicable to establishments collecting or processing raw materials*

1. Centres for collection of raw materials and further transport to processing establishments must be equipped with a cold store for the storage of raw materials at a temperature of 7 °C or below, unless the raw materials are collected and rendered within 12 hours after they were obtained.

2. The processing establishment must be approved and have at least:

   (a) a cold store, unless the raw materials are collected and rendered within 12 hours after they were obtained;

   (b) a dispatch room, unless the establishment dispatches rendered animal fat only in tankers;

   (c) if appropriate, suitable equipment for the preparation of products consisting of rendered animal fats mixed with other foodstuffs and/or seasonings.

B. *Hygiene for rendered animal fat, greaves and by-products*

1. Raw materials must come from animals which, following ante-mortem and post-mortem inspection, have been found fit for human consumption.

2. The raw materials must consist of adipose tissues or bones which are reasonably free from blood and impurities.

3. (a) For the preparation of rendered animal fat, only adipose tissues or bones collected at slaughterhouses, cutting premises or meat processing establishments may be used. Raw materials must be transported and stored until rendering in hygienic conditions and at an internal temperature of 7 °C or below;

   (b) by way of derogation from (a),

   — raw materials may be stored and transported unrefrigerated provided that they are rendered within 12 hours after they were obtained,

   — raw materials collected in retail shops or in premises adjacent to points of sale where the cutting and storage of meat is performed for the sole purpose of supplying the final consumer directly may be used for the preparation of rendered animal fat, provided they are in satisfactory hygiene condition and properly packaged. When the raw materials are not collected daily, they must be chilled immediately after collection.

4. Raw materials must be rendered by heat, pressure or other appropriate method, followed by separation of the fat by decantation, centrifuging, filtration or other appropriate method. The use of solvents is prohibited.

5. Rendered animal fat prepared in accordance with points 1, 2, 3 and 4 may be refined in the same establishment or in another establishment with a view to improving its physico-chemical quality when the fat for refining meets the standards laid down in point 6.

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

	Ruminants			Pigs			Other animal fat	
	Edible tallow		Tallow for refining	Edible pig fat		Lard and other pig 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) Fresh fat obtained from rendering the adipose tissues of swine.

7. Greaves intended for human consumption must be stored:

(i) when rendered at a temperature of 70 °C or less: at a temperature of less than 7 °C for a period not exceeding 24 hours, or at - 18 °C or below;

(ii) when rendered at a temperature of more than 70 °C and having a moisture content of 10 % (m/m) or more:

— at a temperature of less than 7 °C for a period not exceeding 48 hours or a time/temperature ratio giving an equivalent guarantee,

— at - 18 °C or below;

(iii) when rendered at a temperature of more than 70 °C and having a moisture content of less than 10 % (m/m): no specific requirement.

SECTION XIV

Treated stomachs, bladders and intestines

1. In establishments treating stomachs, bladders and intestines it must be ensured that products which cannot be kept at ambient temperature are stored until their dispatch in rooms intended for that purpose. In particular, products which are not salted or dried must be kept at a temperature not exceeding 3 °C.

2. Animal intestines, bladders and stomachs may only be placed on the market if:

(a) the intestines, bladders or stomachs come from animals that have been slaughtered in a slaughterhouse under the supervision of the competent authority and have undergone ante- and post-mortem inspection;

(b) the intestines, bladders or stomachs come from establishments approved by the competent authority;

(c) the intestines, bladders or stomachs have been cleaned and scraped, then salted, heated or dried;

(d) after the treatment referred to in (c), effective measures have been taken to prevent re-contamination of the intestines, stomachs or bladders.

Animal intestines, bladders and stomachs may only be imported from third countries upon presentation of a certificate issued and signed by an official veterinarian attesting the above.

SECTION XV

Gelatine

CHAPTER I

REQUIREMENTS FOR RAW MATERIALS

1. For the production of gelatine intended for human consumption, the following raw materials may be used:

   — bones

   — hides and skins of farmed ruminant animals

   — pig skins

   — poultry skin

   — tendons and sinews

   — wild game hides and skins

   — fish skin and bones.

2. The use of bones obtained from ruminant animals born, reared or slaughtered in countries or regions classified as high BSE risk in accordance with Community legislation is prohibited.

3. The use of hides and skins submitted to tanning processes is prohibited.

4. Raw materials listed in the first five indents of paragraph 1 shall be derived 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 wild game hides and skins from wild game found fit for human consumption.

5. Raw materials must come from food premises approved or registered under the present Regulation.

   Collection centres and tanneries which intend to supply raw material for the production of gelatine intended for human consumption must be specifically authorised or registered for this purpose by the competent authorities and fulfil the following requirements:

   (a) they must have storage rooms with hard floors and smooth walls which 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 to this part is stored and/or processed in these premises, it must be segregated from raw material in conformity with this part throughout the period of receipt, storage, processing and dispatch.

6. Imports into the Community of raw materials for the production of gelatine for human consumption are subject to the following provisions:

   — Member States may authorise the importation of this raw material only from third countries which appear on a the list drawn-up for that purpose,

   — each consignment must be accompanied by a certificate that conforms to the model laid down in accordance with the procedure referred to in Article 6.

CHAPTER II

TRANSPORT AND STORAGE OF RAW MATERIALS

1. During transportation, at the time of delivery to a collection centre, tannery and gelatine-processing establishment, raw materials must be accompanied by a document stating the origin of the raw materials.

