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Legislation

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Acts whose titles are printed in light type are those relating to day-to-day management of agricultural matters, and are generally valid for a limited period.

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II

(Acts whose publication is not obligatory)

COUNCIL

COUNCIL DIRECTIVE 92/116/EEC

of 17 December 1992

amending and updating Directive 71/118/EEC on health problems affecting trade in fresh poultrymeat

THE COUNCIL OF THE EUROPEAN COMMUNITIES,

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

Having regard to the proposals from the Commission (1),

Having regard to the opinion of the European Parliament (2),

Having regard to the opinion of the Economic and Social Committee (3),

Whereas poultrymeat is included in the list of products in Annex II to the Treaty; whereas production of and trade in poultrymeat constitute an important source of income for the farming population;

Whereas in order to ensure the rational development of this sector and to increase its productivity, public health rules affecting production and placing on the market must be laid down at Community level;

Whereas Directive 71/118/EEC (4) established the health conditions to be met for the purpose of trade in poultrymeat;

Whereas the Community must adopt the measures intended progressively to establish the internal market comprising an area without internal frontiers over a period expiring on 31 December 1992;

Whereas Directive 89/662/EEC (5) laid down rules on the checks to be applied with a view to the completion of the internal market, and in particular abolished veterinary checks at frontiers between Member States; whereas, where trade is concerned, these rules must apply to fresh poultrymeat;

Whereas, to achieve this purpose, it is necessary to modify the rules laid down in Directive 71/118/EEC in order to bring it into line with the new approach at Community level;

Whereas prime responsibility for compliance with the requirements of this Directive should lie with producers and the authority should be obliged to monitor application of this principle on own-checks;

Whereas the object of this adaptation must be in particular to standardize health requirements for the production, storage and transport of poultrymeat;

Whereas it seems necessary to exclude certain types of direct sale from the scope of this Directive;

Whereas this Directive should not apply to certain products sold directly by the producer to the consumer;

 ⁽¹) OJ No C 36, 14. 2. 1992, p. 9; OJ No C 84, 2. 4. 1990, p. 71; OJ No C 276, 23. 10. 1991, p. 10; and OJ No C 262, 14. 10. 1981, p. 3.

⁽²⁾ OJ No C 183, 15. 7. 1991, p. 56; and OJ No C 129, 20. 5. 1991, p. 166.

⁽³⁾ OJ No C 332, 31. 12. 1990, p. 56.

⁽⁴⁾ OJ No L 55, 8. 3. 1971, p. 23. Directive as last amended by Directive 90/654/EEC (OJ No L 353, 17. 12. 1990, p. 48).

⁽⁵⁾ OJ No L 395, 30. 12. 1989, p. 13. Directive as amended by Directive 91/496/EEC (OJ No L 268, 24. 9. 1991, p. 56).

Whereas it is possible that, owing to certain particular circumstances, some establishments operating prior to 1 January 1992 will not be able to comply with all the rules laid down by this Directive;

Whereas a system of approval should be introduced for the establishments which meet the health requirements laid down by this Directive, together with a Community inspection procedure to ensure that the conditions for such approval are observed;

Whereas low-capacity establishments should be approved by means of simplified structure and infrastructure criteria, while complying with the rules of hygiene laid down in this Directive;

Whereas health marking of poultrymeat is the most appropriate way of satisfying the competent authorities of the place of destination that a consignment complies with the provisions of this Directive; whereas the health certificate should be maintained for the purposes of verifying the destination of certain poultrymeat, where it is maintained for animal health aspects;

Whereas products placed on the Community market which come from third countries must afford the same degree of protection as regards human health; whereas guarantees equivalent to those offered by products of Community origin should therefore be required in respect of such products and they should be subject to the principles and rules on checks contained in Council Directive 90/675/EEC of 10 December 1990 laying down the principles governing the organization of veterinary checks on products entering the Community from third countries (1);

Whereas, in order to allow the time necessary to set up a Community inspection system to ensure that third countries comply with the guarantees provided for in this Directive, national rules on checks should be maintained for a transitional period as regards these countries;

Whereas the Commission should be entrusted with the task of taking certain measures for implementing this Directive; whereas, to that end, procedures should be laid down establishing close and effective cooperation between the Commission and the Member States within the Standing Veterinary Committee;

Whereas, in view of the Hellenic Republic's particular supply difficulties arising from its geographical situation, special derogations should be permitted for that Member State; whereas for the same reason remote regions should be given additional time to comply with the requirements of this Directive;

Whereas the adoption of specific rules for the products covered by this Directive is without prejudice to the

adoption of rules on food hygiene and safety in general, on which the Commission has submitted a proposal for a framework Directive;

Whereas the deadline for transposition of this Directive must not affect the abolition of veterinary checks at frontiers on 1 January 1993;

Whereas for the sake of clarity Directive 71/118/EEC should be updated,

HAS ADOPTED THIS DIRECTIVE:

Article 1

The title, the Articles and the Annexes to Directive 71/118/EEC shall be replaced by the text set out in Annex B to this Directive.

Article 2

- 1. In Article 3 (A) of Council Directive 77/99/EEC of 21 December 1976 on health problems affecting intra-Community trade in meat products (2), point 2 is hereby amended as follows:
- (a) the first paragraph shall be replaced by the following:
 - '2. have been prepared from fresh meat as defined in Article 2 (d), on the understanding that meat imported from a third country must meet the minimum requirements of Chapter III of Directive 71/118/EEC and have been inspected in accordance with Directive 90/675/EEC;'
- (b) the following shall be inserted in the introductory passage of the second paragraph, after the reference to Directive 64/433/EEC:

'the third subparagraph of Article 4 (1), and Chapter IX of Annex I to Directive 71/118/EEC, and in general any meat declared unfit for human consumption under Community rules'.

- 2. Commission Directive 80/879/EEC of 3 September 1980 on health marking of large packagings of fresh poultrymeat (3) is hereby repealed.
- 3. The second subparagraph of Article 3 (4) (i) of Council Directive 92/45/EEC of 16 June 1992 on public health and animal health problems relating to the killing of

⁽¹⁾ OJ No L 373, 31. 12. 1990, p. 1. Directive as amended by Directive 91/496/EEC (OJ No L 268, 24. 9. 1991, p. 56).

⁽²⁾ OJ No L 26, 31. 9. 1977, p. 85. Directive updated by Directive 92/5/EEC (OJ No L 57, 2. 3. 1992, p. 1), and last amended by Directive 92/45/EEC (OJ No L 268, 14. 9. 1992, p. 35).

⁽³⁾ OJ No L 251, 24. 9. 1980, p. 10. Directive as amended by Decision 92/189/EEC (OJ No L 87, 2. 4. 1992, p. 25).

wild game and the placing on the market of wild-game meat (1) shall be replaced by the following:

'The provisions of point 68 of Chapter XII of Directive 71/118/EEC on the health marking of large packaging shall be applicable *mutatis mutandis* to meat of small wild game;'.

- 4. Council Directive 91/494/EEC of 26 June 1991 on animal health conditions governing intra-Community trade in and imports from third countries of fresh poultrymeat (2) is hereby amended as follows:
- (a) Article 3 (A) (6) shall be replaced by the following:
 - '6. is, if it is intended for a Member State or a region of a Member State recognized as being free of Newcastle disease or a Member State after transit through a third country, accompanied by the health certificate shown in the Annex;'
- (b) the Annex shall be replaced by Annex A to this Directive.
- 5. In point 3 of the second paragraph of Article 2 of 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 (3), 'in Article 1 of Directive 71/118/EEC' shall be replaced by 'in Article 2 of Directive 71/118/EEC'.

Article 3

- 1. Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with this Directive not later than 1 January 1994, except in the case of establishments situated in:
- remote regions, recognized in accordance with Article 17 of Directive 90/675/EEC (4), including —

- as regards the Kingdom of Spain the Canary Islands, and with Article 13 of Directive 91/496/EEC (5), and
- the new Länder of the Federal Republic of Germany covered by restructuring plans,

in respect of which they must comply with this Directive not later than 1 January 1995; products from these establishments must be marketed in the regions concerned.

They shall forthwith inform the Commission of the provisions they adopt.

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

- 2. Member States shall communicate to the Commission the text of the main provisions of national law which they adopt in the field governed by this Directive.
- 3. The fact that the deadline for transposition of this Directive is set at 1 January 1994 shall not prejudice the abolition of veterinary checks at frontiers provided for in Directive 89/662/EEC.

Article 4

This Directive is addressed to the Member States.

Done at Brussels, 17 December 1992.

For the Council
The President
J. GUMMER

⁽¹) OJ No L 268, 14. 9. 1992, p. 35.

⁽²⁾ OJ No L 268, 24 9. 1991, p. 35.

⁽³⁾ OJ No L 268, 24. 9. 1991, p. 41.

^(*) Council Directive of 10 December 1990 laying down the principles governing the organization of veterinary checks on products entering the Community from third countries (OJ No L 373, 31. 12. 1990, p. 1). Directive as amended by Directive 91/496/EEC (OJ No L 268, 24. 9. 1991, p. 56).

⁽⁵⁾ Council Directive of 15 July 1991 laying down the principles governing the organization of veterinary checks on animals entering the Community from third countries and amending Directives 89/662/EEC, 90/425/EEC and 90/675/EEC (OJ No L 268, 24. 9. 1991, p. 56). Directive as amended by Directive 91/628/EEC (OJ No L 340, 11. 12. 1991, p. 17)

ANNEX A

'ANNEX

MODEL

HEALTH CERTIFICATE

for fresh poultrymeat (1)

	No (²):
Plac	e of loading:
Mir	nistry:
Dep	partment:
Ref	erence (²):
I.	Identification of meat
	Meat of:
	(Animal species)
	Nature of cuts:
	Nature of packaging:
	Number of cuts or packages:
	Month(s) and year(s) when frozen:
	Net weight:
	Net weight:
II.	Origin of meat
	Address(es) and veterinary approval number(s) of the approved slaughterhouse(s):
	Address(es) and veterinary approval number(s) of the approved cutting plant(s):
	<u> </u>
	Address(es) and veterinary approval number(s) of the approved cold store(s):
III.	Destination of meat
	The meat will be sent from: (Place of loading)
	to:
	(Country and place of destination)
	by the following means of transport (3):
	Name and address of consignor:
	Name and address of consignee:
•	

⁽¹⁾ Fresh poultrymeat means fresh meat from the following species: domestic fowl, turkeys, guinea fowl, ducks, geese, quail, pigeons, pheasants and partridges which have not undergone any preserving process. However, chilled and frozen meat shall be considered to be fresh meat.

⁽²⁾ Optional.

⁽³⁾ In the case of rail trucks and lorries, state the registration number, in the case of aircraft the flight number, and in the case of boats, the name and, where necessary, the number of the container.

IV. Attestation

I, the undersigned official veterinarian, certify that the poultrymeat described above satisfies the requirements of Council Directive 91/494/EEC of 26 June 1991 on animal health conditions governing intra-Community trade in and imports from third countries of fresh poultrymeat and also the requirements of the second subparagraph of Article 3 (A) (1) of that Directive, if such meat is destined for a Member State or region of a Member State that is recognized as being free of Newcastle disease.'

Place)	, (Date)	
		•
	(Signature of official veterinarian)	

ANNEX B

Council Directive 71/118/EEC on health problems affecting the production and placing on the market of fresh poultrymeat

CHAPTER I

General provisions

Article 1

This Directive lays down health rules for the production and placing on the market of fresh poultrymeat.

This Directive shall not apply to the cutting and storage of fresh poultrymeat in retail shops or in premises adjacent to sales points, where the cutting and storage are performed solely for the purpose of supplying the consumer directly, such operations continuing to be subject to the public health checks provided for in national rules governing retailing.

Article 2

For the purposes of this Directive, the definitions given in Article 2 (l) to (n) and (q) to (s) of Directive 77/99/EEC (1) shall apply.

In addition the following definitions shall apply:

- poultrymeat means all parts fit for human consumption from domestic birds of the following species: domestic fowl, turkeys, guinea-fowl, ducks and geese;
- fresh poultrymeat means poultrymeat, including meat which is vacuum-wrapped or wrapped in a controlled atmosphere, which has not undergone any preserving process other than chilling or freezing;
- 3. carcase means the whole body of a bird referred to in 1 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 shall be optional;
- 4. carcase parts means parts of a carcase as defined in 3;
- 5. offal means fresh poultrymeat other than that of the carcase as defined in 3, even if it remains naturally connected to the carcase, as well as the head and feet where these are presented separately from the carcase;
- (1) OJ No L 26, 31. 1. 1977, p. 85. Directive updated by Directive 92/5/EEC (OJ No L 57, 2. 3. 1992, p. 1), and last amended by Directive 92/45/EEC (OJ No L 268, 14. 9. 1992, p. 35).

- 6. *viscera* means offal from the thoracic, abdominal and pelvic cavities, and also, where appropriate, the trachea, oesophagus and crop;
- 7. official veterinarian means the veterinarian designated by the competent central authority of the Member State;
- 8. auxiliary means a person officially designated by the competent authority pursuant to Article 8 (2) to assist the official veterinarian;
- 9. pre-slaughter health inspection means inspection of live poultry carried out in accordance with Chapter VI of Annex I;
- 10. post mortem *health inspection* means inspection of the slaughtered poultry, after slaughter, in a slaughterhouse, carried out in accordance with Chapter VIII of Annex I;
- 11. means of transport means the freight-carrying parts of motor vehicles, rail vehicles and aircraft and the holds of ships or containers for transport by land, sea or air;
- 12. establishment means an approved slaughterhouse, an approved cutting plant, an approved cold store, an approved rewrapping centre or a unit grouping together several such establishments.

CHAPTER II

Rules applicable to Community production

Article 3

- I. Fresh poultrymeat must meet the following conditions:
 - A. Carcases and offal must:
 - (a) come from an animal inspected before slaughter in accordance with Chapter VI of Annex I and considered, following such inspection, suitable for slaughter for the placing on the market of fresh poultrymeat;
 - (b) have been obtained from an approved slaughterhouse subject to own-checks in accordance with Article 6 (2) and to checks by the competent authority in accordance with Article 8;

- (c) have been treated under satisfactory hygiene conditions in accordance with Chapter VII of Annex I;
- (d) have been inspected post mortem in accordance with Chapter VIII of Annex I and not have been found unfit for human consumption in accordance with Chapter IX of Annex I;
- (e) be given a health marking conforming to the requirements of Chapter XII of Annex I, on the understanding that such marking is not necessary for carcases that are to be cut in the same establishment;
- (f) after post mortem inspection have been handled in accordance with point 46 of Chapter VII of Annex I and stored in accordance with Chapter XIII of Annex I under satisfactory hygiene conditions;
- (g) have been suitably packaged in accordance with Chapter XIV of Annex I; where a protective covering is used, it must satisfy the requirements of that Chapter.

Where appropriate, a decision may be taken to supplement the provisions of this Chapter in accordance with the procedure laid down in Article 21 to take account, in particular, of various forms of presentation used in the trade, provided such forms comply with the rules of hygiene;

- (h) have been transported in accordance with Chapter XV of Annex I;
- (i) be accompanied during their transport by:
 - either a commercial document. This document must:
 - in addition to the particulars provided for in point 66 of Chapter XII of Annex I, bear code numbers by which the competent authority responsible for supervising the establishment of origin can be identified as well as the official veterinarian responsible for the health inspection on the day the meat was produced,
 - be kept by the consignee for at least one year so that it can be produced at the request of the competent authority,
 - or a health certificate shown in Annex VI in the case of fresh poultrymeat referred to in Article 2 from a slaughterhouse situated in a region or area restricted on health grounds, or in the case of fresh poultrymeat to be sent to another Member State after transit through a third country in a sealed means of transport.

Detailed rules for applying this print, and in particular those concerning the allocation of code numbers and the compliance of one or more lists identifying competent authorities, shall be adopted in accordance with the procedure laid down in Article 21.

B. 1. Parts of carcases or boned meat must:

- (a) have been cut and/or boned in cutting plants approved and supervised in accordance with Article 6;
- (b) have been cut and obtained in accordance with the requirements of Chapter VII of Annex I and come from:
 - animals slaughtered in the Community and complying with the requirements set out in A of this Article,
 - carcases of fowl imported from third countries in accordance with Chapter III of Annex I and having undergone the checks provided for in Directive 90/675/EEC (¹);
- (c) have been subject to the check provided for in Article 8 (i) (b) (ii);
- (d) satisfy the requirement of A (c), (h) and (i) of this Article;
- (e) have been wrapped, packaged or labelled in accordance with A (e) and (g) of this Article on the spot or in rewrapping centres specially approved by the competent authority for that purpose;
- (f) have been stored under satisfactory hygiene conditions and in accordance with Chapter XIII of Annex I.
- 2. When cutting plants use fresh meat other than poultrymeat, such meat must conform to the relevant standards of Directives 64/433/EEC (2), 91/495/EEC (3) and 92/45/EEC (4).
- C. Fresh meat which has been stored in accordance with this Directive in a cold store approved by a Member State and which has not thereafter

⁽¹⁾ OJ No L 373, 31. 12. 1990, p. 1. Directive as amended by Directive 91/496/EEC (OJ No L 268, 24. 9. 1991, p. 56).

⁽²⁾ OJ No 121, 29. 7. 1964, p. 2012/64. Directive as last amended by Directive 91/497/EEC (OJ No L 268, 24. 9. 1991, p. 69).

⁽³⁾ OJ No L 268, 24. 9. 1991, p. 41.

⁽⁴⁾ OJ No L 268, 14. 9. 1992, p. 35.

undergone any handling, except in connection with storage, must meet the requirements of A (c), (e), (g) and (h) and B of this Article or be fresh poultrymeat imported from third countries in accordance with Chapter III and be checked in accordance with Directive 90/675/EEC.

- II. Member States may derogate from the requirements of A where farmers with an annual production of under 10 000 birds of the types referred to in point 1 of the second paragraph of Article 2 supply fresh poultrymeat coming from their holdings in small quantities:
 - either directly to the final consumer at the holding or at the weekly markets nearest to 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 locality as that of the producer or in a neighbouring locality.

Member States may specify the extent to which, in derogation from B, the above transaction may also cover cuts.

This exception shall not apply in respect of itinerant sale, sale by mail order or, as regards the retailer, sale at a market.

The above transactions shall continue to be subject to the public health checks provided for in national rules.

- III. In addition, without prejudice to Community animal health requirements, paragraph I shall not apply to:
 - (a) fresh poultrymeat intended for uses other than human consumption;
 - (b) fresh poultrymeat intended for exhibition, special studies or analysis, provided that official control makes it possible to ensure that the meat is not used for human consumption and that, when the special studies or analysis have been carried out, the meat, with the exception of that used for the purposes of analysis, is destroyed;
 - (c) fresh poultrymeat intended exclusively as supplies for international organizations.

Article 4

1. Member States shall ensure that, in addition to the requirements of Article 3 (I) (A) and without prejudice to Community rules on the examination of animals and fresh

meat for the presence of residues, fresh poultrymeat or poultry is subjected:

- (a) to tests for residues where the official veterinarian suspects their presence on the basis of the findings of the pre-slaughter inspections or any other information;
- (b) to the sampling provided for in Annex IV (I) of Directive 92/117/EEC (1).

The tests provided for at (a) must be carried out to test for residues of substances having a pharmacological action and their derivatives, compliance with withdrawal periods, and for other substances transmissible to poultrymeat which are likely to render the consumption of fresh poultrymeat dangerous or harmful to human health.

The testing referred to in the previous subparagraph must be carried out in accordance with proven methods which are scientifically recognized, in particular those laid down at Community or international level.

It must be possible to evaluate the results of the examinations using reference methods established in accordance with the procedure referred to in paragraph 3.

If the results are positive, the official veterinarian shall take appropriate measures to take account of the risk incurred, and in particular to:

- steps up checks on the poultry raised or any quantity of meat obtained in technologically similar conditions and likely to present the same risk,
- step up checks on other flocks on the holding of origin and, should the problem recur, take appropriate measures regarding the holding of origin,
- if there is ambient contamination, take measures regarding the production chain.
- 2. The tolerances for the substances referred to in paragraph 1, other than those referred to in Directive 86/366/EEC (2), shall be established under the procedure provided for in Regulation (EEC) No 2377/90 (3).

(2) OJ No L 221, 7. 8. 1986, p. 43.

⁽¹) Council Directive 92/117/EEC of 17 December 1992 concerning measures for protection against specified zoonoses and specified zoonotic agents in animals and products of animal origin in order to prevent outbreaks of food-borne infections and intoxications (see page 38 of this Official Journal).

³⁾ Council Regulation (EEC) No 2377/90 of 26 June 1990 laying down a Community procedure for the establishment of maximum residue limits of veterinary medicinal products in foodstuffs of animal origin (OJ No L 224, 18. 8. 1990, p. 1). Regulation as last amended by Commission Regulation (EEC) No 675/92 (OJ No L 73, 19. 3. 1992, p. 8).

3. The reference methods shall be established in accordance with the procedure laid down in Article 21.

In accordance with the same procedure, a decision may be taken to extend the examinations to substances other than those referred to in paragraph 1.