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

CONDITIONS TO BE COMPLIED WITH IN THE MANUFACTURE OF GELATINE

1. Gelatine must be produced by a process which ensures that

   — all ruminant bone material which is derived from animals born, reared and slaughtered in countries or regions classified as low BSE risk 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 an equivalent process approved by the Commission after consultation of the appropriate Scientific Committee,

   — 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 once or several times in succession, followed by purification by means of filtration and sterilisation.

2. The use of preservatives, other than sulphur dioxide and hydrogen peroxide, is prohibited.

3. Provided the requirements for gelatine not intended for human consumption are exactly the same as for gelatine intended for human consumption, production and storage may be undertaken in the same establishment.

CHAPTER IV

REQUIREMENTS FOR FINISHED PRODUCTS

Limits for residues

Elements	Limit
As	1 ppm
Pb	5 ppm
Cd	0,5 ppm
Hg	0,15 ppm
Cr	10 ppm
Cu	30 ppm
Zn	50 ppm
Moisture (105 °C)	15 %
Ash (550 °C)	2 %
SO_2 (Reith Williams)	50 ppm
H_2O_2 (European Pharmacopia 1986 (V_2O_2))	10 ppm

ANNEX III

IMPORTATION OF PRODUCTS OF ANIMAL ORIGIN FROM THIRD COUNTRIES

The provisions of this Annex shall apply without prejudice to the animal health requirements for the importation of products of animal origin laid down in Council Regulation . . ./. . . laying down the animal health rules governing the production, placing on the market and importation of products of animal origin intended for human consumption.

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

In order to ensure compliance with the general provisions referred to in Article 12 of Regulation . . . (on the hygiene of foodstuffs), the following shall apply.

In accordance with the procedure referred to in Article 6, the Commission must:

(a) Draw up lists of the third countries or parts of third countries from which imports of products of animal origin are permitted. These lists are to be drawn up after a Community inspection visit.

When drawing up these lists, particular account must be taken of:

(i) the legislation of the third country;

(ii) the organisation of the competent authority of the third country and of its inspection services, of the powers of these services and the supervision to which they are subject, as well as the authority that these services have to monitor effectively the application of their legislation;

(iii) the hygiene conditions of production, manufacture, handling, storage and dispatch actually applied to products of animal origin destined for the Community;

(iv) assurances which the third country can give regarding compliance or equivalence with the relevant health conditions;

(v) experience of marketing of the product from the third country and the results of import controls carried out;

(vi) the results of Community inspection and/or audits carried out in the third country, in particular the results of the assessment of the competent authorities;

(vii) the state of health of the livestock, other domestic animals and wildlife in the third country and the general health situation in the country, which might endanger public health in the Community;

(viii) the regularity and rapidity of the information supplied by the third country relating to the presence of biological hazards, including the presence of marine biotoxins in fishing or aquaculture zones;

(ix) the existence, implementation and communication of a zoonoses control programme;

(x) the legislation of the third country on the use of substances and veterinary medicinal products, including rules on their prohibition or authorisation, their distribution, their marketing and the rules covering administration and inspection;

(xi) the existence, implementation and communication of a residue control programme;

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

(b) For each product or group of products, lay down special import conditions for each third country or group of third countries, having regard to the health situation of the third country or countries concerned.

The special import conditions shall include:

(i) identification of the competent authority responsible for official controls on the products concerned and for signing health certificates;

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

— be drawn up in at least one of the languages of the country of dispatch and of destination and one of those of the Member State in which the inspections at the border inspection post are carried out,

— accompany the products in their original version,

— consist of a single sheet of paper,

— be made out for a single consignee.

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

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

(c) Where considered appropriate, lay down general import conditions for a given product.

II. **Conditions for drawing up and up-dating lists of establishments, including factory vessels and freezer vessels**

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

1. Equivalence agreements

Drawing up and up-dating the lists of establishments must comply with the provisions of the relevant equivalence agreement.

2. By the Commission

In the case of a favourable outcome of the Commission controls referred to under I:

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

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

— compliance with Community requirements,

— supervision by an official inspection service in the third country.

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

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

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

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

— or by a Member State.

(b) Approved lists shall be amended as follows:

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

— the Member States shall have seven working days, from receipt of the modifications to the lists of establishments referred to above to send any written comments to the Commission,

— where written comments are made by at least one Member State, the Commission shall inform the Member States within five working days and include the point at the next meeting of the Standing Veterinary Committee for decision in accordance with the procedure referred to in Article 6,

— where no comments are received from the Member States within the time limit referred to in the second indent, the modifications to the list shall be considered to have been accepted by the Member States. The Commission shall inform the Member States within five working days, and imports shall be authorised from such establishments five working days after receipt of this information by the Member States,

— the Commission shall shall publish the lists in the Official Journal of the European Communities.

3. EU authorisation to a third country to draw up and up-date lists of establishments.

Following a Commission on-the-spot inspection and/or audit for the criteria listed in point I, the competent authority of a third country may be granted the possibility to draw up and up-date lists, on the following conditions:

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

— compliance with Community requirements,

— supervision by an official inspection service in the third country.

Each establishment must be given an approval number.

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

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

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

— to ensure correction of deficiencies within an appropriate time-limit and

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

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

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

4. Case-by-case decisions

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

III. **Other provisions**

1. Only products from a third country which

— are prepared in the third country of dispatch or, with regard to fishery products, on factory vessels or freezer vessels of the third country of dispatch,

— are obtained or prepared in another third country than the third country of dispatch, provided the product comes from an approved establishment in a third country appearing on a Community list,

— where appropriate, are prepared in the Community or manufactured therein,

may be imported into the Community.

2. If necessary, special conditions for the importation of products intended for specific purposes may be adopted by the Commission in accordance with the procedure referred to in Article 6.