4. Until the entry into force of the implementing measures for this Article, national rules shall remain applicable, subject to the general provisions of the Treaty.

Article 5

- 1. Without prejudice to Directives 91/494/EEC (¹), 81/602/EEC (²) and 88/146/EEC (³) or to the restrictions imposed by Directive 92/117/EEC, poultrymeat cannot be placed on the market for the purposes of human consumption where:
- (a) it originates from poultry affected by the disease referred to in Directive 91/494/EEC;
- (b) it shows traces of residues in quantities which exceed the tolerance to be set in accordance with Article 4 (2) or has been treated with antibiotics, tenderizers or preservatives, unless those preservatives are authorized under Community legislation, on the understanding that agents used specifically to promote water retention are prohibited, as well as any quantity of poultrymeat obtained in technologically similar conditions and likely as a result to present the same risk:
- (c) it originates from animals found to have one of the faults listed in point 53 (a) of Chapter IX of Annex I;
- (d) it has been declared unfit for human consumption pursuant to points 53 (b) and 54 of Chapter IX of Annex I.
- 2. Pending the entry into force of any Community provisions, this Directive shall not affect the provisions of Member States concerning the treatment of poultrymeat by ionizing and ultraviolet radiation. Any trade in products which have undergone this type of treatment shall be subject to Article 5 (2) of Directive 89/662/EEC. To that end, the Member State of origin which has recourse to such treatment shall not dispatch products treated by such a process to a Member State the legislation of which forbids such treatment within its territory and which has informed the Commission and other Member States of the existence of such a ban in the Standing Veterinary Committee.

Article 6

1. Each Member State shall draw up a list af approved establishments other than those referred to in Article 7, each of which shall have a veterinary approval number. It shall send this list to the other Member States and to the Commission.

A single approval number may be given to an establishment processing or rewrapping products obtained from or with raw materials covered by one of the Directives referred to in Article 2 (d) of Directive 77/99/EEC.

The competent authority shall not approve an establishment unless it is satisfied that it complies with this Directive.

Where hygiene is found to be inadequate and where the measures provided for in the second paragraph of point 51 of Chapter VIII of Annex I have proved insufficient to remedy the situation, the competent national authority shall temporarily suspend approval.

If the operator of the establishment, the owner or his agent does not make good the shortcomings noted within the period fixed by the competent national authority, the latter shall withdraw approval.

The Member States in question shall take account here of the conclusions of any check carried out in accordance with Article 10. The other Member States and the Commission shall be informed of the withdrawal of approval.

2. The operator of the establishment, the owner or his agent must conduct regular checks on the general hygiene of conditions of production in his establishment, *inter alia* by means of microbiological controls.

Checks must cover utensils, fittings and machinery at all stages of production and, if necessary, products.

The operator of the establishment, the owner or his agent must be in a position, upon request from the competent authority, to inform the official veterinarian or the Commission's veterinary experts of the nature, frequency and results of the checks conducted, together with the name of the investigating laboratory if need be.

The nature of the checks, their frequency, as well as the sampling methods and the methods for bacteriological examination shall be established in accordance with the procedure laid down in Article 21.

3. The operator of the establishment, the owner or his agent must establish a staff training programme enabling workers to comply with conditions of hygienic production adapted to the production structure.

⁽¹⁾ OJ No L 268, 24. 9. 1991, p. 35.

⁽²⁾ OJ No L 222, 7. 8. 1981, p. 32. Directive as amended by Directive 85/358/EEC (OJ No L 191, 23. 7. 1985, p. 46).

⁽³⁾ OJ No Ľ 70, 16. 3. 1988, p. 16.

The official veterinarian responsible for the establishment must be involved in the planning and implementation of that programme.

- 4. The operator of a cutting plant or of a rewrapping centre, the owner or his agent must keep records of fresh poultrymeat entering and leaving the establishment, specifying the nature of the poultrymeat received.
- 5. Inspection and supervision of establishments shall be carried out under the responsibility of the official veterinarian who, in accordance with Article 8 (2), may be assisted in purely material tasks by auxiliaries. The official veterinarian must at all times have free access to all parts of establishments in order to ensure that this Directive is being complied with.

The official veterinarian must regularly analyse the results of the checks provided for in 2. He may, on the basis of this analysis, conduct further microbiological examinations at all stages of production or on the products.

The results of these analyses shall be written up in a report, the conclusions and recommendations of which shall be notified to the operator of the establishment, the owner or his agent, who shall rectify the shortcomings noted with a view to improving hygiene.

Article 7

- A. In accordance with Annex II, Member States may exempt slaughterhouses handling under 150 000 birds per year from the structure or infrastructure requirements of Annex I, provided they satisfy the following requirements:
 - 1. the establishments concerned must be the subject of special veterinary registration and be given a specific approval number linked to the local supervisory unit.

In order to be approved by the competent national authority:

- (a) the establishment must fulfil the conditions for approval laid down in Annex II;
- (b) the operator of the slaughterhouse, the owner or his agent must keep a register of:
 - animals entering the establishment and slaughter products leaving it,
 - the checks carried out,
 - the results of those checks.

This information shall be communicated to the competent authority at its request;

- (c) the slaughterhouse must notify the veterinary service of the time of slaughter and the number and the origin of the animals, and send it a copy of the health attestation shown in Annex IV;
- (d) the official veterinarian or an auxiliary must be present at the time of evisceration to ensure compliance with the hygiene rules laid down in Chapters VII and VIII of Annex I.
 - Where the official veterinarian or the auxiliary cannot be present at the time of slaughter, the meat may not leave the establishment until the *post mortem* inspection has been carried out in accordance with Article 8 (2), on the day of slaughter, except in the case of meat covered by point 49 of Chapter VIII of Annex I;
- (e) the competent authority must monitor the chain of distribution of meat coming from the establishment and the appropriate marking of products declared unfit for human consumption as well as their subsequent destination and use.
 - Member States shall draw up a list of establishments benefiting from such derogations and shall forward this list, and any subsequent amendments thereto, to the Commission;
- (f) the competent authority must ensure that fresh meat from the establishments referred to in (e) is marked with stamps or labels approved for the purpose in accordance with the procedure laid down in Article 21, showing the administrative district of the health unit under which the establishment comes;
- 2. derogations may also be granted by the competent authority in accordance with Annex II in the case of cutting plants which are not situated in an approved establishment and which are approved pursuant to Article 4 (2) of Directive 64/433/EEC, provided the cutting plant does not handle more than three tonnes per week, subject to compliance with the temperature requirement laid down in point 49 of Chapter VIII of Annex I.

The provisions of Chapters VIII and X and point 64 of Chapter XI of Annex I shall not apply to storage and cutting operations in the establishments referred to in the first subparagraph;

3. meat that has been judged to comply with the hygiene and health inspection requirements laid down by this Directive must be marked with a stamp showing the administrative district of the health unit responsible for the establishment of origin. The model of this stamp shall be determined in accordance with the procedure laid down in Article 21;

4. meat must be

- (i) kept for direct sale on the local market, fresh or processed, to retailers or to the consumer without pre-packaging or pre-wrapping;
- (ii) transported from the establishment to the consignee under hygienic conditions of transport.
- B. The Commission's veterinary experts may, in conjunction with the competent national authority and in so far as is necessary for the uniform application of this Article, carry out on-site checks on a representative number of establishments benefiting from the conditions laid down in this Article.
- C. Member States may derogate from the structural requirements provided for in Chapter I for low-capacity cold stores in which meat is stored only if it is packaged.
- D. Detailed rules for implementing this Article shall be adopted in accordance with the procedure laid down in Article 21.
- E. The Council shall, before 1 January 1998, review the provisions of this Article on the basis of a report from the Commission.

Article 8

- 1. Member States shall ensure that:
- (a) all farms delivering poultry of the species referred to in point 1 of the second paragraph of Article 2 to slaughterhouses are kept under veterinary supervision;
- (b) it is guaranteed that:
 - in slaughterhouses approved in accordance with Article 6, at least one official veterinarian is present throughout the post mortem inspection;
 - (ii) in cutting plants approved in accordance with Article 6, a member of the inspection team referred to in the third subparagraph of paragraph 2 is present at least once a day when meat is being worked on, to check the general hygiene of the plant and the register of fresh meat entering and leaving it;
 - (iii) in cold stores, a member of the inspection team referred to in the third subparagraph of paragraph 2 is regularly present.
- 2. The official veterinarian may be assisted by auxiliaries placed under his authority and responsibility in carrying out the following operations:
- (a) if they fulfil the conditions in point 3 (a) of Annex III, collecting the information needed to assess the health status of the flock of origin, in accordance with Chapter VI of Annex I, which the official veterinarian is to use to make his diagnosis;

- (b) if they fulfil the conditions in point 3 (b) of Annex III:
 - (i) checking that the conditions of hygiene provided for in Chapters I, V, VII and X of Annex I and in Annex II, and the conditions provided for in point 47 of Annex I are met;
 - (ii) establishing that the cases referred to in point 53 of Chapter IX of Annex I are not present at the post mortem inspection;
 - (iii) carrying out the inspection provided for in (a) and (b) of the second paragraph of point 47 of Chapter VIII of Annex I, and especially the quality assessment of the carcases and trimmings, provided that the official veterinarian is actually able to supervise the work of the auxiliaries on the spot;
 - (iv) supervising the health marking provided for in point 67 of Chapter XII of Annex I;
 - (v) carrying out the health control of cut and stored meat;
 - (vi) monitoring transport vehicles or containers and the loading conditions provided for in Chapter XV of Annex I.

Only persons who satisfy the requirements of Annex III may be appointed as auxiliaries following a test organized by the competent central authority of the Member State or by the authority appointed by that central authority.

In order to provide the assistance referred to above, the auxiliaries must form part of an inspection team under the supervision and responsibility of the official veterinarian. They must be independent of the establishment concerned. The competent authority of the Member State concerned shall determine the composition of the inspection team for each establishment in such a way that the official veterinarian is able to supervise the above operations.

Detailed rules governing the assistance referred to in this Article shall, in so far as necessary, be determined in accordance with the procedure laid down in Article 21.

3. The competent authority may permit the staff of the undertaking who have received special training from the official veterinarian, the general criteria for which shall be established under the procedure laid down in Article 21 before 1 October 1993, to carry out the operations provided for in (a) and (b) of the second paragraph of point 47 of Chapter VIII of Annex I under the direct supervision of the official veterinarian.

Article 9

Member States shall entrust to a central service or body the task of collecting and using the results of pre-slaughter and *post mortem* inspections carried out by the official veterinarian and relating to the diagnosis of diseases transmissible to man. Where such a disease is diagnosed, the results of the specific case shall be communicated as soon as possible to the competent veterinary authorities responsible for supervision of the flock from which the animals originated.

Member States shall submit to the Commission information on certain diseases, particularly where diseases transmissible to man have been diagnosed.

The Commission shall, in accordance with the procedure laid down in Article 21, adopt detailed rules for implementing this Article, in particular with regard to:

- the regularity with which information has to be submitted to the Commission,
- the type of information,
- the disease to which the collection of information is to apply,
- procedures for collecting and using information.

Article 10

1. Veterinary experts from the Commission may, in so far as is necessary for the uniform application of this Directive and in cooperation with the competent national authorities, make on-site checks. To do this, they may verify by checking a representative percentage of establishments whether the competent authorities are checking that approved establishments are complying with this Directive. The Commission shall inform the Member States of the results of the checks carried out.

A Member State in whose territory a check is being carried out shall give the experts all the assistance they need for the performance of their duties.

The general provisions for implementing this Article shall be adopted in accordance with the procedure laid down in Article 21.

After obtaining the opinion of the Member States in the Standing Veterinary Committee, the Commission shall draw up a recommendation concerning the rules to be followed in carrying out the checks provided for in this paragraph.

2. Before 1 January 1995 the Council shall review this Article on the basis of a report from the Commission, which may be accompanied by proposals.

Article 11

Member States may, by way of derogation from the requirements of Article 3 (I) (A) (a), authorize the stunning, bleeding and plucking of birds intended for the production for 'foie gras' on the fattening farm, provided that these operations are carried out in a separate room

which satisfies the requirements of Chapter II (14) (b) of Annex I, and that, in accordance with Chapter XV of Annex I, the uneviscerated carcases are transported immediately to an approved cutting plant which is equipped with a special room as defined under (ii) in the second indent of point 15 (b), of Chapter III of Annex I, where the carcases must be eviscerated within 24 hours under the supervision of the official veterinarian.

Article 12

- 1. Member States may authorize use of the process of chilling fresh poultrymeat by immersion in water if it is carried out in accordance with the conditions laid down in points 42 and 43 of Chapter VII of Annex I. Chilled fresh meat obtained in accordance with this process may be marketed either chilled or frozen.
- 2. Member States in which this process is used must inform the Commission and the other Member States as soon as possible and in any case before 1 January 1994.
- 3. Member States may not object to the introduction into their territory of fresh poultrymeat chilled in accordance with points 42 and 43 of Chapter VII of Annex I when the use of this chilling process is indicated on the accompanying document referred to in Article 3 (I) (A) (i), provided that:
- (a) either the meat has been frozen after chilling without undue delay;
- (b) or chilled poultrymeat is produced under the same conditions in their territory.

Article 13

The rules laid down in Directive 89/662/EEC (1) shall apply in particular to checks at origin, to the organization of and follow-up to the checks to be carried out by the Member State of destination, and to the protective measures to be implemented.

CHAPTER III

Provisions applicable to imports into the Community

Article 14

A. The conditions applicable to the placing on the market of fresh poultrymeat imported from third countries must be considered, under the procedure

 ⁽¹) OJ No L 395, 30. 12. 1989, p. 13. Directive as last amended by Directive 90/654/EEC (OJ No L 353, 17. 12. 1990, p. 48).

provided for in Article 21, as at least equivalent to those laid down for the placing on the market of fresh poultrymeat obtained in accordance with Articles 3 to 6 and 8 to 13.

- B. For the purposes of uniform application of A, the following paragraphs shall apply.
 - 1. In order to be imported into the Community, fresh poultrymeat must:
 - (a) come from third countries or parts of third countries listed in accordance with Article 9
 (1) and (2) of Directive 91/494/EEC and meet the requirements of this Directive;
 - (b) come from establishments for which the competent authority of the third country has provided the Commission with guarantees that these establishments meet the requirements of this Directive;
 - (c) be accompanied by the certificate referred to in Article 12 of Directive 91/494/EEC supplemented by a declaration to the effect that the meat fulfils the requirements of Chapter II and any additional conditions, or offers the equivalent guarantees referred to in 2 (b) of this paragraph. If necessary, the content of this declaration shall be established under the procedure laid down in Article 21.
 - 2. The following shall be established under the procedure laid down in Article 21:
 - (a) a Community list of establishments which satisfy the requirements in (b). Pending the compilation of that list, Member States are authorized to maintain the controls provided for in Article 11 (2) of Directive 90/675/EEC and the national health certificate required for establishments which have been the subject of national approval;
 - (b) the specific conditions and the equivalent guarantees relating to the requirements of this Directive, other than those enabling meat to be excluded from human consumption in accordance with Article 3 (I) (A) (d) and those laid down in Chapter VI, in points 42 and 43 of Chapter VII and in Chapter VIII of Annex I. Such conditions and guarantees may not be less stringent than those laid down in Articles 3 to 6 and 8 to 13.
 - Experts from the Commission and the Member States shall carry out on-the-spot checks to verify whether:
 - (a) the guarantee given by the third country regarding the conditions of production and placing on the market can be considered equivalent to those applied in the Community;

(b) the conditions of paragraphs 1 and 2 are fulfilled.

The experts from the Member States responsible for these checks shall be appointed by the Commission, acting on a proposal from the Member States.

These checks shall be made on behalf of the Community, which shall bear the cost of any expenditure in this connection. The frequency of and procedures for these checks shall be determined under the procedure laid down in Article 21.

4. Pending the organization of the checks referred to in paragraph 3, national rules applicable to inspection in third countries shall continue to apply, subject to notification, through the Standing Veterinary Committee, of any failure to comply with hygiene rules found during these inspections.

Article 15

The list provided for in Article 14 (B) (2) may include only third countries or parts of third countries:

- (a) from which imports are not prohibited pursuant to Articles 9 to 12 of Directive 91/494/EEC;
- (b) which, in view of their legislation and the organization of their veterinary services and of their inspection services, the powers of such services and the supervision to which they are subject, have been recognized, in accordance with Article 3 (2) of Directive 72/462/EEC (1) or Article 9(2) of Directive 91/494/EEC, as capable of guaranteeing the implementation of their legislation in force; or
- (c) the veterinary services of which are able to guarantee that health requirements at least equivalent to those laid down in Chapter II are being complied with.

Article 16

- 1. Member States shall ensure that fresh poultrymeat is imported into the Community only if it:
- is accompanied by the certificate provided for in Article 14 (B) (1) (c),
- has satisfied the checks required by Directive 90/675/EEC.
- 2. Pending the establishment of detailed rules for implementing this chapter:
- the national rules applicable to imports from third countries for which such requirements have not been

OJ No L 302, 31. 12. 1972, p. 28. Directive as last amended by Directive 91/688/EEC (OJ No L 377, 31. 12. 1991, p. 18).

- adopted at Community level shall continue to apply, provided that they are not more favourable than those laid down in Article 14 (B) (2) (b),
- imports must take place under the conditions laid down in Article 11 (2) of Directive 90/675/EEC.

Article 17

The principles and rules laid down in Directive 90/675/EEC shall apply, with particular reference to the organization of and follow-up to the checks to be carried out by the Member States and the safeguard measures to be implemented.

Pending implementation of the decisions provided for in Article 8 (3) of Directive 90/675/EEC, imports must take place in accordance with Article 11 (2) of that Directive.

CHAPTER IV

Final provisions

Article 18

- 1. The provisions of the Annexes shall not apply to establishments situated on certain islands of the Hellenic Republic where the production of such establishments is exclusively reserved for local consumption.
- 2. The arrangements for applying paragraph 1 shall be adopted under the procedure provided for in Article 21. Under the same procedure it may be decided to amend the provisions of that paragraph with a view to the progressive extension of Community standards to all establishments situated on the islands referred to in that paragraph.

Article 19

The Annexes shall be amended by the Council acting by a qualified majority on a proposal from the Commission, in particular to adapt them to technological and scientific progress.

Article 20

In accordance with the procedure laid down in Article 21, the following may be adopted:

- special conditions for the approval of establishments in wholesale markets,
- rules for the marking of products from a rewrapping centre and supervision procedures enabling the establishment of origin of the raw materials to be traced.

Article 21

- 1. Where the procedure laid down in this Article is to be followed, matters shall without delay be referred to the Standing Veterinary Committee (hereinafter called 'the Committee') set up by Decision 68/361/EEC (1) by its chairman, either on his own initiative or at the request of a Member State.
- 2. The representative of the Commission shall submit to the Committee a draft of the measures to be taken. The Committee shall deliver its opinion on the draft within a time limit which the chairman may lay down according to the urgency of the matter. The opinion shall be delivered by the majority laid down in Article 148 (2) of the Treaty in the case of decisions which the Council is required to adopt on a proposal from the Commission. The votes of the representatives of the Member States within the Committee shall be weighted in the manner set out in that Article. The chairman shall not vote.
- (a) The Commission shall adopt the measures envisaged and implement them immediately if they are in accordance with the opinion of the Committee.
 - (b) If the measures envisaged are not in accordance with the opinion of the Committee, or if no opinion is delivered, the Commission shall without delay submit to the Council a proposal relating to the measures to be taken. The Council shall act by a qualified majority.

If, within three months from the date of referral to the Council, the Council has not acted, the Commission shall adopt the proposed measures save where the Council has rejected the said measures by a simple majority.

Article 22

This Directive is addressed to the Member States.

ANNEX I

CHAPTER I

GENERAL CONDITIONS FOR THE APPROVAL OF ESTABLISHMENTS

Establishments must have at least:

- 1. in rooms where fresh meat is produced, worked on or stored and in areas and corridors through which fresh meat is transported:
 - (a) waterproof flooring which is easy to clean and disinfect, rotproof and laid in such a way as to facilitate the draining of water; the water must be channelled towards drains fitted with gratings and traps to prevent odours. However:
 - in the case of rooms referred to in point 14 (e) of Chapter II, point 15 (a) of Chapter III and point 16 (a) od Chapter IV, channelling of water towards drains fitted with gratings and traps is not required and, in the case of premises referred to in point 16 (a), a device with which water may easily be removed is sufficient,
 - in the case of rooms referred to in point 17 (a) of Chapter IV which store only wrapped or
 packaged meat and in areas and corridors through which fresh meat is transported, waterproof
 and rotproof flooring is sufficient;
 - (b) smooth, durable, impermeable walls, with a light-coloured, washable coating up to a height of at least two metres; in chilling or refrigeration rooms and in stores the walls must be coated at least to storage height. Wall to floor junctions must be rounded or similarly finished except in the rooms referred to in point 17 (a) of Chapter IV.
 - However, the use of wooden walls in the rooms referred to in point 17 of Chapter IV does not constitute grounds for withdrawing approval provided they were built before 1 January 1994;
 - (c) door and window frames in hard-wearing, non-corrodible material and, if of wood, with a smooth and impermeable covering on all surfaces;
 - (d) insulation materials which are rotproof and odourless;
 - (e) adequate ventilation and good extraction of steam;
 - (f) adequate natural or artificial lighting which does not distort colours;
 - (g) a clean and easily cleaned ceiling; failing that, a roof covering with an interior surface which fulfils these conditions;
- 2. (a) as near as possible to the work stations, a sufficient number of facilities for cleaning and disinfecting hands and for cleaning tools with hot water. Taps must not be hand-operable or arm-operable.
 - For washing hands, these facilities must have hot and cold running water or water premixed to a suitable temperature, cleaning and disinfecting products and hygienic means of drying hands;
 - (b) facilities for disinfecting tools, with water supplied at not less than 82 °C;
- 3. appropriate arrangements for protection against pests such as insects and rodents;
- 4. (a) instruments and working equipment such as automatic equipment for working on meat, cutting tables, tables with detachable cutting surfaces, containers, conveyor belts and saws, made of corrosion-resistant material not liable to taint meat and easy to clean and disinfect. Surfaces coming into, or capable of coming into contact with meat, including welds and joins, must be maintained smooth. The use of wood is forbidden except in rooms where the only fresh meat stored is hygienically packaged fresh poultrymeat;
 - (b) corrosion-resistant fittings and equipment meeting hygiene requirements for:
 - meat handling,
 - storing meat containers, in such a way that neither the meat nor the containers come into direct contact with the floor or walls;

- (c) facilities, including suitably laid out and equipped reception and marshalling areas, for the hygienic handling and protection of meat during loading and unloading;
- (d) special watertight non-corrodible containers, with lids and fasteners to prevent unauthorized persons from removing things from them, for keeping meat not intended for human consumption, or a lockable room for such meat if the quantities are large enough to necessitate this or if the meat is not removed or destroyed at the end of each working day; where such meat is removed through conduits, these must be so constructed and installed as to avoid any risk of contamination of the fresh poultrymeat;
- (e) rooms for the hygienic storage of materials for wrapping and packaging where such activities are carried out in the establishment;
- 5. refrigeration equipment to keep the internal temperature of the meat at the levels required by this Directive. This equipment must include a system for draining off water of condensation without any possibility of contamination of the fresh poultrymeat;
- 6. an adequate pressurized supply of potable water within the meaning of Directive 80/778/EEC (1). Non-potable water pipes must be clearly distinguished from those used for potable water;
- 7. an adequate supply of hot potable water within the meaning of Directive 80/778/EEC;
- 8. a liquid and solid waste disposal system which meets hygiene requirements;
- 9. an adequately equipped lockable room for the exclusive use of the veterinary service, or suitable facilities in the case of stores referred to in Chapter IV and of rewrapping centres;
- 10. facilities enabling the veterinary inspections provided for in this Directive to be carried out efficiently at any time;
- 11. an adequate number of changing rooms with smooth, waterproof, washable walls and floors, wash basins, showers and flush lavatories so equipped as to protect the clean parts of the building from contamination.
 - Lavatories must not open directly on to the work rooms. Showers are unnecessary in cold stores receiving and shipping hygienically wrapped fresh meat only. Wash basins must have hot and cold running water or water premixed to a suitable temperature, materials for cleaning and disinfecting hands and hygienic means of drying hands. Wash basin taps must not be hand-operable or arm-operable. There must be a sufficient number of such wash basins near the lavatories;
- 12. a place and adequate facilities for cleaning and disinfecting means of transport for meat except in the case of cold stores receiving and shipping hygienically packed fresh meat only. Slaughterhouses must have a separate place and separate facilities for cleaning and disinfecting means of transport and crates used for poultry for slaughter. However, these places and facilities are not compulsory if provisions exist requiring that means of transport or crates be cleaned and disinfected at officially authorized facilities;
- 13. a room or secure place for the storage of detergents, disinfectants and similar substances.

CHAPTER II

SPECIAL CONDITIONS FOR THE APPROVAL OF POULTRY SLAUGHTERHOUSES

- 14. In addition to the general requirements, slaughterhouses must have at least:
 - (a) a room or covered space which is sufficiently large and easy to clean and disinfect for the pre-slaughter inspection provided for in the second paragraph of point 28 of Chapter VI and to accommodate the birds referred to in point 1 of the second paragraph of Article 2 of this Directive;

⁽¹⁾ OJ No L 229, 30. 8. 1980, p. 11. Directive as last amended by Directive 91/692/EEC (OJ No L 377, 31. 12. 1991, p. 48).

- (b) a slaughter room large enough for stunning and bleeding on the one hand, and plucking and any scalding on the other, to be carried out in separate places. Any communication between the slaughter room and the room or space referred to in (a) other than the narrow opening through which only slaughter poultry may pass must have an automatically closing door;
- (c) an evisceration and preparation room 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, so as to prevent contamination. Any communication between the evisceration and preparation room and the slaughter room other than the narrow opening through which only slaughter poultry may pass must have an automatically closing door;
- (d) if necessary, a dispatching room;
- (e) one or more sufficiently large chilling or refrigerating rooms, with a lockable facility, for fresh poultrymeat which has been detained;
- (f) a room or space for collecting feathers unless these are treated as waste;
- (g) separate wash basins and lavatories for staff handling live birds.

CHAPTER III

SPECIAL CONDITIONS FOR THE APPROVAL OF CUTTING PLANTS

- 15. In addition to the general requirements, cutting plants must have at least:
 - (a) chilling or refrigerating rooms large enough for meat preservation;
 - (b) a room for cutting, boning and wrapping,
 - in so far as this operation is carried out in the cutting plant:
 - (i) a room for the evisceration of geese and ducks reared for the production of 'foie gras', which have been stunned, bled and plucked on the fattening farm;
 - (ii) a room for the evisceration of poultry referred to in point 49 of Chapter VIII;
 - (c) a room for packaging, where such operations are carried out in the cutting plant, unless the conditions provided for in point 74 of Chapter XIV are fulfilled.

CHAPTER IV

SPECIAL CONDITIONS FOR THE APPROVAL OF COLD STORES

- 16. In addition to the general requirements, stores in which fresh meat is stored in accordance with the first indent of point 69 of Chapter XIII must have at least:
 - (a) sufficiently large chilling and refrigerating rooms, which are easy to clean and in which fresh meat can be stored at the temperature provided for in the first indent of point 69;
 - (b) a recording thermometer or recording telethermometer in or for each storage area.
- 17. In addition to the general requirements, stores in which fresh poultrymeat is stored in accordance with the second indent of point 69 of Chapter XIII must have at least:
 - (a) sufficiently large chilling and refrigerating rooms which are easy to clean and in which fresh poultrymeat can be stored at the temperature provided for in the second indent of point 69;
 - (b) a recording thermometer or recording telethermometer in or for each storage area.

CHAPTER V

HYGIENE OF STAFF, PREMISES AND EQUIPMENT IN THE ESTABLISHMENTS

- 18. Absolute cleanliness shall be required of staff, premises and equipment.
 - (a) Staff handling exposed or wrapped fresh meat or working in rooms and areas in which such meat is handled, packaged or transported must in particular wear clean and easily cleanable headgear, footwear and light-coloured working clothes or other protective clothing. Staff engaged in working on or handling fresh meat must wear clean working clothes at the commencement of each working day and must renew such clothing during the day as necessary and must wash and disinfect their hands several times during the working day and each time work is resumed. Persons who have been in contact with sick birds or infected meat must immediately afterwards carefully wash their hands and arms with hot water and then disinfect them. Smoking is forbidden in work rooms and storerooms and in other areas and corridors through which fresh meat is transported.
 - (b) No animal may enter the establishments except, in the case of slaughterhouses, animals for slaughter. Rodents, insects and other vermin must be systematically destroyed.
 - (c) Equipment and instruments used for handling live poultry and working on fresh poultrymeat must be kept clean and in a good state of repair. They must be carefully cleaned and disinfected several times during the working day, at the end of the day's work and before being re-used when they have been soiled.
 - (d) Crates for delivering poultry must be made of non-corrodible material, be easy to clean and disinfect. They must be cleaned and disinfected each time they are emptied.
- 19. Rooms, instruments and working equipment must not be used for purposes other than work on fresh poultrymeat, fresh meat or game meat authorized in accordance with Directives 91/495/EEC and 92/45/EEC or meat preparations or products unless they are cleaned and disinfected before re-use.

This restriction shall not apply to transport equipment used on the premises referred to in point 17 (a), when the meat is packaged.

- 20. Poultrymeat and containers thereof must not come into direct contact with the floor.
- 21. Potable water must be used for all purposes; however, non-potable water may be used for steam production, fire fighting, cooling refrigeration equipment and removing waste feathers in the slaughterhouse provided that the pipes installed for this purpose preclude the use of such water for other purposes and present no danger of contamination of fresh meat. Non-potable water pipes must be clearly distinguished from pipes used for potable water.
- Feathers and by-products of slaughter unfit for human consumption must be taken away immediately.
 - The spreading of sawdust or any other similar substance on the floor of the workroom and fresh poultrymeat storage rooms is prohibited.
- 23. Detergents, disinfectants and similar substances must be used in such a way that instruments, working equipment and fresh meat are not adversely affected. Their use must be followed by thorough rinsing of such instruments and working equipment with potable water.
- 24. Persons likely to contaminate meat are prohibited from working on it and handling it.

When recruited, any person working on and handling fresh meat shall be required to prove, by a medical certificate, that there is no medical impediment to such employment. The medical supervision of such a person shall be governed by the national legislation in force in the Member State concerned.

CHAPTER VI

PRE-SLAUGHTER HEALTH INSPECTION

- 25. (a) The official veterinarian of the slaughterhouse may authorize the slaughter of a consignment of poultry from a holding only, without prejudice to the certificate shown in Model 5 in Annex IV to Directive 90/539/EEC, where:
 - (i) the poultry intended for slaughter is accompanied by the health attestation provided for in Annex IV; or,
 - (ii) 72 hours before the arrival of the poultry at the slaughterhouse he was in possession of a document to be determined by the competent authority containing:
 - relevant up-to-date information regarding the flock of origin, in particular details taken from the holding's records referred to in 27 (a) covering the type of poultry to be slaughtered,
 - proof that the holding of origin is under the supervision of an official veterinarian.

This information must be assessed by the official veterinarian prior to deciding what measures are to be taken with respect to fowl coming from the holding concerned, particularly the type of pre-slaughter inspection.

- (b) Where the conditions provided for in (a) are not met, the official veterinarian of the slaughterhouse may either postpone slaughter or where compliance with the welfare rules requires authorize slaughter having first carried out the tests provided for under 27 (b), and must have an official veterinarian inspect the holding of origin of the fowl concerned with a view to obtaining this information. Any costs associated with the application of this paragraph shall be charged to the farmer in accordance with rules to be decided on by the competent authority.
- (c) However, in the case of farmers with an annual production of not more than 20 000 domestic fowl, 15 000 ducks, 10 000 turkeys, 10 000 geese or an equivalent quantity of the other species of fowl referred to in point 1 of the second paragraph of Article 2, the pre-slaughter inspection referred to in 27 (b) may be carried out at the slaughterhouse. In that case the farmer must provide a declaration to the effect that his annual production does not exceed the said figures.
- (d) The farmer must keep for a minimum of two years the records referred to in point 27 (a) for submission to the competent authority on demand.
- 26. The owner, the person authorized to dispose of the poultry or their representative must facilitate the pre-slaughter inspection operations and in particular assist the official veterinarian in any handling deemed necessary.

The official veterinarian must carry out the pre-slaughter inspection in accordance with professional rules, in adequate lighting.

- 27. Pre-slaughter inspection on the farm of origin referred to in point 25 shall comprise:
 - (a) checking of the farmers' records, which must include at least the following, depending on the type of poultry:
 - day of arrival of the birds,
 - source of the birds,
 - number of birds,
 - actual performance of the particular breeds (e.g. weight gain),
 - mortality,
 - suppliers of feedingstuffs,
 - type, period of use and withdrawal periods of feed additives,
 - comsumption of feedingstuffs and water,
 - examination and diagnosis of the attending veterinarian, together with any laboratory results,
 - type of any medicinal product, with dates of administration and withdrawal, given to the birds,
 - date and type of any vaccines given,
 - weight gain during the fattening period,

- results of any previous official health inspections of birds from the same flock,
- number of birds sent for slaughter,
- expected date of slaughter;
- (b) the additional examination needed to establish a diagnosis where the birds:
 - (i) are suffering from a disease which can be transmitted to humans or to animals or are behaving, on an individual or collective basis, in such a way as to indicate that such a disease may occur;
 - (ii) show disturbance of general behaviour or signs of sickness which may make the meat unfit for human consumption;
- (c) regular sampling of water and feed with a view to checking compliance with withdrawal periods;
- (d) the results of tests for zoonotic agents carried out in accordance with Directive 92/117/EEC.
- 28. At the slaughterhouse, the official veterinarian shall ensure that the poultry is identified, check compliance with Chapter II of Directive 91/628/EEC (1) and in particular check whether the poultry has suffered injury during transport.

Moreover, in the event of doubt concerning the identity of a consignment of poultry and where the poultry must undergo pre-slaughter health inspection at the slaughterhouse in accordance with point 25 (c), the official veterinarian must examine each crate if the poultry show the symptoms referred to in point 27 (b).

- 29. Where the poultry has not been slaughtered within three days of its examination and the issue of the health attestation provided for in point 25 (a) (i):
 - where the poultry has not left the holding of origin, a new health attestation must be issued,
 - or, after assessing the reasons for the delay, the official veterinarian of the slaughterhouse shall authorize slaughter if there is no health reason to prevent it, if need be following a further examination of the poultry.
- 30. Without prejudice to the requirements of Directive 91/494/EEC, slaughter for the purpose of human consumption must be forbidden if the clinical symptoms of the following diseases have been established:
 - (a) ornithosis;
 - (b) salmonellosis.

The official veterinarian may, at the request of the owner of the poultry or of his representative, authorize the slaughter at the end of the normal slaughter process provided precautions are taken to keep to a minimum the risk of spreading bacteria and to clean and disinfect the facilities after the slaughter, with the meat resulting from the slaughter being handled as if it were meat declared unfit for human consumption.

- 31. The official veterinarian must:
 - (a) forbid slaughter where he has evidence that the meat from the animals concerned would be unfit for human consumption;
 - (b) postpone slaughter were the withdrawal period for residues has not been respected;
 - (c) ensure, with regard to clinically healthy poultry from a flock slaughter of which is obligatory under a programme for the control of infectious disease, that the poultry is slaughtered at the end of the day or under conditions such that any contamination of other poultry is avoided. Member States may dispose of this meat in their territories according to their national rules.
- 32. The official veterinarian must immediately notify the competent authority of any prohibition of slaughter, giving reasons, and provisionally place the poultry affected by that slaughter prohibition in safekeeping.

⁽¹) OJ No L 340, 11. 12. 1991, p. 17.

CHAPTER VII

HYGIENE REQUIREMENTS FOR SLAUGHTER AND THE HANDLING OF FRESH MEAT

- 33. Only live poultry may be brought into slaughter premises. As soon as they are brought into those premises the birds must be slaughtered immediately after stunning, except in the case of slaughter according to religious rite.
- 34. Bleeding must be completed and carried out in such a way that the blood cannot cause contamination outside the place of slaughter.
- 35. Slaughter poultry must be plucked immediately and completely.
- 36. Evisceration must be carried out immediately in the case of total evisceration or within the period laid down in point 49 of Chapter VIII in the case of partial or deferred evisceration. Slaughtered poultry must be opened in such a way that the cavities and all the relevant viscera can be inspected. For this purpose the viscera to be inspected may either be detached or left attached to the carcase by their natural connections. If detached, they must be identifiable as belonging to a given carcase.

However, ducks and geese reared and slaughtered for the production of 'foie gras' may be eviscerated within 24 hours, provided that uneviscerated carcases are as soon as possible reduced to and then kept at the temperature laid down in the first indent of point 69 of Chapter XIII, and transported in accordance with the rules of hygiene.

37. After inspection, the viscera which have been removed must be separated immediately from the carcase, and the parts unfit for human consumption removed at once.

Viscera or parts of viscera remaining in the carcase must, with the exception of the kidneys, be removed entirely if possible, under satisfactory hygiene conditions.

- 38. It is forbidden to clean poultrymeat by wiping with a cloth or to fill the carcase with anything other than edible offal or neck offal from poultry slaughtered in the slaughterhouse.
- 39. It is forbidden to cut the carcase or remove or treat the poultrymeat before the inspection has been completed. The official veterinarian may prescribe any other handling required by the inspection.
- 40. Detained meat, on the one hand, and meat declared unfit for human consumption in accordance with point 53 of Chapter IX or not allowed for human consumption in accordance with point 54 of Chapter IX, on the other, and feathers and waste must be removed as soon as possible to the rooms, facilities or containers provided for in point 4 (d) of Chapter I and point 14 (e) and (f) of Chapter II and must be so handled that contamination is kept to a minimum.
- 41. After inspection and evisceration, fresh poultrymeat must be cleaned immediately and chilled in accordance with the hygiene requirements to ensure compliance with the temperature laid down in Chapter XIII as soon as possible.
- 42. Poultrymeat to be subjected to an immersion chilling process in accordance with the process described in point 43 must, immediately after evisceration, be thoroughly washed by spraying and immersed without delay. The spraying must be carried out by means of equipment which washes both the internal and external surfaces of the carcases efficiently.

For carcases weighing:

- not more than 2,5 kg, at least 1,5 litres of water must be used per carcase,
- between 2,5 kg and 5 kg, at least 2,5 litres of water must be used per carcase,
- 5 kg or more, at least 3,5 litres of water must be used per carcase.
- 43. The immersion chilling process must meet the following requirements:
 - (a) the carcases must pass through one or more tanks of water or of ice and water, the contents of which are continuously renewed. Only the system whereby the carcases are constantly propelled by mechanical means through a counterflow of water is acceptable;

- (b) the temperature of the water in the tank or tanks measured at the points of entry and exit of the carcases must not be more than + 16 °C and + 4 °C respectively;
- (c) it must be carried out in such a way that the temperature specified in the first indent of point 69 of Chapter XIII is reached in the shortest possible time;
- (d) the minimum flow of water throughout the whole chilling process referred to in (a) must be:
 - 2,5 litres per carcase weighing 2,5 kg or less,
 - 4 litres per carcase weighing between 2,5 kg and 5 kg,
 - 6 litres per carcase weighing 5 kg or more.

If there are several tanks, the inflow of fresh water and the outflow of used water in each tank must be regulated in such a way as to progressively decrease in the direction of movement of the carcases, the fresh water being divided between the tanks in such a way that the flow of water through the last tank is not less than:

- 1 litre per carcase weighing 2,5 kg or less,
- 1,5 litres per carcase weighing between 2,5 kg and 5 kg,
- 2 litres per carcase weighing 5 kg or more.

The water used for first filling the tanks must not be included in the calculation of these quantities;

(e) the carcases must not remain in the first part of the apparatus or the first tank for more than half an hour or in the rest of the apparatus or the other tank(s) for longer than is strictly necessary.

All necessary precautions must be taken to ensure that, in the event of interruptions of the process, the transit time laid down in the first subparagraph is complied with.

Whenever the equipment stops, the official veterinarian must satisfy himself prior to the re-setting in motion that the carcases still meet the requirements of this Directive and are fit for human consumption or, if such is not the case, ensure that they are transported as soon as possible to the premises provided for in point 4 (d) of Chapter I;

- (f) each piece of equipment must be entirely emptied, cleaned and disinfected whenever this is necessary at the end of the period of work and at least once a day;
- (g) calibrated control equipment must permit adequate and continued supervision of the measuring and recording of:
 - the water consumption during spray-washing before immersion,
 - the temperature of the water in the tank or tanks at the points of entry and exit of the carcases,
 - the water consumption during immersion,
 - the number of carcases in each of the weight-ranges listed in (d) and in point 42;
- (h) the results of the various checks carried out by the producer must be kept and submitted on request to the official veterinarians;
- (i) the correct functioning of the chilling plant and its effect on the hygiene level shall be evaluated pending adoption, in accordance with the procedure set out in Article 21 of this Directive, of Community microbiological methods by scientific microbiological methods recognized by the Member States, the contamination of the carcases with total and enterobacteriacea bacteria being compared before and after immersion. Such comparison must be carried out when the plant is first brought into use and after that periodically and in any case each time any alterations are made to the plant. The functioning of the various parts must be regulated so as to ensure a satisfactory standard of hygiene.
- 44. Until the inspection has been completed, it must not be possible for carcases and offal not inspected to come into contact with carcases and offal already inspected, and the removal, cutting or further treatment of the carcase is forbidden.
- 45. It must not be possible for meat detained or declared unfit for human consumption or inedible by-products to come into contact with meat declared fit for human consumption, and the former must be placed as soon as possible in special rooms or containers located and laid out in such a way as to avoid any contamination of other fresh meat.

46. The drawing and trussing, handling, further treatment and transport of meat, including offal, must be performed meeting all hygiene requirements. Where such meat is packaged, the conditions laid down in point 14 (d) of Chapter II and in Chapter XIV must be complied with. Packaged or wrapped meat must be stored in a separate room from exposed fresh meat.

CHAPTER VIII

POST MORTEM HEALTH INSPECTION

47. The poultry must be inspected immediately after slaughter under suitable lighting.

As part of this inspection:

- (a) the following parts:
 - (i) the surface of the bird's body, excluding head and feet save where these are intended for human consumption;
 - (ii) the viscera; and
 - (iii) the body cavities,

must be subjected to visual inspection and, where necessary, palpation and incision;

- (b) attention must also be paid to:
 - (i) anomalies of consistency, colour and smell, in the carcases;
 - (ii) major anomalies resulting from slaughtering operations;
 - (iii) proper functioning of the slaughter equipment.

The official veterinarian must in any event:

- (a) subject to a detailed inspection a random sample of the birds rejected in the *post mortem* health inspection, the meat of which was declared unfit for human consumption in accordance with point 53 of Chapter IX;
- (b) examine a random sample of 300 birds taken from the entire consignment which has undergone the post mortem inspection, for an inspection of the viscera and the body cavities;
- (c) carry out a special *post mortem* inspection of the poultrymeat if there are other indications that the meat from that poultry could be unfit for human consumption.

The owner or the person authorized to dispose of the poultry must cooperate to the extent required in carrying out the *post mortem* inspection. He must make the poultry and poultrymeat available in a condition suitable for inspection. He must provide adequate additional assistance at the request of the inspector. If the person authorized to dispose of the poultry does not fulfil his cooperation obligations, the inspection shall be suspended until he cooperates to the extent required for the inspection.

- 48. In the case of partly eviscerated poultry ('effilé') whose intestines were removed immediately, the viscera and the body cavities of at least 5% of the slaughtered poultry from each consignment shall be inspected after evisceration. If during such inspection anomalies are discovered in a number of birds, then all the birds in the consignment shall be inspected in accordance with point 47.
- 49. In the case of New York dressed poultry:
 - (a) the post mortem health inspection in accordance with point 47 shall take place at the latest 15 days after slaughter, during which period it must be stored at a temperature not exceeding + 4 °C;
 - (b) at the end of this period at the latest, it must be eviscerated in the slaughterhouse where the slaughtering was performed or in another approved cutting plant fulfilling the additional requirements under (ii) in the second indent of point 15 (b) of Chapter III and in this last case, be accompanied by the health attestation shown in Annex V;
 - (c) the poultrymeat must not bear the health mark referred to in Chapter XII before the evisceration referred to in point (b) has been performed.
- 50. The taking of samples to examine for residues must be carried out by spot checks and in any case in the event of justified suspicion. In the case of examination for residues by sampling, examination shall be

carried out for the residues referred to in Group A III and Group B I (a) and (c) and II (a) of Annex I to Directive 86/469/EEC (1).

The obligation to examine for residues of substances with pharmacological action referred to in the second subparagraph of Article 4 (1) of this Directive shall not apply to poultry from holdings under official veterinary control where examination for those residues is carried out on the holdings of origin.

51. Where a disease is suspected on the basis of the pre-slaughter or *post mortem* inspection, the official veterinarian may ask for the requisite laboratory tests to be carried out if he considers them necessary to substantiate his diagnosis or to detect substances with pharmacological action likely to be present given the pathological condition observed.

In the event of doubt, the official veterinarian may perform the further cuts and inspections of the relevant parts of the poultry necessary in order to reach a definitive diagnosis.

Where the official veterinarian finds that the hygiene rules laid down in this Directive are clearly being breached or that adequate health inspection is being hampered, he shall be empowered to take action with regard to the use of equipment or premises and to take any measure required, up to and including a reduction in the rate of production or interruption of the production process.

52. The results of the pre-slaughter and post mortem inspections shall be recorded by the official veterinarian and, where transmissible diseases are diagnosed, communicated to the competent veterinary authority responsible for supervision of the holding from which the animals originated, as well as to the owner of the holding of origin or his representative, who must take account of and keep such information and submit it to the official veterinarian carrying out the ante mortem inspection during the subsequent production period.

CHAPTER IX

DECISION OF THE OFFICIAL VETERINARIAN AT THE POST MORTEM INSPECTION

- 53. (a) Poultrymeat shall be declared totally unfit for human consumption where the post mortem inspection reveals any of the following:
 - generalized infectious disease and chronic localization in organs of pathogenic micro-organisms transmissible to humans,
 - systematic mycosis and local lesions in organs suspected of having been caused by pathogenic agents transmissible to humans or their toxins,
 - extensive subcutaneous or muscular parasitism and systematic parasitism,
 - poisoning,
 - cachexia,
 - abnormal smell, colour or taste,
 - malignant or multiple tumours,
 - general soiling or contamination,
 - major lesions and ecchymosis,
 - extensive mechanical lesions, including those due to extensive scalding,
 - insufficient bleeding,
 - residues of substances exceeding the authorized standards or residues of prohibited substances,
 - ascites.
 - (b) Parts of a slaughtered animal which show localized lesions or contaminations not affecting the health of the rest of the meat shall be declared unfit for human consumption.
- 54. The head separated from the carcase with the exception of the tongue, comb, wattles and caruncles and the following viscera, are excluded from use for human consumption: trachea, lungs separated from the carcase in accordance with point 37 of Chapter VII, oesophagus, crop, intestine and gall bladder.

⁽¹⁾ OJ No L 275, 26. 9. 1986, p. 36. Directive as amended by Decision 89/187/EEC (OJ No L 66, 10. 3. 1989, p. 37).

CHAPTER X

PROVISIONS CONCERNING MEAT INTENDED FOR CUTTING

- 55. The carcase shall be cut up into parts and boned only in approved cutting rooms.
- 56. The operator of the plant, the owner or his representative must facilitate operations for supervising the plant, in particular any handling which is considered necessary, and must place the necessary facilities at the disposal of the supervisory service. In particular, he must be able on request to inform the official veterinarian responsible for supervision of the source of the meat brought into his cutting plant and the origin of the animals slaughtered.
- 57. Without prejudice to point 19 of Chapter V, meat which does not fulfil the requirements of Article 3 (I) (B) (1) of this Directive may not be placed in approved cutting plants unless placed in special storage areas; it must be cut up in other places or at other times than meat which does fulfil those requirements. The official veterinarian must at all times have access to all storage rooms and work rooms in order to satisfy himself that the preceding provisions are rigorously observed.
- 58. Fresh meat intended for cutting must, as soon as it is brought in, be placed in the cutting room and, until cut up, in the room provided for in point 15 (a) of Chapter III.

However, notwithstanding point 41 of Chapter VII, meat may be transported directly from the slaughter room to the cutting room.

In such cases the slaughter room and the cutting room must be sufficiently near to each other and located in the same group of buildings, since the meat to be cut must be transferred in one operation from one room to the other by means of an extension of the mechanical handling system from the slaughter room, and cutting must be carried out immediately. As soon as the prescribed cutting and packaging are completed, the meat must be transported to the chilling room provided for in point 15 (a) of Chapter III.

- 59. Meat must be brought into the rooms referred to in point 15 (b) of Chapter III as required. As soon as cutting and, where appropriate, packaging are completed, the meat must be transported to the chilling room provided for in point 15 (a).
- 60. Except in the case of meat cut while warm, cutting may take place only if the meat has reached a temperature not exceeding + 4 °C.
- 61. Cleaning of fresh meat by wiping with a cloth is prohibited.
- 62. Cutting must be carried out in such a way as to avoid any soiling of the meat. Splinters of bone and clots of blood must be removed. Meat obtained from cutting and not intended for human consumption must be collected in the containers or rooms referred to in point 4 (d) of Chapter I as it is cut.

CHAPTER XI

HEALTH MONITORING OF CUT MEAT AND STORED MEAT

- 63. Approved cutting plants, approved rewrapping centres and approved cold stores must be supervised by a member of the inspection team referred to in the third subparagraph of Article 8 (2) of this Directive.
- 64. The supervision provided for in point 63 must include the following tasks:
 - supervision of the entry and exit of fresh meat,
 - health inspection of fresh meat held in the establishment,
 - supervision of the cleanliness of the premises, facilities and instruments provided for in Chapter V,
 and of staff hygiene, including their clothing,
 - any other supervision which the official veterinarian considers necessary for ensuring compliance with this Directive.

CHAPTER XII

HEALTH MARKING

- 65. Health marking must be carried out under the supervision of the official veterinarian. For this purpose, the latter shall supervise:
 - (a) the health marking of meat;
 - (b) the labels and wrapping material when marked as provided for in this Chapter.
- 66. The health mark must include:
 - (a) for meat wrapped in individual units or for small packages,
 - on the upper part, the initials of the consigning country in capitals (i.e. one of the following): B, DK, D, EL, E, F, IRL, I, L, NL, P, UK,
 - in the centre, the veterinary approval number of the establishment or; where appropriate, the cutting premises or rewrapping centre,
 - on the lower part, one of the following sets of initials: CEE, EØF, EWG, EOK, EEC, or EEG.

The letters and figures must be 0,2 centimetres high;

(b) for large packages, an oval mark at least 6,5 cm wide by 4,5 cm high, including the information listed under (a).

The letters must be at least 0,8 cm high and the figures at least 1 cm high. The health mark may, in addition, include an indication enabling the veterinarian who carried out the health inspection of the meat to be identified.

The material used for marking must meet all hygiene requirements and the information referred to in (a) shall appear on it in perfectly legible form.

- 67. (a) The health marking referred to in point 66 (a) must be made:
 - on or visibly beneath wrappers or other packaging of individually packed carcases,
 - on non-individually wrapped carcases by apposition of a seal or label, which may be used only
 once,
 - on or visibly beneath wrappers or other packaging of parts of carcases or offal wrapped in small quantities.
 - (b) The health marking referred to in point 66 (b) must be made on large packages containing carcases, parts of carcases or offal marked in accordance with (a).
 - (c) Where a health marking appears on the wrapper or packaging:
 - it must be applied in such a way that it is destroyed when the wrapper or packaging is opened, or
 - the wrapper or packaging must be sealed in such a way that it cannot be re-used after opening.
- 68. The health marking of carcases, parts of carcases or offal as provided for in point 67 (a) shall not be necessary in the following cases:
 - Consignments of carcases, including those which have had parts removed pursuant to point 53 (b) of Chapter IX, shall be dispatched from an approved slaughterhouse to approved cutting premises for cutting therein subject to the following conditions:
 - (a) the large packaging containing the fresh poultrymeat should bear, on the external surface, the health mark in accordance with the third indent of point 67 (a) and with point 67 (c);
 - (b) the dispatch office shall maintain a record of the amount, type and destination of consignments dispatched in accordance with this Directive;
 - (c) the recipient cutting premises shall maintain a record of the amount, type and origin of consignments received in accordance with this Directive;
 - (d) the health mark on the large packaging shall be destroyed when the large packaging is opened in cutting premises under the supervision of the official veterinarian;
 - (e) the destination and intended use of the consignment shall be clearly indicated on the external surface of the large packaging in accordance with this point and with Annex VII.

- 2. Consignments of carcases, including those which have had parts removed pursuant to point 53 (b) of Chapter IX, parts of carcases and the following offal: hearts, livers and gizzards, shall be dispatched from an approved slaughterhouse, cutting premises or rewrapping centre to a meat and meat product establishment for treatment subject to the following conditions:
 - (a) the large packaging containing the fresh poultrymeat shall bear, on the external surface, the health mark in accordance with the third indent of point 67 (a) and with point 67 (c);
 - (b) the dispatch office shall maintain a record of the amount, type and destination of consignments dispatched in accordance with this Directive;
 - (c) the recipient meat and meat product establishment shall maintain a record of the amount, type and origin of consigments received in accordance with this Directive;
 - (d) when the fresh poultrymeat is intended for use in meat products for intra-Community trade, the health mark of the large packaging shall be destroyed when the large packaging is opened in an establishment under the supervision of the competent authority;
 - (e) the destination and intended use of the consignment shall be clearly indicated on the external surface of the large packaging in accordance with this point and with Annex VII.
- 3. Consignments of carcases, including those which have had parts removed pursuant to point 53 (b) of Chapter IX, shall be dispatched from an approved slaughterhouse, rewrapping centre or cutting premises to restaurants, canteens and institutions for direct supply to the final user after heat treatment, subject to the following conditions:
 - (a) the packaging containing the fresh poultrymeat shall bear, on the external surface, the health mark in accordance with the third indent of point 67 (a) and with point 67 (c);
 - (b) the dispatch office shall maintain a record of the amount, type and destination of the consignments dispatched in accordance with this Directive;
 - (c) the recipient outlet shall maintain a record of the amount, type and origin of consignments received in accordance with this Directive;
 - (d) outlets shall be subject to control by a competent authority, which must be given access to the records kept;
 - (e) the destination and intended use of the consignment shall be clearly indicated on the external surface of the large packaging in accordance with this point and with Annex VII.

CHAPTER XIII

STORAGE

- 69. After the chilling provided for in point 41, fresh poultrymeat must be kept at a temperature which may not at any time exceed + 4 °C.
 - Frozen poultrymeat must be kept at a temperature which may not at any time exceed 12 °C.
 - Packaged fresh poultrymeat must not be stored in the same room as unpackaged fresh meat.

CHAPTER XIV

WRAPPING AND PACKAGING OF FRESH MEAT

- 70. (a) Packaging (for example packing cases, paperboard boxes) must fulfil all rules of hygiene, and in particular:
 - must not alter the organoleptic characteristics of the meat,
 - must not be capable of transmitting to the meat substances harmful to human health,
 - must be strong enough to ensure effective protection of the meat during transportation and handling;
 - (b) packaging must not be re-used for meat unless it is made of corrosion-resistant materials which are easy to clean and has been previously cleaned and disinfected.

71. Where cut fresh meat or offal is wrapped, this operation must be carried out immediately after cutting and in accordance with hygiene requirements.

Wrapping must be transparent and colourless or, in the case of coloured transparent wrapping, designed in such a way as to leave the wrapped meat or offal partially visible. It must also fulfil the conditions of the first and second indents of point 70 (a); it may not be used again for wrapping meat.

Parts of poultry or offal separated from the carcase must always be wrapped in a firmly sealed protective covering satisfying the above criteria.

- 72. Wrapped meat must be packaged.
- 73. However, when wrapping fulfils all the protective conditions of packaging it need not be transparent and colourless and placing in a second container is not necessary provided that the other conditions of point 70 are fulfilled.
- 74. Cutting, boning, wrapping and packaging operations may take place in the same room if the packaging is re-usable as described in point 70 (b) or subject to the following conditions:
 - (a) the room must be sufficiently large and so arranged that the hygiene of the operations is assured;
 - (b) the packaging and wrapping must be enclosed in a sealed protective covering immediately after manufacture; this covering must be protected from damage during transport to the establishment and stored under hygienic conditions in a separate room in the establishment;
 - (c) the rooms for storing packaging material must be dust and vermin-free and have no air connection with rooms containing substances which might contaminate fresh meat. Packaging must not be stored on the floor;
 - (d) packaging must be assembled under hygienic conditions before being brought into the room;
 - (e) packaging must be hygienically brought into the room and used without delay. It must not be handled by staff handling fresh meat;
 - (f) immediately after packaging the meat must be placed in the storage room provided.
- 75. The packaging referred to in this Chapter may contain only cut fresh poultrymeat.

CHAPTER XV

TRANSPORT

- 76. Fresh meat must be transported in means of transport provided with a hermetic closing system or, in the case of fresh meat imported in accordance with Directive 90/675/EEC or fresh meat transiting through the territory of a third country, in sealed means of transport, designed and equipped in such a way that the temperatures specified in Chapter XIII are maintained throughout transportation.
- 77. Means of transport intended for transporting such meat must meet the following requirements:
 - (a) their inside surfaces must be smooth and easy to clean and disinfect;
 - (b) they must be provided with efficient devices for protecting the meat against insects and dust and be watertight.
- 78. Means of transport intended for transporting meat may in no case be used for transporting live animals or any products likely to affect or contaminate meat.

- 79. No other product likely to affect the hygiene of the poultrymeat or to contaminate it may be transported at the same time as the meat in the same means of transport.
 - Packaged meat must be transported in separate means of transport from unpackaged meat unless, within the same means of transport, an adequate physical separation is provided so as to protect unpackaged meat.
- 80. Fresh poultrymeat may not be transported in a vehicle or container which is not clean and has not been disinfected.
- 81. The operator of the plant, the owner or his representative must ensure that transport vehicles and loading conditions are such as to enable the hygiene requirements of this Chapter to be met. A member of the inspection team provided for in the third subparagraph of Article 8 (2) of this Directive must check that this provision is complied with.

ANNEX II

CHAPTER I

GENERAL CONDITIONS FOR APPROVAL OF LOW-CAPACITY ESTABLISHMENTS

Low-capacity establishments must have at least:

- 1. in rooms where fresh meat is produced and worked on:
 - (a) waterproof flooring which is easy to clean and disinfect, rotproof and laid in such a way as to
 facilitate the draining of water; the water must be channelled towards drains fitted with gratings and
 traps to prevent odours;
 - (b) smooth, durable, impermeable walls, with a light-coloured, washable coating up to a height of at least two metres.
 - However, the use of wooden walls in the rooms referred to in point 16 of Chapter IV of Annex I does not constitute grounds for withdrawing approval provided they were built before 1 January 1994;
 - (c) doors in easily cleanable, rotproof and odourless material.
 - Where meat is stored in the establishment concerned, that establishment must have storage premises which satisfy the aforementioned requirements;
 - (d) insulation materials which are rotproof and odourless;
 - (e) adequate ventilation and if necessary good extraction of steam;
 - (f) adequate natural or artificial lighting which does not distort colours;
- 2. (a) as near as possible to the work stations, a sufficient number of facilities for cleaning and disinfecting hands and for cleaning tools with hot water. For washing hands, these facilities must have hot and cold running water or water premixed to a suitable temperature, cleaning and disinfecting products and hygienic means of drying hands;
 - (b) facilities on the spot or in an adjacent room for disinfecting tools, with hot water supplied at not less than 82 °C;
- 3. appropriate arrangements for protection against pests such as insects and rodents;
- 4. (a) instruments and working equipment such as cutting tables, tables with detachable cutting surfaces, containers, conveyor belts and saws, made of corrosion-resistant material, not liable to taint meat and easy to clean and disinfect. The use of wood is forbidden;
 - (b) corrosion-resistant fittings and equipment meeting hygiene requirements for:
 - meat handling,
 - storing meat containers, in such a way that neither the meat nor the containers come into direct contact with the floor or walls;
 - (c) special watertight non-corrodible containers, with lids and fasteners to prevent unauthorized persons from removing things from them, for keeping meat not intended for human consumption; such meat must be removed or destroyed at the end of each working day;
- 5. refrigeration equipment to keep the internal temperature of the meat at the levels required by this Directive. This equipment must include a drainage system linked to the waste-water pipes which presents no risk of contamination of the meat;
- 6. an adequate pressurized supply of potable water within the meaning of Directive 80/778/EEC. However, a non-potable water supply is authorized in exceptional cases for steam production, fire fighting and the cooling of refrigeration equipment, provided that the pipes installed for this purpose preclude the use of this water for other purposes and present no risk of contamination of fresh meat. Non-potable water pipes must be clearly distinguished from those used for potable water;
- 7. an adequate supply of hot potable water within the meaning of Directive 80/778/EEC;

- 8. a system for the hygienic disposal of waste water;
- 9. at least one wash basin and flush lavatories. The latter must not open directly onto the work rooms. The wash basin must have hot and cold running water or water premixed to a suitable temperature, hygienic materials for cleaning and disinfecting the hands and hygienic means of drying hands. The wash basin must be near the lavatories.

CHAPTER II

SPECIAL CONDITIONS FOR THE APPROVAL OF LOW-CAPACITY SLAUGHTERHOUSES

- 10. In addition to the general requirements, low-capacity slaughterhouses must have at least:
 - (a) a slaughter room large enough for stunning and bleeding on the one hand, and plucking and any scalding on the other, to be carried out in separate places;
 - (b) in the slaughter room, walls washable up to a height of at least two metres or up to the ceiling;
 - (c) an evisceration and preparation room which is large enough for evisceration to be carried out in a place sufficiently far from other work stations, or separated from them by a partition, so as to prevent contamination;
 - (d) a refrigerating room of sufficient capacity in relation to the size and type of animals slaughtered, with in any case a separate lockable section of a minimum size reserved for observing the carcases undergoing analysis.
 - Derogations from this requirements may be granted by the competent authority on a case-by-case basis where meat is removed immediately from such slaughterhouses for delivery to cutting plants or butcher shops in the immediate vicinity of the slaughterhouse, provided that transportation takes not more than one hour.
- 11. Animals brought into the slaughter room must be immediately slaughtered after stunning, save in the case of slaughter according to religious rite.
- 12. Sick or suspect animals must not be slaughtered in the establishment concerned except where a derogation is granted by the competent authority.

Where a derogation is granted, slaughter must be performed under the supervision of the competent authority and steps taken to prevent contamination; the premises must be specially cleaned and disinfected under official supervision before being used again.

ANNEX III

PROFESSIONAL QUALIFICATIONS OF AUXILIARIES

- 1. Only candidates who prove that they have:
 - (a) followed a theoretical course, including laboratory demonstrations, authorized by the competent authorities of the Member States on the subjects referred to in point 3 (a);
 - (b) received practical training under the supervision of an official veterinarian

shall be eligible for the test referred to in the second subparagraph of Article 8 (2) of this Directive. The practical training shall take place in slaughterhouses, cutting plants, cold stores and inspection posts for fresh meat or, for the pre-slaughter inspection, in a holding.

- 2. However, auxiliaries fulfilling the requirements of Annex III to Directive 64/433/EEC may follow a training course where the theoretical part is reduced to four weeks.
- 3. The test referred to in the second subparagraph of Article 8 (2) of this Directive shall consist of a theoretical part and a practical part and shall cover the following subjects:
 - (a) for the inspection of holdings:
 - (i) theoretical part:
 - familiarity with the poultry industry organization, economic significance, production methods, international trade, etc.,
 - anatomy and pathology of poultry,
 - basic knowledge of diseases viruses, bacteria, parasites, etc.,
 - monitoring for disease and use of medicinal products/vaccines and residue testing,
 - hygiene and health inspection,
 - welfare on the farm, during transport and at the slaughterhouse,
 - environmental controls in buildings, on farms and in general,
 - national and international rules,
 - consumer attitudes and quality control;
 - (ii) pratical part:
 - visits to farms of different types and different methods of rearing,
 - visits to production establishments,
 - loading and unloading of means of transport,
 - visits to laboratories,
 - veterinary checks,
 - documentation,
 - practical experience;
 - (b) for inspection at slaughterhouses:
 - (i) theoretical part:
 - basic knowledge of anatomy and physiology of slaughtered animals,
 - basic knowledge of pathology of slaughtered animals,
 - basic knowledge of pathological anatomy of slaughtered animals,
 - basic knowledge of hygiene and in particular industrial hygiene, slaughter, cutting and storage hygiene and hygiene of work,
 - knowledge of methods and procedure for the slaughter, inspection, preparation, wrapping, packaging and transport of fresh meat,
 - knowledge of the laws, regulations and administrative provisions relating to the carrying out
 of their work,
 - sampling procedures;
 - (ii) practical part:
 - inspection and assessment of slaughtered animals,
 - determination of animal species through examination of typical parts of the animal,
 - determination of a number of parts of slaughtered animals in which changes have occurred, and comments thereon,
 - post mortem inspection in a slaughterhouse,
 - hygiene control,
 - sampling.

ANNEX IV

MODEL

HEALTH ATTESTATION (1)

for poultry transported from the holding to the slaughterhouse

Con	npetent service:	••••••			No (2):	•
I.	Identification of anim	als				
	Animal species:					
	Number of animals:					
	Identification mark: .					
II.	Origin of animals					
	Address of holding of	-				
			•••••			
II.	Destination of animal	s				
	The animals will be t	-	•			
	by the following mea					
V.	Attestation	· ·				
	I, the undersigned, o slaughter on the abo found to healthy.					
		÷	•		·	
		(Place)			, (Date)	
				nature of official vete		<u>.</u>

⁽¹⁾ This certificate is valid for 72 hours.
(2) Optional.

ANNEX V

MODEL

HEALTH ATTESTATION

for the carcases of poultry for delayed evisceration or for carcases of ducks and geese reared for the production of 'foie gras', stunned, bled and plucked on the fattening farm and transported to a cutting plant which is equipped with a separate room for evisceration

	npetent service: No ('):
I.	Identification of uneviscerated carcases
	Species:
	Number of uneviscerated carcases:
I.	Origin of uneviscerated carcases
	Address of fattening farm:
I.	Destination of uneviscerated carcases
	The uneviscerated carcases will be transported to the following cutting plant:
٧.	Attestation
	I, the undersigned, official veterinarian, attest that the uneviscerated carcases described above are of birds which were examined before slaughter on the abovementioned fattening farm at (time)
	(Place), (Date)
	(Signature of official veterinarian)

⁽¹⁾ Optional.

ANNEX VI

MODEL

HEALTH CERTIFICATE

for fresh poultrymeat (1)

	No (²):
Plac	e of loading:
Mir	nistry:
Den	partment:
-	erence (²):
I.	Identification of meat
÷	Meat of: (Animal species)
	Nature of cuts:
	Nature of packaging:
	Number of cuts or packages:
	Month(s) and year(s) when frozen:
_	Net weight:
	The Height
II.	Origin of meat
	Address(es) and veterinary approval number(s) of the approved slaughterhouse(s):
	Address(es) and veterinary approval number(s) of the approved cutting plant(s):
	Address(es) and veterinary approval number(s) of the approved cold store(s):
III.	Destination of meat
	The meat will be sent from: (Place of loading)
	to:
	(Country and place of destination)
	by the following means of transport (3):
	Name and address of consignor:
	Name and address of consignee:

⁽¹⁾ Fresh poultrymeat means, in accordance with the Directive referred to in IV of this certificate, any parts fit for human consumption of domestic animals of the following species: fowl, turkeys, guinea fowl, ducks, geese, quail, pigeons, pheasants and partridges, which have not undergone any preserving process; however, chilled and frozen meat shall be considered to be fresh meat.

⁽²⁾ Optional.
(3) In the case of rail trucks and lorries, state the registration number, in the case of aircraft the flight number, and in the case of boats, the name and, where necessary, the number of the container.

IV. Attestation

- I, the undersigned, official veterinarian, certify that:
- (a) the poultrymeat described above satisfies the requirements of Council Directive 91/494/EEC of 26 June 1991 on animal health conditions governing intra-Community trade in and imports from third countries of fresh poultrymeat and also the requirements of the second subparagraph of Article 3 (A) (1) of that Directive, if such meat is destined for a Member State or region of a Member State that is recognized as being free of Newcastle disease;
- (b) the poultrymeat described above,
 - the packaging of the meat described above,

bear a mark proving that:

- · the meat comes from animals slaughtered in approved slaughterhouses,
 - the meat was cut in an approved cutting plant;
- (c) this meat has been passed as fit for human consumption following a veterinary inspection carried out in accordance with Council Directive 71/118/EEC of 15 February 1971 on health problems affecting trade in fresh poultrymeat or 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;
- (d) the transport vehicles or containers and the loading conditions of this consignment meet the hygiene requirements laid down in Directive 71/118/EEC.

(Place)	 •••••	 	·····,	(Date)	
		ture of the o			

ANNEX VII

INDICATION TO BE APPLIED TO LARGE PACKAGING

Intended use: cutting/heat treatme	ent (¹)	•		
Address of destination:		 		
		 	······································	•••••••
(¹) Delete as appropriate.	,			

COUNCIL DIRECTIVE 92/117/EEC

of 17 December 1992

concerning measures for protection against specified zoonoses and specified zoonotic agents in animals and products of animal origin in order to prevent outbreaks of food-borne infections and intoxications

THE COUNCIL OF THE EUROPEAN COMMUNITIES,

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

Having regard to the proposal from the Commission (1),

Having regard to the opinion of the European Parliament (2),

Having regard to the opinion of the Economic and Social Committee (3),

Whereas live animals and products of animal origin appear on the list in Annex II to the Treaty; whereas livestock farming and the placing on the market of products of animal origin constitute an important source of income for the farming population;

Whereas the rational development of this sector and an improvement in its productivity may be achieved by the implementation of veterinary measures aimed at protecting and raising the level of public and animal health in the Community;

Whereas it is necessary to prevent and reduce, by appropriate measures, the appearance of zoonoses which pose a threat to human health in particular, through food of animal origin;

Whereas the Community has already undertaken action for the eradication of certain zoonotic diseases and in particular bovine tuberculosis, bovine brucellosis, brucellosis in sheep and goats, and rabies; whereas it is advisable to collect epidemiological information on those diseases;

Whereas those measures should apply without prejudice to Council Directive 89/397/EEC of 14 June 1989 on the official control of foodstuffs (4);

Whereas, in order to assess the priorities for preventive action, it is necessary to collect information in the Member States on the incidence of zoonotic diseases in the human population, in domestic animals, in animal feedingstuffs and wildlife;

Whereas the Commission should follow the development of the epidemiological situation so as to propose the appropriate measures; Whereas the situation with respect to salmonellosis justifies the adoption of immediate control measures for certain types of farming at risk;

Whereas the harmonization of the essential requirements concerning the protection of public health presupposes prior designation of Community liaison and reference laboratories and the implementation of technical and scientific actions;

Whereas detailed rules governing the Community's financial contribution towards certain actions laid down in this Directive have been laid down by Council Decision 90/424/EEC of 26 June 1990 on expenditure in the veterinary field (5);

Whereas it is appropriate to make provision for a procedure establishing close effective cooperation between the Member States and the Commission for the adoption of implementing measures,

HAS ADOPTED THIS DIRECTIVE:

Article 1

This Directive lays down rules for the collection of information on zoonoses and zoonotic agents and the relevant measures to be taken in the Member States and at Community level.

Article 2

For the purposes of this Directive:

- zoonosis means any disease and/or infection which is likely to be naturally transmitted from animals to man;
- 2. zoonotic agent means any bacterium, virus or parasite which is likely to cause a zoonosis;
- 3. approved national laboratory means a laboratory approved or recognized by the competent authority of a Member State to carry out examinations of official samples in order to detect a zoonotic agent;

⁽¹⁾ OJ No C 253, 27. 9. 1991, p. 2.

⁽²⁾ OJ No C 326, 16. 2. 1991, p. 223.

⁽³⁾ OJ No C 79, 30. 3. 1992, p. 6.

⁽⁴⁾ OJ No L 186, 30. 6. 1989, p. 23.

⁽⁵⁾ OJ No L 224, 18. 8. 1990, p. 19. Decision as amended by Decision 91/133/EEC (OJ No L 66, 13. 3. 1991, p. 18).

- 4. sample means a sample taken by the owner of or person responsible for the establishment or the animals, or taken on his behalf, to be examined for a zoonotic agent;
- 5. official sample means a sample taken by the competent authority to test for a zoonotic agent. The official sample bears a reference to the species, the type, the amount and the method of collection, and the identification of the origin of the animal or the product of animal origin; this sample is to be taken without prior warning;
- 6. competent authority means the central authority or authorities of a Member State which is/are responsible for monitoring provisions concerning public health, animal health or other veterinary matters arising from this Directive, or any other authority to which such responsibility has been delegated by the central authority.

Article 3

- 1. Each Member State shall ensure that measures taken in accordance with this Directive by the competent authority are coordinated at national and local level, in particular in relation to epidemiological surveys.
- 2. The competent authority at local level shall be assisted by approved national laboratories.
- 3. Each Member State shall designate the approved national reference laboratories for the zoonoses and zoonotic agents listed in Annex I, point I, at which the identification of a zoonotic agent or final confirmation of its presence may be carried out.

Article 4

- 1. Member States shall ensure that:
- (a) the operators or managers of establishments approved in accordance with Directives 64/433/EEC (¹), 71/118/EEC (²) and 77/99/EEC (³) are obliged to keep for a minimum period to be specified by the competent authority and to communicate to the latter at its request, the results of examinations for the presence of the zoonoses listed in Annex I, point I;
- (b) the isolation and identification of zoonotic agents or the establishment of any other evidence of their
- (1) OJ No 121, 29. 7. 1964, p. 2012/64. Directive as last amended by Directive 91/497/EEC (OJ No L 268,
- 24. 9. 1991, p. 69).
 (2) OJ No L 55, 8. 3. 1971, p. 23. Directive as last amended and updated by Directive 92/116/EEC (see page 1 of this Official Journal).
- (3) OJ No L 26, 31. 1. 1977, p. 85. Directive updated by Directive 92/5/EEC (OJ No L 57, 2. 3. 1992, p. 1), and last amended by Directive 92/45/EEC (OJ No L 268, 14. 9. 1992, p. 35).

- presence rests with the person responsible for the laboratory or, where the identification is carried out elsewhere than at a laboratory, with the person responsible for the examination;
- (c) the diagnosis and identification of a zoonotic agent are reported to the competent authority;
- (d) the competent authority collects information on any zoonotic agents the presence of which has been confirmed in the course of the tests or examinations carried out and on any clinical cases in humans or animals of the zoonoses listed in Annex I, point I;
- (e) the other Member States are regularly informed within the Standing Veterinary Committee set up by Decision 68/361/EEC (4) of clinical cases recorded in accordance with (d).
- 2. In accordance with the procedure laid down in Article 16, the provisions of this Article may be extended to cover the zoonoses and zoonotic agents listed in Annex I, points II and III.

Article 5

- 1. The competent authority shall evaluate the information collected in accordance with Article 4 (1) (d). It shall report to the Commission, by 31 March each year, the trends and sources of the zoonotic infections recorded during the previous year.
- 2. Paragraph 1 shall not rule out more frequent reporting to the Commission by Member States, or requests from the Commission for additional information, where the circumstances warrant. The Commission shall evaluate the information supplied by Member States and shall report to the Standing Veterinary Committee before 1 October each year.
- 3. The Commission shall, before 1 January 1996, submit a report to the Council on experience acquired, accompanied by proposals to improve the reporting system, on which the Council will take a decision by a qualified majority.

Article 6

The Commission shall follow the development of the situation in relation to zoonoses in the Community, particularly on the basis of the information collected pursuant to Articles 5 and 8, and:

(a) shall conduct specific studies, in particular in relation to the evaluation of risks from zoonotic agents, diagnostic procedures and control measures, in collaboration with the competent national laboratories, the Community reference laboratories referred to in Article 13 and the Scientific Veterinary Committee set up by Decision 81/651/EEC (5);

⁽⁴⁾ OJ No L 255, 18. 10. 1968, p. 23.

⁽⁵⁾ OJ No L 233, 19. 8. 1981, p. 32. Decision as amended by Decision 86/105/EEC (OJ No L 93, 8. 4. 1986, p. 14).

- (b) shall, in accordance with the procedure laid down in Article 16, establish the methods of collecting samples and carrying out examinations in the national laboratories referred to in Article 3 (2) and (3). In the case of salmonella this shall be done before the date laid down in Article 17;
- (c) shall establish guidelines for measures to combat zoonoses.

Article 7

The systems for tracing the movement of farm animals laid down in Commission Decision 89/153/EEC (1) shall be enforced in relation to the measures for zoonoses and zoonotic agents laid down in this Directive.

Article 8

1. Member States shall submit to the Commission before 1 October 1993 the national measures which they are taking to achieve the objectives of this Directive in respect of the zoonoses listed in Annex I, points I and II, with the exception of those already being taken for brucellosis and tuberculosis under plans already approved within the framework of Community legislation.

They may include measures to detect the zoonoses and zoonotic agents listed in Annex I, point III.

Member States which have national plans for the detection of the zoonoses listed in Annex I, point II, may submit them to the Commission as the information required in accordance with the first subparagraph.

Member States shall forward to the Commission, every year, a report on the epidemiological situation for trichinosis.

The Commission shall examine the measures communicated by the Member States to determine whether they are compatible with the objectives of this Directive. It shall inform the Member States, meeting in the Standing Veterinary Committee, of its conclusions.

2. In the case of salmonella in fowls, Member States must forward to the Commission before 1 January 1994 plans drawn up in accordance with the criteria laid down in Annexes II and III. These plans must:

- (a) specify as regards salmonella the measures taken to comply with the minimum requirements laid down in Annex III;
- (b) take into account the specific situation in each Member State;
- (c) indicate the number of approved national laboratories at which examination and identification of salmonella will take place and the approval procedures for those laboratories.
- 3. In accordance with the procedure laid down in Article 16:
- the plans referred to in paragraph 2, amended if necessary, shall be approved not later than six months after their submission,
- amendments or additions may be made to a plan previously approved in order to take account of developments in the situation in the Member State concerned or in one of its regions.

Article 9

1. Detailed rules governing the Community's financial contribution towards the measures for slaughter and destruction and official sampling imposed pursuant to Annex III, Section I, point V and towards the operation of the laboratories listed in Annex IV shall be laid down in accordance with Decision 90/424/EEC.

As regards the measures provided for in Annex III, the financial contribution provided for in Decision 90/424/EEC must not benefit breeders who have contravened the requirements of this Directive.

50% of the cost of applying the slaughter and destruction measures referred to in the first subparagraph shall be met from the aforementioned Community financial contribution.

- 2. In Article 4 of Decision 90/424/EEC the following paragraph 3 shall be added:
 - '3. The provisions of Article 3, with the exception of the fourth indent of paragraph 2 and the second indent of paragraph 5, shall apply when a zoonosis listed in Directive 92/117/EEC occurs, provided that this occurrence is an immediate risk to human health. This condition will be fulfilled when the decision provided for in Article 3 (3) is taken.'

Article 10

1. Member States shall implement as from 1 January 1994 the minimum measures laid down for salmonella in Annex III, Section I.

⁽¹⁾ OJ No L 59, 2. 3. 1989, p. 33.

Member States must, before 1 January 1994, establish rules specifying the measures to be taken to avoid the introduction of salmonella onto a farm, taking account of the principles set out in Annex II to Directive 90/539/EEC.

The Council, acting by a qualified majority before 1 January 1995 on a proposal from the Commission drawn up in the light of an opinion from the Scientific Veterinary Committee and on the basis of experience gained at the time this Directive was implemented, shall decide on the measures required to control salmonella in flocks of layers.

Pending the adoption of such measures, Member States may, with due regard for the rules of the Treaty, maintain their national rules in respect of layers.

2. The Council, acting by a qualified majority on a proposal drawn up by the Commission on the basis of the information gathered in accordance with Articles 5 and 6 and Article 8 (1), shall decide whether specific measures to control other zoonoses of comparable seriousness are needed.

Article 11

1. Experts from the Commission may, in so far as is necessary for the uniform application of this Directive and in cooperation with the competent authorities of the Member States, make on-the-spot checks. To do this, they may verify by checking a representative percentage of holdings whether the Member States are ensuring compliance with this Directive. The Commission shall inform the competent authority of the results of the checks made.

The Member State concerned shall take any measures which may prove necessary to take account of the results of the checks. If the Member State does not take such measures, after the situation has been examined by the Standing Veterinary Committee appropriate measures may be decided on under the procedure laid dow in Article 16.

2. The detailed rules for implementing this Article, especially as regards the frequency and method of carrying out the checks referred to in the first subparagraph of paragraph 1, shall be adopted under the procedure set out in Article 16.

Article 12

The safeguard measures provided for in Directive 90/425/EEC (¹) concerning veterinary checks to be carried out in trade with a view to the completion of the internal market shall apply for the purposes of this Directive.

Article 13

The Community reference laboratories listed in Annex IV shall, in accordance with the tasks and duties described therein, be responsible, for liaison with and coordination of the national reference laboratories referred to in Article 3 (3).

Article 14

1. Admission to, or retention on, the Community list of third countries or parts thereof from which imports are authorized in health terms shall be subject to the submission, by the third country concerned, of a plan giving details of the guarantees afforded by that country as regards inspections for zoonoses and zoonotic agents.

The effect of these guarantees must be no less than that resulting from the guarantees provided for by this Directive.

The Commission shall approve the plans in question in accordance with the procedure provided for in Article 16. Alternative guarantees to those resulting from the application of this Directive may be allowed in accordance with that procedure, provided that they are not more favourable than those applicable to trade.

- 2. Where no decision pursuant to paragraph 1 has been taken with regard to a given third country by 31 December 1995, entry of that country on the list referred to in paragraph 1 shall be suspended in accordance with the procedure provided for in Article 16.
- 3. Compliance by the competent authorities of third countries with the execution of the plans shall be verified when the Community experts carry out the checks provided for in Community rules.

Article 15

The Annexes may be amended or supplemented by the Council, acting by a qualified majority on a proposal from the Commission.

In particular, Annex III shall be reviewed under this procedure before 1 January 1996.

Article 16

- 1. Where the procedure laid down in this Article is to be followed, matters shall be referred without delay to the Committee by its chairman, either on his own initiative or at the request of a Member State.
- 2. Within the Committee the votes of the Member States shall be weighted as provided for in Article 148 (2) of the Treaty. The chairman shall not vote.

OJ No L 224, 18. 8. 1990, p. 29. Directive as last amended by Directive 91/496/EEC (OJ No L 268, 24. 9. 1991, p. 56).

- 3. The Commission representative shall submit a draft of the measures to be taken. The Committee shall deliver its opinion on those measures within a time limit which the chairman may set according to the urgency of the matter submitted. Opinions shall be delivered by a majority of 54 votes.
- 4. (a) The Commission shall adopt the measures and implement them immediately where they are in accordance with the opinion of the Committee.
 - (b) Where they are not in accordance with the opinion of the Committee, or if no opinion is delivered, the Commission shall forthwith submit to the Council a proposal concerning the measures to be taken. The Council shall adopt the measures by a qualified majority.

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

Article 17

1. Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with this Directive before 1 January 1994.

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

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

Article 18

This Directive is addressed to the Member States.

Done at Brussels, 17 December 1992.

For the Council
The President
J. GUMMER

ANNEX I

LIST OF THE ZOONOSES COVERED BY ARTICLE 4

- I. Tuberculosis due to Mycobacterium bovis
 - Brucellosis and the agents thereof
 - Salmonellosis and the agents thereof
 - Trichinosis.
- II. Campylobacteriosis
 - Echinococcosis
 - Listeriosis
 - Rabies
 - Toxoplasmosis
 - Yersiniosis
 - Other zoonoses and the agents thereof.
- III. Any other zoonosis not found in the Community and the agents of that zoonosis.

ANNEX II

CRITERIA FOR DRAWING UP PLANS FOR MONITORING SALMONELLA IN FOWL FLOCKS

- I. The plans must indicate:
 - the number and type of samples to be taken,
 - the number and type of official samples to be taken,
 - the methods of sampling,
 - the methods of examination of the samples and identification of the zoonotic agents.
- II. The plans must take into account the following criteria for establishing the sampling procedures:
 - (a) factors likely to encourage the spread of one or more zoonoses;
 - (b) previous history of the zoonosis in question in a country or region, in domestic animals or wildlife;
 - (c) the animal population concerned as regards:
 - total size of population,
 - homogenity of the population group,
 - age of animals,
 - animal production;
 - (d) the environment of the farms as regards:
 - regional differences,
 - density of flocks,
 - relations with urban areas,
 - relations with areas populated by wildlife;
 - (e) farm production systems including:
 - intensive farming units,
 - extensive farming units,
 - husbandry systems, in particular feeding regimes and animal health care measures;
 - (f) problems likely to arise in the light of known precedents and other information;
 - (g) the required degree of protection according to the nature and gravity of the zoonosis in question.

ANNEX III

INSPECTION FOR SALMONELLA

Section I

MONITORING AND CONTROL — PRESENCE OF SALMONELLA IN BREEDING FLOCKS

I. Breeding flocks

A breeding flock comprises at least 250 birds (Gallus gallus), kept or reared on a single holding for the production of hatching eggs.

II. Monitoring for salmonella in breeding flocks

The owner or the person responsible for hatcheries or for a breeding flock must, at his own expense, have samples taken for analysis for the detection of salmonella either in an approved national laboratory or in a laboratory recognized by the competent authority, with the minimum levels of sampling indicated below being respected.

A. Rearing flocks

Samples must be taken from birds being reared for breeding purposes at least when the chicks are
one day old, when the birds are four weeks old and two weeks prior to pullets entering the laying
phase.

2. The samples to be taken must comprise:

- (a) in the case of day-old chicks, samples from the internal linings of the boxes in which the chicks were delivered to a holding and from the carcases of chicks found to be dead on arrival; and
- (b) in the case of pullets at four weeks of age or two weeks prior to entering the laying phase, pooled faeces samples made up of separate samples of fresh faeces each weighing not less than 1 g taken at random from a number of sites in the building in which the birds are kept, or, where the birds have free access to more than one building on a particular holding, from each group of buildings on the holding in which the birds are kept;
- (c) the number of sites from which separate faeces samples are to be taken in order to make a pooled sample shall be as follows:

Number of birds kept in a building	Number of faeces samples to be taken in the building or group of buildings on the holding				
1— 24	(number equal to the number of birds up to a maximum of 20)				
25— 29	20				
30— 39	25				
40— 49	30				
50— 59	35				
60— 89	40				
90—199	50				
200—499	55				
500 or more	60				

B. Adult breeding flocks

1. All adult breeding flocks must be sampled at least every two weeks during the laying period.

- 2. Breeding flocks whose eggs are hatched at a hatchery with a total incubator capacity of less than 1 000 eggs must be sampled on the holding and the samples to be taken shall consist of a pooled faeces sample made up of separate faeces samples, each weighing not less than 1 g, collected in accordance with point A (2) (b).
- 3. Breeding flocks whose eggs are hatched at a hatchery with a total incubator capacity of 1 000 eggs or more must be sampled through the hatchery and the samples to be taken shall consist of:
 - (a) pooled samples of meconium taken from 250 chicks hatched from eggs supplied to the hatchery from each breeding flock; or
 - (b) samples of carcases of 50 chicks which are dead in the shells of eggs or which have been hatched from eggs supplied to the hatchery from each breeding flock.
- 4. Such samples must also be taken from breeding flocks comprising less than 250 birds whose eggs are hatched in hatcheries with a total incubator capacity of 1 000 eggs or more.
- 5. Every eight weeks, the sampling provided for in point B must be replaced by official sampling, which must be conducted in accordance with point 4.

C. Examination of samples for salmonella

The total number of samples taken in each building may be pooled for analysis.

The analyses and tests for salmonella shall be carried out by methods recognized in accordance with the procedure laid down in Article 16 of this Directive, after consultation of the Scientific Veterinary Committee, or, pending recognition, by tried and tested national methods which afford the guarantees laid down in Decision 89/610/EEC (1).

III. Notification of results

Where, as a result of monitoring carried out in accordance with point II, the presence of Salmonella enteritidis or Salmonella typhimurium is detected in a breeding flock, the person responsible for the laboratory carrying out the examination, the person carrying out the examination or the owner of the flock shall notify the results to the competent authority.

IV. Investigation of flocks declared positive after monitoring

Where the presence of Salmonella enteritidis or Salmonella typhimurium is notified in accordance with point III, the flock shall be officially sampled in order to confirm the initial results. A sample of birds must be taken at random from within each house of birds on the farm, the size of sample being selected in accordance with the table at point II (A) (2) (c). For the purposes of examination, the birds from each house must be grouped into batches of five and samples of liver, ovary and intestines taken from each bird in the batch must be examined for salmonella using analyses and tests recognized in accordance with the procedures laid down in Article 16 of this Directive or pending such recognition by tried and tested national methods.

V. Measures to be taken in respect of flocks where infection is confirmed

The measures must comply with the following minimum standards.

- 1. Where, as a result of an investigation carried out in accordance with point IV, the presence of Salmonella enteritidis or Salmonella typhimurium is confirmed in the birds in a house, the following measures must be taken:
 - (a) no bird may leave the house concerned unless the competent authority has authorized the slaughter and destruction under supervision or slaughter in a slaughterhouse designated by the competent authority in accordance with (c);
 - (b) non-incubated eggs produced by the birds in the house in question must be destroyed on the spot or after appropriate marking be taken under supervision to an approved egg-processing establishment to be heat treated in accordance with the requirements of Directive 89/437/EEC (2);

⁽¹⁾ OJ No L 351, 2. 12. 1989, p. 34.

 ⁽²⁾ OJ No L 212, 22. 7. 1989, p. 87. Directive as last amended by Directive 91/684/EEC (OJ No L 376, 31. 12. 1991, p. 38).

- (c) all the birds in the house must be slaughtered in accordance with Annex I, Chapter VI, point 31 (c) of Directive 71/118/EEC, the official veterinarian of the slaughterhouse being informed of the decision to slaughter, in accordance with Annex I, Chapter VI, point 25 (a) of that Directive, or be slaughtered and destroyed so as to reduce as much as possible the risk of spreading salmonella
- 2. Once a house occupied by a flock infected with Salmonella enteritidis or Salmonella typhimurium has been emptied of birds, effective cleansing and disinfection must be carried out, including safe disposal of manure or litter, in accordance with procedures laid down by the local veterinary authority. Restocking must be with chicks satisfying the requirements of point II (A) (1).
- 3. Where eggs for hatching from flocks in which the presence of Salmonella enteriditis or Salmonella typhimurium has been confirmed are still present in a hatchery, they must be destroyed or treated as high risk material in accordance with Directive 90/667/EEC (1).
- VI. Under the procedure provided for in Article 16 and following the opinion of the Scientific Veterinary Committee, to be ascertained before 1 October 1993,
 - (a) surveillance systems based on a serological check at the holding may be recognized if they offer guarantees equivalent to the system of inspection at the hatchery provided for in point II (A) (1), (B) (3) and (4) and (C);
 - (b) alternative solutions to compulsory slaughter provided for in point V (c), such as antibiotic treatment, may be approved for breeding flocks;
 - (c) specific rules may be established with a view to safeguarding valuable genetic material.

The checks provided for in this Chapter may, according to the procedure laid down in Article 16, be reviewed in the light of the development of scientific knowledge.

Section II

INSPECTION FOR SALMONELLA AT THE FINAL PRODUCTION STAGE OF COMPOUND FEEDINGSTUFFS FOR POULTRY

When official samples are being taken on a holding or in cases of justified suspicion, sampling may be carried out on the compound feedingstuffs used to feed poultry.

Where a sample is positive for salmonella, the competent authority shall carry out an investigation in order to

- (a) identify the source of contamination, in particular by means of official samples taken at different stages of production;
- (b) examine the application of rules and controls concerning the disposal and processing of animal waste and in particular those laid down in Directive 90/667/EEC;
- (c) establish procedures for good manufacturing practices and ensure compliance with recognized procedures.

⁽¹⁾ Council Directive 90/667/EEC of 27 November 1990 laying down the veterinary rules for the disposal and processing of animal waste, for its placing on the market and for the prevention of pathogens in feedingstuffs of animal or fish origin and amending Directive 90/425/EEC (OJ No L 363, 27. 12. 1990, p. 51).

ANNEX IV

CHAPTER I

LIST OF COMMUNITY REFERENCE LABORATORIES FOR ZOONOSES (a)

I. Epidemiology of zoonoses

Institut für Veterinärmedizin (Robert von Ostertag-Institut) Postfach 33 00 13 Thielallee 88/92 D-1000 Berlin (Federal Republic of Germany)

II. Salmonella

Rijksinstituut voor de Volksgezondheid PO Box 1 NL-3720 BA Bilthoven (The Netherlands)

CHAPTER II

DUTIES AND TASKS OF THE COMMUNITY REFERENCE LABORATORY

- 1. The Community reference laboratories listed in Chapter I shall be responsible for:
 - providing national reference laboratories with details of analytical methods and comparative testing,
 - coordinating the application by national reference laboratories of the methods referred to in the first indent, in particular by organizing comparative testing,
 - coordinating research into new analytical methods and informing national reference laboratories of advances in this field,
 - conducting initial and further training courses for the benefit of staff from national reference laboratories.
 - providing scientific and technical assistance to the Commission, especially in cases where the results of analyses are contested between Member States.
- 2. The Community reference laboratories shall ensure that the following operating conditions are maintained:

They must:

- have suitably qualified staff with adequate training in the techniques applied to the detection of zoonoses,
- possess the equipment and substances needed to carry out the tasks provided for in 1,
- have an appropriate administrative infrastructure,
- ensure that their staff respect the confidential nature of certain subjects, results or communications,
- have sufficient knowledge of international standards and practices.

⁽a) Without prejudice to the reference laboratories for brucellosis, tuberculosis and rabies.

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of 17 December 1992

laying down animal health and public health requirements governing trade in and imports into the Community of products not subject to the said requirements laid down in specific Community rules referred to in Annex A (I) to Directive 89/662/EEC and, as regards pathogens, to Directive 90/425/EEC

THE COUNCIL OF THE EUROPEAN COMMUNITIES,

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

Having regard to the proposals from the Commission (1),

Having regard to the opinions of the European Parliament (2),

Having regard to the opinions of the Economic and Social Committee (3),

Whereas products of animal origin are included in the list of products in Annex II to the Treaty; whereas the placing on the market of such products constitutes an important source of income for part of the farming population;

Whereas in order to ensure rational development in this sector and increase productivity, animal health and public health rules for the products in question should be laid down at Community level;

Whereas the Community must adopt the measures intended progressively to establish the internal market consisting of an area without internal frontiers, over a period expiring on 31 December 1992;

Whereas in view of the abovementioned objectives the Council has laid down animal health rules applicable to fresh meat, poultrymeat, meat products, game meat, rabbit meat and milk products;

Whereas, save where otherwise provided, trade in products of animal origin must be liberalized, without prejudice to recourse to possible safeguard measures;

Whereas, given the significant risk of the spread of diseases to which animals are exposed, for certain products of animal origin particular requirements should be specified to be imposed when they are placed on the market for the purposes of trade, particularly when intended for regions with a high health status;

(1) OJ No C 327, 30. 12. 1989, p. 29; and OJ No C 84, 2. 4. 1990, p 102.

(2) OJ No C 113, 7. 5. 1990, p. 205; and OJ No C 149, 18. 6. 1990, p. 259.

(3) OJ No C 124, 21. 5. 1990, p. 15; and OJ No C 182, 23. 7. 1990, p. 250.

Whereas, when Directive 92/65/EEC was adopted, the Commission agreed to disassociate the animal health aspects applicable to animals from those applicable to products;

Whereas, so as to allow checks at borders between Member States to be abolished on 1 January 1993, animal health and public health rules should be fixed to apply to all products subject to such checks trade in and imports of which have not yet been harmonized at Community level;

Whereas, to achieve this objective, certain existing rules should be adapted for the adoption of the aforesaid measures;

Whereas a system of approval should be introduced for the third countries and establishments which meet the requirements laid down by this Directive, together with a Community inspection procedure to ensure that the conditions for such approval are observed;

Whereas the accompanying document for products is the best way of satisfying the competent authority of the place of destination that a consignment complies with the provisions of this Directive; whereas the public health or animal health certificate should be maintained for the purposes of verifying the destination of certain imported products;

Whereas the rules, principles and safeguard measures established by Council Directive 90/675/EEC of 10 December 1990 laying down the principles governing the organization of veterinary checks on products entering the Community from third countries (*) should apply here:

Whereas, in the context of intra-Community trade, the rules laid down in Directive 89/662/EEC should also be applied;

Whereas the Commission should be entrusted with the task of adopting certain measures for implementing this Directive; whereas, to that end, procedures should be laid down establishing close and effective cooperation between the Commission and the Member States within the Standing Veterinary Committee;

Whereas, in view of the particular supply difficulties arising from its geographical situation, special derogations should be permitted for the Hellenic Republic;

⁽⁴⁾ OJ No L 373, 31. 12. 1990, p. 1.

Whereas the adoption of specific rules for the products covered by this Directive is without prejudice to the adoption of rules on food hygiene and safety in general, on which the Commission has submitted a proposal for a framework Directive,

HAS ADOPTED THIS DIRECTIVE:

CHAPTER I

General provisions

Article 1

This Directive lays down the animal health and public health requirements governing trade in and imports into the Community of products of animal origin (including trade samples taken from such products) not subject to the said requirements laid down in specific Community rules referred to in Annex A (I) to Directive 89/662/EEC (¹) and, as regards pathogenic agents, to Directive 90/425/EEC.

This Directive shall be without prejudice to the adoption of more detailed rules on animal health in the framework of the aforesaid specific rules nor the maintenance of restrictions on trade or imports of products covered by the specific rules referred to in the first paragraph based on the rules of public health.

Article 2

- 1. For the purposes of this Directive:
- (a) trade means trade as defined by Article 2 (2) of Directive 89/662/EEC;
- (b) trade sample means a sample of no commercial value, taken on behalf of the owner or the person responsible for an establishment, which is representative of a given product of animal origin produced by that establishment, or constitutes a specimen of a product of animal origin the manufacture of which is contemplated, and which, for the purposes of subsequent examination, must bear a reference to the type of product, its composition and the species of animal from which it was obtained;
- (c) serious transmissible disease means all diseases covered by Directive 82/894/EEC (2);
- (d) pathogenic agents means any collection or culture of organisms or any derivative, present either alone or in the form of a manipulated combination of such a
- (1) OJ No L 395, 30. 12. 1989, p. 13. Directive as last amended by Directive 91/496/EEC (OJ No L 268, 24. 9. 1991, p. 56).
- (2) OJ No L 378, 31. 12. 1982, p. 58. Directive as last amended by Decision 90/134/EEC (OJ No L 76, 22. 3. 1990, p. 23).

- collection or culture of organisms capable of causing disease in any living being (other than man) and any modified derivatives of these organisms, which can carry or transmit an animal pathogen, or the tissue, cell culture, secretions or excreta by which or by means of which an animal pathogen can be carried or transmitted; this definition does not include the immunological veterinary medicinal products authorized pursuant to Directive 90/677/EEC (3);
- (e) processed animal protein intended for animal consumption means animal protein which has been treated so as to render it suitable for direct use as a feedingstuff or as an ingredient in a feedingstuff for animals. It includes fishmeal, meatmeal, bonemeal, hoofmeal, hornmeal, bloodmeal, feathermeal, dry greaves and other similar products including mixtures containing these products;
- (f) processed animal protein intended for human consumption means greaves, meatmeal and pork-rind powder referred to in Article 2 (b) of Directive 77/99/EEC (4);
- (g) apiculture product means honey, beeswax, royal jelly, propolis or pollen, not intended for human consumption or for industrial use.
- 2. In addition, the definitions contained in Article 2 of Directives 89/662/EEC, 90/425/EEC and 90/675/EEC shall apply mutatis mutandis.

Article 3

Member States shall ensure that:

- trade in and imports of products of animal origin referred to in Article 1 together with gelatins not intended for human consumption are not prohibited or restricted for animal health or public health reasons other than those arising from the application of this Directive or from Community legislation, and in particular any safeguard measures taken,
- any new product of animal origin whose placing on the market in a Member State is authorized after the date provided for in Article 20 may not be the subject of trade or importation until a decision has been taken in accordance with the first paragraph of Article 15 after evaluation and, if appropriate, the opinion of the Scientific Veterinary Committee set up by Decision 81/651/EEC (3), of the real risk of the spread of serious transmissible diseases which could result from movement of the product, not only for the species from which the product originates but also for other species which could carry the disease, become a focus of disease or a risk to human health.

(3) OJ No L 373, 31. 12. 1990, p. 26.

⁽⁴⁾ OJ No L 26, 31. 1. 1977, p. 85. Directive updated by Directive 92/5/EEC (OJ No L 57, 2. 3. 1992, p. 1), and last amended by Directive 92/45/EEC (OJ No L 268, 14. 9. 1992, p. 35).

⁽⁵⁾ OJ No L 233, 19. 8. 1981, p. 32.

— the other products of animal origin referred to in Article 2 (b) of Directive 77/99/EEC may not be the subject of trade or importation from third countries unless they meet the requirements of that Directive and the relevant requirements of this Directive.

CHAPTER II

Provisions applicable to trade

Article 4

Member States shall take the necessary measures to ensure that, for the purposes of applying Article 4 (1) of Directive 89/662/EEC and Article 4 (1) (a) of Directive 90/425/EEC, the products of animal origin referred to in Annexes I and II and the second and third indents of Article 3 of this Directive may, without prejudice to the particular provisions to be adopted in implementation of Articles 10 (3) and 11, be the subject of trade only if they satisfy the following requirements:

- 1. they must meet the requirements of Article 5 and the specific requirements laid down in Annex I as regards animal health aspects and Annex II as regards public health aspects,
- 2. they must come from establishments which:
 - (a) undertake, in the light of the specific requirements laid down in Annexes I and II for the products the establishment produces, to:
 - comply with the specific production requirements set out in this Directive,
 - establish and implement methods of monitoring and checking the critical points on the basis of the processes used,
 - depending on the products, take samples for analysis in a laboratory recognized by the competent authority for the purpose of checking compliance with the standards established by this Directive,
 - keep a record, whether written or otherwise recorded, of the information obtained pursuant to the preceding indents for presentation to the competent authority. The results of the various checks and tests in particular shall be kept for at least two years,
 - guarantee the administration of marking and labelling,
 - should the result of the laboratory examination or any other information available to them reveal the existence of a serious animal health or public health hazard, inform the competent authority,

- consign, for purposes of trade, only products accompanied by a commercial document indicating the nature of the product, the name and, where appropriate, the veterinary approval number of the establishment of production;
- (b) they are under supervision by the competent authority to ensure that the operator or manager of the establishment complies with the requirements of this Directive;
- (c) they were registered by the competent authority on the basis of assurances from the establishment guaranteeing compliance with the requirements of this Directive.

Article 5

Member States shall ensure that every necessary measure is taken to guarantee that products of animal origin referred to in Annexes I and II are not dispatched for purposes of trade from any holding, situated in a zone subject to restrictions because of the occurrence of a disease to which the species from which the product is derived is susceptible or from any establishment or zone from which movements or trade would constitute a risk to the animal health status of the Member States except where products are heat-treated in accordance with Community legislation.

Particular assurances permitting, by way of derogation from the first paragraph, the movement of certain products may be adopted under the procedure laid down in Article 18 within the framework of safeguard measures.

Article 6

Member States shall ensure that trade in pathogenic agents is subject to strict rules to be defined under the procedure laid down in Article 18.

Article 7

- 1. The rules on checks established by Directive 89/662/EEC and, as regards pathogenic agents, by Directive 90/425/EEC shall apply, in particular as regards the organization of and follow-up to the checks to be carried out, to the products covered by this Directive.
- 2. Article 10 of Directive 90/425/EEC shall apply to the products covered by this Directive.
- 3. For the purposes of trade, the provisions of Article 12 of Directive 90/425/EEC shall be extended to establishments supplying products of animal origin covered by this Directive.
- 4. Without prejudice to the specific provisions of this Directive, the competent authority shall carry out any

checks it may deem appropriate where it is suspected that this Directive is not being complied with.

5. Member States shall take the appropriate administrative or penal measures to penalize any infringement of this Directive, in particular where it is found that the certificates or documents drawn up do not correspond to the actual state of the products referred to in Annexes I and II, or that the products in question do not satisfy the requirements of this Directive or have not undergone the checks provided for therein.

Article 8

In Chapter 1 (1) of Annex A to Directive 92/46/EEC (1) the following subparagraph is added:

'Milk and milk products must not come from a surveillance zone defined in accordance with Directive 85/511/EEC unless the milk has undergone pasteurization (71,7 °C for 15 seconds) under the supervision of the competent authority.'

CHAPTER III

Provisions applicable to imports into the Community

Article 9

The requirements applicable to imports of products covered by this Directive must offer at least the guarantees provided for in Chapter II, including those established in implementation of Article 6, and those laid down in the second and third indents of Article 3.

Article 10

- 1. For the purposes of uniform application of Article 9, the following provisions shall apply.
- 2. The products referred to in Annexes I and II and in the second and third indents of Article 3 may be imported into the Community only if they satisfy the following requirements:
- (a) unless otherwise specified in Annexes I and II, they must come from a third country or part of a third country on a list to be drawn up and updated in accordance with the procedure provided for in Article 18:
- (b) except for the products referred to in Chapter 5 (B) of Annex I, they must come from establishments for which the competent authority of the third country has provided the Commission with guarantees that they meet the requirements of paragraph 3 (a);
- (c) in the cases specifically provided for in Annexes I and II and in the second and third indents of Article 3,
- (1) OJ No L 268, 14. 9. 1992, p. 1.

they must be accompanied by an animal health or public health certificate corresponding to a specimen to be drawn up under the procedure provided for in Article 18, certifying that the products meet the additional conditions or offer the equivalent guarantees referred to in paragraph 3 (a) and come from establishments offering such guarantees, and signed by an official veterinarian or, as appropriate, by any other competent authority recognized under the same procedure.

- 3. Under the procedure provided for in Article 18:
- (a) specific requirements shall be established in particular for the protection of the Community from certain exotic diseases or diseases transmissible to man or guarantees equivalent to those conditions.

The specific requirements and equivalent guarantees established for third countries may not be more favourable than those laid down in Annexes I and II and in the second and third indents of Article 3;

- (b) a Community list shall be drawn up of third country establishments which satisfy the requirements of paragraph 2 (b);
- (c) the nature of any treatment or the measures to be taken to avoid recontamination of animal casings, eggs and egg products shall be established.
- 4. The decisions provided for in paragraphs 2 and 3 must be taken on the basis of evaluation and, if appropriate, the opinion of the Scientific Veterinary Committee, of the real risk of the spread of serious transmissible diseases or of diseases transmissible to man which could result from movement of the product, not only for the species from which the product originates but also for other species which could carry the disease or become a focus of disease or a risk to public health.
- 5. Experts from the Commission and the Member States shall carry out on-the-spot inspections to verify whether the guarantees given by the third country regarding the conditions of production and placing on the market can be considered equivalent to those applied in the Community.

The experts from the Member States responsible for these inspections shall be appointed by the Commission, acting on proposals from the Member States.

These inspections shall be made on behalf of the Community, which shall bear the cost of any expenditure involved.

Pending organization of the inspections referred to in the first subparagraph, national rules applicable to inspection in third countries shall continue to apply, subject to notification, through the Standing Veterinary Committee,

of any failure to comply with the guarantees offered in accordance with paragraph 3 found during these inspections.

6. Pending compilation of the lists provided for in paragraphs 2 (a) and 3 (b), Member States are authorized to maintain the controls provided for in Article 11 (2) of Directive 90/675/EEC and the national certificate required by products imported under existing national rules.

Article 11

The procedure provided for in Article 18 shall be used to stipulate specific animal health requirements for imports into the Community and the nature and content of accompanying documents for products referred to in Annex I intended for experimental laboratories.

Article 12

1. The principles and rules laid down in Directives 90/675/EEC and 91/496/EEC (¹) shall apply, with particular reference to the organization of and follow-up to the inspections to be carried out by the Member States and the safeguard measures to be implemented.

However, for certain types of product of animal origin, derogations may be adopted in accordance with the procedure laid down in Article 18, from the physical check provided for in Article 8 (2) of Directive 90/675/EEC.

2. In Article 4 (1) of Directive 90/675/EEC, the following subparagraph is added:

However, where products of animal origin arrive in containers or are wrapped or packaged under vacuum, the identity check may be limited to ensuring that the seals placed by the official veterinarian or the competent authority on the container or package are intact and that the indications given thereon correspond to those included in the accompanying document or certificate.'

Article 13

- 1. Member States may, by issuing an appropriate licence, permit the importation from third countries of products of animal origin referred to in Annexes I and II in the form of trade samples.
- 2. The licence mentioned in paragraph 1 must accompany the consignment and contain full details of the specific conditions under which the consignment may be imported, including any derogations from the checks provided for by Directive 90/675/EEC.
- 3. Where the consignment enters one Member State for onward transmission to a second Member State, the first

(1) OI No L 268, 24. 9. 1991, p. 56.

Member State shall ensure that the consignment is accompanied by the appropriate licence. Movement shall take place in accordance with the provisions of Article 11 (2) of Directive 90/675/EEC. The responsibility for ensuring that the consignment complies with the conditions of the licence (and whether entry into its territory should be permitted) shall rest with the Member State which issues the licence.

CHAPTER IV

Common final provisions

Article 14

1. Article 3 (d) of Directive 72/461/EEC (2) shall be deleted.

Commission Decisions 92/183/EEC (3) and 92/187/EEC (4) shall continue to apply for the requirements of this Directive, without prejudice to any amendments to be made to them under the procedure provided for in Article 18.

- 2. Directive 90/667/EEC is hereby amended as follows:
- (a) in Article 13 the following paragraph shall be added:
 - '2. With a view to ensuring that the controls provided for in paragraph 1 are followed up:
 - (a) processed products obtained from low-risk or high-risk materials must satisfy the requirements of Chapter 6 of Annex I to Directive 92/118/EEC (*);
 - (b) low-risk materials, high-risk materials intended for processing in a plant designated in another Member State in accordance with the second sentence of Article 4 (1) and processed products obtained from high-risk or low-risk materials must be accompanied:
 - if they come from a plant approved in accordance with Article 4 or 5, by a commercial document specifying;
 - if appropriate, the nature of the treatment,
 - whether the product contains ruminant proteins,
 - if they come from another plant, by a certificate issued and signed by an official veterinarian indicating:
 - the methods of treatment used on the consignment,
 - the result of the salmonella tests,

⁽²⁾ OJ No L 302, 31. 12. 1972, p. 24. Directive as last amended by Directive 91/687/EEC (OJ No L 377, 31. 12. 1991, p. 16).

⁽³⁾ OJ No L 84, 31. 3. 1992, p. 33.

⁽⁴⁾ OJ No L 87, 2. 4. 1992, p. 20.

- whether the product contains ruminant proteins.
- (*) OJ No L 62, 15. 3. 1993, p. 49.';
- (b) in Article 6, 'shall be established under the procedure laid down in Article 19' shall be replaced by 'are laid down under Chapter 10 of Annex I to Directive 92/118/EEC';
- (c) in Article 14 the first paragraph shall be deleted.

Article 15

The Council, acting by a qualified majority on a proposal from the Commission, shall adopt any new Annex laying down specific requirements for other products capable of presenting a real risk of spreading serious transmissible diseases or a real risk to human health.

The Annexes shall, where the need arises, be amended under the procedure provided for in Article 18 in compliance with the general principles set out in the second indent of Article 3.

Article 16

- 1. Member States shall be authorized to make the entry into their territory of products of animal origin referred to in Annexes I and II and in the second and third indents of Article 3 which were produced in the territory of a Member State and have passed through the territory of a third country subject to production of an animal health or public health certificate certifying compliance with the requirements of this Directive.
- 2. Member States which have recourse to the possibility laid down in paragraph 1 shall so inform the Commission and the other Member States within the Standing Veterinary Committee set up by Decision 68/361/EEC (1).

Article 17

- 1. Annexes A and B to Directives 89/662/EEC and 90/425/EEC shall be replaced by the texts set out in Annex III to this Directive.
- 2. Directive 77/99/EEC is hereby amended as follows:
- in Article 2 (b), point (iv) shall be deleted and points (v) and (vi) shall become (iv) and (v) respectively;

- Article 6 (2) shall read:
 - '2. Under the procedure laid down in Article 20, additional conditions may be set for the other products of animal origin so as to ensure the protection of public health.'

Article 18

Where reference is made to the procedure provided for in this Article, the Standing Veterinary Committee shall act in accordance with the rules laid down in Article 17 of Directive 89/662/EEC.

Article 19

Under the procedure provided for in Article 18, transitional measures may be adopted for a period of up to three years beginning on 1 July 1993 to facilitate the transition to the new arrangements established by this Directive.

Article 20

1. Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with Articles 12 (2) and 17 by 1 January 1993 and with the other requirements of this Directive before 1 January 1994. They shall forthwith inform the Commission thereof.

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

- 2. Member States shall communicate to the Commission the texts of the main provisions of national law which they adopt in the field governed by this Directive.
- 3. The setting of the deadline for transposition into national law at 1 January 1994 shall be without prejudice to the abolition of veterinary checks at frontiers provided for by Directives 89/662/EEC and 90/425/EEC.

Article 21

This Directive is addressed to the Member States.

Done at Brussels, 17 December 1992.

For the Council
The President
J. GUMMER

⁽¹⁾ OJ No L 255, 18. 10. 1968, p. 23.

ANNEX I

SPECIFIC ANIMAL HEALTH REQUIREMENTS

CHAPTER 1

Liquid milk, dried milk and dried-milk products not intended for human consumption

Intra-Community trade in and imports of liquid milk, dried milk and dried-milk products not intended for human consumption are subject to the following conditions:

- any container in which the product is transported must be marked to indicate the nature of the product;
- 2. each consignment must be accompanied by, as appropriate, a commercial document referred to in the last indent of Article 4 (2) (a) or the health certificate referred to in Article 10 (2) (c), bearing the name and approval number of the processing or treatment plant and stating that the product has been heat-treated in accordance with paragraph 3 (a); this document or certificate must be retained by the consignee for a period of at least one year;
- 3. the document or certificate referred to in paragraph 2 must show that:
 - (a) during processing or treatment the milk was subjected to a minimum temperature of 71,7 °C for at least 15 seconds or any equivalent combination or, in the case of dried milk or dried-milk products, the heat treatment during spray or roller drying was of equivalent effectiveness;
 - (b) and, in the case of dried milk and dried-milk products, that the following requirements have been met:
 - (i) after completion of the drying process, every precaution was taken to prevent contamination of the product;
 - (ii) the final product was packed in new containers; and
 - (c) in the case of bulk containers, before the liquid milk, dried milk, or dried-milk product was loaded in any vehicle or container for conveyance to its destination, the said vehicle or container was disinfected using a product approved by the competent authorities.

Furthermore, imports of liquid milk, dried milk and dried-milk products may be authorized only from third countries or parts of third countries included on the lists provided for in Article 23 of Directive 92/46/EEC and meeting the conditions set out in Article 26 of that Directive.

CHAPTER 2

Animal casings

A. Trade

Trade in animal casings is subject to production of a document specifying the plant of origin which must be:

- where the casings are salted or dried at the point of origin and where salted or dried casings are subsequently handled for other purposes, a plant approved by the competent authority,
- in other cases, a plant approved in accordance with Directive 64/433/EEC (1), provided the casings are transported in such a way as to avoid contamination.

B. Imports from third countries

Imports of animal casings from any third country are subject to production of the certificate referred to in Article 10 (2) (c), issued and signed by an official veterinarian of the exporting third country, stating that:

⁽¹⁾ OJ No 121, 29. 7. 1964, p. 2012/64. Directive as last amended by Directive 91/497/EEC (OJ No L 268, 24. 9. 1991, p. 69).

- (i) the casings come from plants approved by the competent authority of the exporting country;
- (ii) the casings have been cleaned, scraped and then either salted or bleached (or as an alternative to salting or bleaching, that they have been dried after scraping);
- (iii) after the treatment in (ii), effective steps were taken to prevent the recontamination of the casings.

CHAPTER 3

Hides and skins of ungulates not covered by Directive 64/433/EEC or 72/462/EEC

Trade in and imports from third countries of hides and skins of ungulates are subject to the condition that each consignment is accompanied either by the commercial document provided for in the last indent of Article 4 (2) (a) or by a health certificate referred to in Article 10 (2) (c) stating:

- (a) as regards hides and skins of ungulates, except for pigs, that:
 - (i) the hides or skins were not obtained from animals which originated in an area or country under restriction as regards the species in question due to outbreak of a serious transmissible disease;
 - (ii) the hides or skins were dried, dry-salted or wet-salted or have undergone a chemical treatment a minimum of 14 days before dispatch;
 - (iii) the consignment has not been in contact with any other animal product or live animals presenting a risk of spreading a serious transmissible disease.

These requirements do not apply where the hides or skins have been kept separate for 21 days or have been undergoing transport for 21 uninterrupted days;

- (b) as regards pig skins, that:
 - the pigs from which the skins were derived had been in the country of export for at least three months prior to slaughter;
 - (ii) the skins were dried, dry-salted or wet-salted or have undergone a chemical treatment a minimum of 14 days before dispatch;
 - (iii) no case of African swine fever or swine vesicular disease was recorded in the country of origin or, in the case of regionalization, in the region of origin in the 12-month period preceding dispatch;
 - (iv) the consignment has not been in contact with any other animal product or live animals presenting a risk of spreading a serious transmissible disease.

Imports of untreated hides and skins are authorized only from third countries from which imports of fresh meat of the corresponding species are authorized pursuant to Community rules.

CHAPTER 4

Pet food containing low-risk materials within the meaning of Directive 90/667/EEC

- 1. Each consignment of petfood in hermetically sealed containers must be accompanied by a certificate issued and signed by an official veterinarian of the country of origin stating that the product has been subjected to heat treatment to a minimum Fc value of 3,0.
- 2. Each consignment of semi-moist petfood must be accompanied either by the commercial document or by the certificate provided for in Article 13 (2) (b) of Directive 90/667/EEC stating that:
 - (i) the raw materials of animal origin from which the petfood was manufactured were obtained solely from healthy slaughtered animals, the meat from which had been passed as fit for human consumption;
 - (ii) the ingredients of animal origin have been subjected to a heat treatment of at least 90 °C throughout their substance;

- (iii) after processing, effective steps were taken to ensure that the consignment was not exposed to recontamination.
- 3. Dried petfood must satisfy the following requirements:
 - (a) the raw materials from which the petfood was manufactured were low-risk materials in accordance with Articles 2, 5 and 17 of Directive 90/667/EEC;
 - (b) each consignment is accompanied by a commercial document or certificate provided for in Article 13(2) (b) of Directive 90/667/EEC stating that:
 - (i) the dried petfood consisted of products of slaughtered animals heat-treated so as to achieve a temperature throughout their substance of at least 90 °C, on the understanding that the treatment was not necessary for finished products the ingredients of which had undergone such treatment:
 - (ii) after heat treatment, every precaution was taken to ensure that the product was not contaminated in any way prior to shipment;
 - (iii) the product is packed in new containers (bags or sacks);
 - (iv) the production process has been tested, with satisfactory results, in accordance with Chapter III (2) of Annex II to Directive 90/667/EEC.
- 4. Each consignment of products manufactured from processed hides must be accompanied by a commercial document or certificate provided for in Article 13 (2) (b) of Directive 90/667/EEC stating that the products have been subjected to a heat treatment during processing sufficient to destroy pathogenic organisms (including salmonella) and that effective steps were taken after processing to prevent contamination of the products.

CHAPTER 5

Bones and bone products (excluding bone meal), horns and horn products (excluding horn meal) and hooves and hoof products (excluding hoof meal)

Trade in and imports of the products in question are subject to the following conditions:

- A. where they are intended for human or animal consumption:
 - where trade is concerned, bones, horns and hooves are subject to the animal health requirements laid down in Directive 72/461/EEC;
 - 2. where trade is concerned, bone products, horn products and hoof products are subject to the animal health requirements provided for in Directive 80/215/EEC (1);
 - 3. where imports are concerned, bones, bone products, horns, horn products, hooves and hoof products are subject to the requirements of Directive 72/462/EEC (2);
- B. where they are intended for uses other than human or animal consumption, including those intended to be processed with a view to the manufacture of gelatins:
 - 1. Member States shall authorize the importation of bone and bone products (excluding bone meal), horns and horn products (excluding horn meal) and hooves and hoof products (excluding hoof meal) provided that:
 - (i) the products are dried before export and not chilled or frozen;
 - (ii) the products are conveyed only by land and sea from their country of origin direct to a border inspection post in the Community and are not transhipped at any port or place outside the Community;
 - (iii) following the document checks provided for in Directive 90/675/EEC, the products are conveyed directly to the manufacturing plant;
 - 2. each consignment must be accompanied by an undertaking from the importer that products imported under this chapter will not be diverted for direct use in human or animal food.

⁽¹) OJ No L 47, 21. 2. 1980, p. 4. Directive as last amended by Directive 91/687/EEC (OJ No L 377, 31. 12. 1991,

 ⁽²⁾ OJ No L 302, 31. 12. 1972, p. 28. Directive as last amended by Directive 91/688/EEC (OJ No L 377, 31. 12. 1991, p. 18).

A declaration to this effect must be presented to the official veterinarian at the border inspection post at first point of entry of the goods into the Community and be annotated by him, and thereafter shall accompany the consignment to its destination.

under the procedure provided for in Article 18 of this Directive, in the light of the animal health situations and guarantees as regards controls on origin offered by a third country, derogations from some of these requirements may be permitted.

CHAPTER 6

Processed animal protein

I. Without prejudice to any restrictions imposed as regards BSE or to the restrictions on the feedings of ruminant protein to ruminants, trade in and imports of processed animal protein are subject:

A. as regards trade:

- in processed animal protein intended for human foodstuffs, to the production of the document or certificate provided for in Directive 77/99/EEC stating that the requirements of that Directive have been complied with,
- in processed animal proteins intended for animal feedingstuffs, to the production of the document or certificate provided for in Article 13 of Directive 90/667/EEC;

B. as regards imports:

- 1. to production of a health certificate as provided for in Article 10 (2) (c), signed by the official veterinarian of the country of origin and stating that:
 - (a) the product:
 - (i) where it is intended for animal consumption, has undergone appropriate heat treatment with the result that it complies with the biological standards laid down in Annex II, Chapter III to Directive 90/667/EEC;
 - (ii) where it is intended for human consumption, fulfils the requirements of Directive 80/215/EEC;
 - (b) every precaution has been taken after treatment to prevent contamination of the product treated;
 - (c) samples have been taken and tested for salmonella when the consignment left the country of origin;
 - (d) the results of these tests are negative;
- 2. following document checks of the certificate referred to in 1, to sampling by the competent authority at the border inspection post without prejudice to point II:
 - (i) of each consignment of products submitted in bulk;
 - (ii) at random of consignments of products packaged in the manufacturing plant;
- 3. for release for free circulation in Community terrifory of consignments of processed animal protein, to prove that the results of the sampling carried out pursuant to B (1) (c) have proved negative, if necessary after reprocessing;
- C. national rules existing on the date of notification of this Directive concerning the requirements applicable as regards BSE and scrapie for animal proteins may be maintained pending a decision on the type of heat treatment capable of destroying the agent responsible.

Trade in and imports of meat meal and bone meal remain subject to Article 5 (2) of Directive 89/662/EEC and Article 11 (2) of Directive 90/675/EEC.

II. Member States may carry out random sampling of bulk consignments originating in a third country from which the last six consecutive tests have proved negative. Where during one of these checks a result has proved positive, the competent authority of the country of origin must be informed so that it can take appropriate measures to remedy the situation. These measures must be brought to the attention of the

competent authority responsible for the import checks. In the event of a further positive result from the same source, further tests must be carried out on all consignments from the same source until the requirements laid down in the first sentence are again satisfied.

- III. Member States must keep records of the results of sampling carried out on all consignments which have undergone sampling.
- IV. In accordance with Article 3 (3) of Directive 89/662/EEC, transhipment of consignments is permitted only through ports which have been approved under the procedure laid down in Article 18, provided that a bilateral agreement has been reached between Member States to allow checking of the consignments to be deferred until they reach the border inspection post of the Member State of final destination.
- V. Where a consignment proves to be positive for salmonella, it is either:
 - (a) re-exported from the Community;
 - (b) used for purposes other than animal feeds. In this case, the consignment may leave the port or storage depot only on condition that it is not incorporated into animal feedingstuffs;
 - (c) re-processed in a treatment plant approved pursuant to Directive 90/667/EEC or any plant approved for decontamination. Movement from the port or storage depot shall be controlled by permit from the competent authority and the consignment shall not be released until it has been treated, tested for salmonella by the competent authority in accordance with Annex II, Chapter III, to Directive 90/667/EEC and a negative result obtained.

CHAPTER 7

Blood and blood products of animal origin

(with the exception of equidae)

- 1. Trade in blood and blood products shall take place in accordance with the general provision of Article 4 of this Directive.
- 2. Imports of blood products intended for the pharmaceutical industry are subject to the production of a health certificate provided for in Article 10 (2) (c) certifying compliance with the provisions on the identity of the materials concerned, their packaging, transport conditions, storage, handling and processing, as well as the provisions regarding the disposal of the wrapping, the packaging and the residues of processing so as to preclude any danger to public health or animal health, without prejudice to imports for human consumption which are still subject to the requirements of Directive 72/462/EEC.
- 3. Imports of blood products of animal origin of species other than equidae intended for other purposes are subject to the production of the animal health certificate provided for in Article 10 (2) (c), signed by the official veterinarian and stating that, if the country of origin was considered, in accordance with the procedure laid down in Article 18, to represent a health risk, as regards foot-and-mouth disease and/or blue tongue virus:
 - (a) either the products:
 - come from a slaughterhouse situated in a zone with a 10 km radius free from the diseases in question to which the species from which the product comes is susceptible, and
 - come from an animal which (or whose mother):
 - had been in the country of origin for three months, and
 - had been subjected to pre-slaughter and post mortem inspection and found free from the diseases in question.

In the case of consignments meeting the requirements set out above:

- except in the case provided for in point 5, each consignment of blood products must be taken
 directly from the port of entry to a laboratory for treatment and any residues resulting from
 treatment must be destroyed immediately,
- a sample must be collected from each batch of blood products and dispatched to a laboratory approved under the procedure laid down in Article 18 for the purpose of testing for the presence of foot-and-mouth disease virus and blue tongue virus,
- the batch may not be released from the laboratory until the test sample is found negative for the presence of foot-and-mouth disease virus and/or blue tongue virus,

- the importer shall be responsible for meeting any costs associated with the carrying out of tests pursuant to Directive 90/675/EEC;
- (b) or the products have undergone one of the following treatments:
 - they have been heated at a temperature of at least 65 °C for at least three hours, or
 - they have been irradiated at 2,5 mega rads, or
 - they have been subjected to a change in pH to a pH 5 for three hours;
- (c) or in the case of blood products for use as *in-vitro* diagnostic or laboratory reagents, they have been shipped in sealed, impervious containers. It that case:
 - the containers or their outside packaging must be clearly labelled 'For use as *in-vitro* diagnostic or laboratory reagents only', and
 - the blood products may be used as an in-vitro diagnostic or laboratory reagent only and any product literature must state that the products or their residues must not be allowed to come into contact with ruminating animals or swine.
- 4. Member States shall authorize the importation of blood products from third countries regarded as free of serious transmissible diseases provided that the blood products are accompanied by a veterinary certificate stating that they come from an animal originating in a Member State or one of the aforesaid third countries.
- 5. Any blood products put up in sealed, impermeable containers may be stored in establishments placed under the permanent supervision of an official veterinarian provided these products are kept separate from all other products of animal origin stored in that establishment.

CHAPTER 8

Serum from equidae

- 1. In order to be the subject of trade, serum must come from equidae which show none of the serious transmissible diseases referred to in Directive 90/426/EEC (1) or of the serious transmissible diseases to which equidae are susceptible and have been obtained in bodies or centres not subject to health restrictions pursuant to that Directive.
- 2. Serum from equidae may be imported only if it comes from equidae born and raised in a third country from which the importation of horses for slaughter is authorized and was obtained, processed and dispatched in conditions to be specified under the procedure laid down in Article 18.

CHAPTER 9

Lard and rendered fats

- Member States shall authorize the importation into the Community of lard and rendered fats from third
 countries appearing on the list annexed to Decision 79/542/EEC from which the importation of fresh
 meat of the species concerned is permitted.
- 2. Where there has been an outbreak of a serious transmissible disease in the previous 12 months before export in a country mentioned in paragraph 1, each consignment of lard or rendered fats must be accompanied by a certificate referred to in Article 10 (2) of this Directive stating that:
 - A. the lard or rendered fats have been subjected to one of the following heat treatment processes:
 - (i) at least 70 °C for at least 30 minutes; or

⁽¹⁾ OJ No L 224, 18. 8. 1990, p. 42. Directive as last amended by Decision 92/130/EEC (OJ No L 47, 22. 2. 1992, p. 26).

- (ii) at least 90 °C for at least 15 minutes; or
- (iii) a minimum temperature of 80 °C in a continuous rendering system;
- B. where the lard of rendered fats are packaged, they have been packed in new containers and all precautions have been taken to prevent their recontamination;
- C. where bulk transport of the product is intended, the pipes, pumps and bulk tank and any other bulk container tanks or bulk road tanker used in the transportation of the products from the manufacturing plant either directly on to the ship or into shore tanks or direct to establishments were inspected and found to be clean before use.

CHAPTER 10

Raw material for the manufacture of animal feedingstuffs and pharmaceutical or technical products

- Raw material means fresh meat, glands, organs and other offal as well as intestinal mucuses which are
 not intended for human consumption. Raw material shall be regarded as fresh if it has only undergone
 refrigeration or other treatment not resulting in sufficiently safe destruction of pathogenic agents. The
 substances involved may only be low-risk substances within the meaning of Directive 90/667/EEC.
- Raw material must be accompanied by a commercial document or certificate, provided for in Article 13
 (2) of Directive 90/667/EEC, or a certificate complying with the model to be laid down under the procedure provided for in Article 18 and must satisfy the requirements of Decision 92/183/EEC.
- 3. In trade the original of the health certificate or commercial document must be submitted to the veterinary authorities responsible for the processing plant and the intermediate storage warehouse cold storage facility or sorting facility; in the case of imports into the Community, it must be submitted to the border control authority.
- 4. The raw material must be transported directly to approved or registered processing plants which meet the conditions laid down in Directive 90/667/EEC or to cold-storage facilities approved for intermediate storage. Prior to processing, raw material for manufacturing pharmaceuticals may also be sorted and stored in facilities specially approved for the purpose by the Member States. Member States shall inform the Commission of the approval of such sorting facilities.
- 5. The raw material may be transported to the processing plant only in watertight and properly sealed containers or vehicles. The legend 'Only for the manufacture of petfood' or 'Only for the manufacture of pharmaceuticals or technical products' must appear on the recipients and accompanying documents, depending on the intended purpose. The name and address of the consignee undertaking must appear on the containers and accompanying papers.
- 6. The vehicles and containers used to transport the goods, together with all items of equipment or appliances which have come into contact with the untreated raw material, must be cleaned and disinfected. Packaging material must be incinerated or disposed of by some other means in accordance with instructions from the official veterinarian.
- 7. Intermediate storage of the raw material shall be permissible only in cold storage facilities approved for the purpose, subject to authorization and under the supervision of the official veterinarian. The raw material must be stored separately from other goods and in such a way as to prevent any propagation of epizootic diseases.
- 8. At the processing plant the raw material shall be treated in such a way as to kill any pathogenic agents and rule out any danger to domestic herds. Removal of raw material from the plant for safe disposal in processing plants approved or registered for the purpose in accordance with Directive 90/667/EEC shall be permissible only in exceptional cases and with the authorization of the official veterinarian. The provisions of points 5, 6 and 9 shall apply correspondingly to the transportation of the raw material and to the notification of the official veterinarian responsible for the processing plant.
- 9. When the raw material is transported from the plant of origin, or beyond the Community's external border:
 - the official veterinarian responsible for the plant of origin in the case of intra-Community trade, or

- the border inspection authority in the case of imports into the Community

shall notify the official veterinarian responsible for the processing plant, intermediate storage warehouse or sorting facility of that fact by means of the 'Animo system', by telex or by fax.

- 10. Imports into the Community are also subject to the following provisions:
 - (a) Member States shall authorize the importation of raw material into the Community only from third countries which appear on the list laid down in Council Decision 79/542/EEC or in a special Commission Decision on a specific raw material;
 - (b) following the border check the raw materials shall, under the supervision of the competent veterinary authority, be transported either directly to an approved or registered processing plant which is under the constant supervision of an official veterinarian and has given a guarantee that the raw materials will be used only for the permitted purpose and that they will not leave the plant untreated, or to an approved intermediate storage or approved sorting facility;
 - (c) the health certificate bearing the file mark of the border inspection authority or a certified copy of that certificate must accompany the goods until they reach the destination plant.

CHAPTER 11

Rabbit meat and farmed game meat

Member States shall ensure that rabbit meat and farmed game meat are imported only if:

- (a) they come from third countries included:
 - (i) for furred farm game, on the list of countries from which fresh meat of the corresponding species may be imported pursuant to Directive 72/462/EEC;
 - (ii) for feather farmed game, on the list of countries from which fresh poultrymeat may be imported pursuant to Directive 91/494/EEC (1);
 - (iii) for rabbit meat, on a list to be drawn up under the procedure laid down in Article 18;
- (b) they satisfy at least the requirements laid down in Chapters II and III respectively of Directive 91/495/EEC (2);
- (c) they come from establishments offering the guarantees provided for in (b) and recognized under the procedure provided for in Article 18 or, pending the list referred to in (a) (iii), from establishments approved by the competent authorities;
- (d) each batch of meat is accompanied by the health certificate provided for in Article 10 (2) (c).

CHAPTER 12

Apiculture products

- 1. Apiculture products intended exclusively for use in apiculture:
 - (a) must not come from an area which is the subject of a prohibition order associated with an occurrence of American foulbrood or acarioasis, if in the case of acarioasis the Member State of destination has obtained additional guarantees in accordance with Article 14 (2) of Directive 92/65/EEC (3);
 - (b) must meet the requirements imposed by Article 8 (a) of Directive 92/65/EEC.
- 2. Any derogations must be established, as necessary, under the procedure laid down in Article 18 of this Directive.

⁽¹⁾ OJ No L 268, 24. 9. 1991, p. 25.

⁽²⁾ OJ No L 268, 24. 9. 1991, p. 41.

⁽³⁾ OJ No L 268, 14. 9. 1992, p. 54.

CHAPTER 13

Game trophies

Trade in and imports of untreated game trophies must be accompanied by the commercial document provided for in the last indent of Article 4 (2) (a) or by the health certificate provided for in Article 10 (2) (c) stating that:

- the trophies in question do not come from animals originating in an area subject to restrictions as a result
 of the presence of serious transmissible diseases;
- 2. the trophies in question are completely dry and without residual meat and that they were dried or dry-salted or wet-salted for at least 14 days before they were dispatched;
- 3. the consignment has not been in contact with any other product of animal origin or any animal likely to contaminate it;
- 4. once dry, the product was disinfected with products authorized by the competent authority of the dispatching country;
- 5. the trophies were packaged in new, transparent packaging.

CHAPTER 14

Manure for treatment of the soil (a)

Processed manure products

All organic fertilizers have been treated to ensure that the product is free from pathogenic agents.

Treated manure products meeting the following requirements may be the subject of trade or imports:

- exempt from salmonella:
 absence of salmonella in 25 g of treated product;
- exempt from enterobacteriaceae:
 based on the aerobic bacteria count (< 1 000 cfu per gram of treated product);
- reduced level of spore-forming bacteria and toxin formation:
 moisture content < 14%, product aW value < 0,7.

Products must be stored in such a way that, once processed, contamination or secondary infection and dampness is impossible.

Products must therefore be stored in:

- well-sealed and insulated silos, or
- properly sealed packs (plastic bags or 'big bags').

Unprocessed manure

Only unprocessed manure from chicken and equidae may be the subject of trade or import. This manure must originate in a region free of serious transmissible animal diseases, in particular:

- foot-and-mouth disease,
- Newcastle disease,

⁽a) Manure means any mixture of excrement and urine of cattle, pigs, equidae and chicken.

- swine fever,
- avian influenza,
- African swine fever,
- African horse sickness,
- swine vesicular disease.

If necessary, bacteriological standards may be established under the procedure laid down in Article 18 of this Directive.

CHAPTER 15

Unprocessed wool, hair, bristles, feathers and parts of feathers

- 1. Sheep's wool, ruminant hair and pig bristles shall be considered to be 'unprocessed' if they have not undergone factory washing or been obtained from tanning, and feathers and parts of feathers shall be considered 'unprocessed' if they have not been treated with a steam current or by some other method ensuring that no pathogens are transmitted.
- 2. Unprocessed sheep's wool, ruminant hair, pig bristles, feathers and parts of feathers (the goods) may only be traded in or imported if they are securely enclosed in packaging and dry. However, trade in and imports of pig bristles from countries or regions in which African swine fever is endemic are prohibited except for pig bristles which:
 - (a) have been boiled, dyed or bleached; or
 - (b) have undergone some other form of treatment which is certain to kill pathogenic agents, provided that evidence to this effect is submitted in the form of a certificate from the veterinarian responsible for the place of origin. Factory washing shall not be regarded as a form of treatment for the purposes of this provision.
- 3. The provisions of this chapter shall not apply to trade or imports of decorative feathers or feathers:
 - (a) carried by travellers for their private use; or
 - (b) which are the subject of trade in or imports into the Community in the form of consignments sent to private individuals for non-industrial purposes.
- 4. The goods must be sent directly to the plant of destination or the warehouse for storage in conditions such that any spread of pathogenic agents is avoided.

ANNEX II

SPECIFIC PUBLIC HEALTH CONDITIONS

CHAPTER 1

Imports from third countries of meat products obtained from poultrymeat, farmed game meat, wild game meat and rabbit meat

Member States shall ensure that meat products obtained from poultrymeat, farmed game meat, wild game meat and rabbit meat are not imported unless:

- (a) they come from a third country listed in accordance with:
 - (i) Article 14 of Directive 71/118/EEC for poultrymeat;
 - (ii) Article 16 of Directive 92/45/EEC for wild game meat;
 - (iii) a list to be established for rabbit meat and farmed-game meat under the procedure provided for in Article 18;
- (b) the fresh meat used meets the appropriate requirements of Article 14 of Directive 71/118/EEC for poultrymeat, Article 16 of Directive 92/45/EEC for wild game meat, Article 3 of Directive 91/495/EEC for rabbit meat and Article 6 of that Directive for farmed-game meat;
- (c) they come from an establishment offering the same guarantees as those referred to in Directive 77/99/EEC and approved in accordance with the procedure provided for in Article 18 or, pending the adoption of such a decision, by the competent authority of the Member State with imports of these products remaining subject to the rules in Article 11 (2) of Directive 90/675/EEC;
- (d) they are prepared, checked and handled in accordance with the appropriate requirements provided for in Directive 77/99/EEC;
- (e) each consignment of meat products is accompanied by a health certificate established in accordance with the procedure provided for in Article 18.

CHAPTER 2

Before 1 January 1994, the health conditions applicable to the following shall be established in accordance with the procedure laid down in Article 18:

- putting on the market in and imports of eggs and imports of egg products intended for human consumption, without prejudice to the rules laid down within the framework of the common organization of the market,
- the preparation of gelatins intended for human consumption,
- trade in and import of honey, frogs' legs and snails intended for human consumption.

ANNEX III

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CONSOLIDATED VERSION OF ANNEXES A AND B TO DIRECTIVE 89/662/EEC

'ANNEX A

VETERINARY LEGISLATION

CHAPTER I

- Council Directive 64/433/EEC of 26 June 1964 on health problems affecting intra-Community trade in fresh meat (OJ No 121, 29. 7. 1964, p. 2012/64).
- Council Directive 71/118/EEC of 15 February 1971 on health problems affecting trade in fresh poultrymeat (OJ No L 55, 8. 3. 1971, p. 23).
- Council Directive 72/461/EEC of 12 December 1972 on health problems affecting intra-Community trade in fresh meat (OJ No L 302, 31. 12. 1972, p. 24).
- Council Directive 77/99/EEC of 21 December 1976 on health problems affecting intra-Community trade in meat products (OJ No L 26, 31. 1. 1977, p. 85).
- Council Directive 80/215/EEC of 22 January 1980 on animal health problems affecting intra-Community trade in meat products (OJ No L 47, 21. 2. 1980, p. 4).
- Council Directive 88/657/EEC of 14 December 1988 laying down the requirements for the production of, and trade in, minced meat, meat in pieces of less than 100 grams and meat preparations (OJ No L 382, 31. 12. 1988, p. 3).
- 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 (OJ No L 212, 22. 7. 1989, p. 87).
- Council Directive 91/67/EEC of 28 January 1991 concerning the animal health conditions governing the placing on the market of aquaculture animals and products (OJ No L 46, 19. 2. 1991, p. 1).
- 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 (OJ No L 268, 24. 9. 1991, p. 1).
- 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 (OJ No L 268, 24. 9. 1991, p. 15).
- Council Directive 91/494/EEC of 26 June 1991 on animal health conditions governing intra-Community trade in and imports from third countries of fresh poultrymeat (OJ No L 268, 24. 9. 1991, p. 35).
- Council Directive 91/495/EEC of 27 November 1991 concerning public health and animal health problems affecting the production and placing on the market of rabbit meat and farmed game meat (OJ No 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 (OJ No L 268, 14. 9. 1992,
 p. 35).
- 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 (OJ No L 268, 14. 9. 1992, p. 1).

CHAPTER II

Council Directive 92/118/EEC of 17 December 1992 laying down animal health and public health requirements governing trade in and imports into the Community of products not subject to the said requirements laid down in specific Community rules referred to in Annex A (I) to Directive 89/662/EEC and, as regards pathogens, to Directive 90/425/EEC (with the exception of pathogens).

ANNEX B

PRODUCTS NOT SUBJECT TO COMMUNITY HARMONIZATION, BUT TRADE IN WHICH WOULD BE SUBJECT TO THE CHECKS PROVIDED FOR BY THIS DIRECTIVE

Other products of animal origin included neither in Annex B to this Directive nor in the Annex to Directive 90/425/EEC: these products will be defined under the procedure laid down in Article 18.'

II

CONSOLIDATED VERSION OF ANNEXES A AND B TO DIRECTIVE 90/425/EEC

'ANNEX A

CHAPTER I

VETERINARY LEGISLATION

Section 1

- Council Directive 64/432/EEC of 26 June 1964 on animal health problems affecting intra-Community trade in bovine animals and swine (OJ No 121, 29. 7. 1964, p. 1977/64).
- Council Directive 88/407/EEC of 14 June 1988 laying down the animal health requirements applicable to intra-Community trade in and imports of deep-frozen semen of domestic animals of the bovine species (OJ No L 194, 22. 7. 1988, p. 10).
- Council Directive 89/556/EEC of 25 September 1989 on animal health conditions governing intra-Community trade in and importation from third countries of embyros of domestic animals of the bovine species (OJ No L 302, 19. 10. 1989, p. 1).
- Council Directive 90/426/EEC of 26 June 1990 on the health policy conditions governing the movement of equidae and their import from third countries (OJ No L 224, 18. 8. 1990, p. 42).
- Council Directive 90/429/EEC of 26 June 1990 laying down the animal health requirements applicable to intra-Community trade in and imports of semen of domestic animals of the porcine species (OJ No L 224, 18. 8. 1990, p. 62).
- Council Directive 90/539/EEC of 15 October 1990 on animal health conditions governing intra-Community trade in, and imports from third countries of, poultry and hatching eggs (OJ No L 303, 31. 10. 1990, p. 6).
- Council Directive 90/667/EEC of 27 November 1990 laying down the veterinary rules for the disposal and processing of animal waste, for its placing on the market and for the prevention of pathogens in feedstuffs of animal or fish origin and amending Directive 90/425/EEC (OJ No L 363, 27. 12. 1990, p. 51).
- Council Directive 91/67/EEC of 28 January 1991 concerning the animal health conditions governing the placing on the market of aquaculture animals and products (OJ No L 46, 19. 2. 1991, p. 1).
- Council Directive 91/68/EEC of 28 January 1991 on animal health conditions governing intra-Community trade in ovine and caprine animals (OJ No L 46, 19. 2. 1991, p. 19).
- Council Directive 91/628/EEC of 19 November 1991 on the protection of animals during transport and amending Directives 90/425/EEC and 91/496/EEC (OJ No L 340, 11. 12. 1991, p. 17).

Section 2

Council Directive 92/65/EEC of 13 July 1992 laying down animal health requirements governing trade in and imports into the Community of animals, semen, ova and embryos not subject to animal health requirements laid down in specific Community rules referred to in Annex A (I) (1) to Directive 90/425/EEC (OJ No L 268, 14. 9. 1992, p. 54).

- For pathogens:

Council Directive 92/118/EEC of 17 December 1992 laying down animal health and public health requirements governing trade in and imports into the Community of products not subject to the said requirements laid down in specific Community rules referred to in Annex A (I) to Directive 89/662/EEC and, as regards pathogens, to Directive 90/425/EEC.

CHAPTER II

ZOOTECHNICAL LEGISLATION

- Council Directive 77/504/EEC of 25 July 1977 on pure-bred breeding animals of the bovine species (OJ No L 206, 12. 8. 1977, p. 8).
- Council Directive 88/661/EEC of 19 December 1988 on the zootechnical standards applicable to breeding animals of the porcine species (OJ No L 382, 31. 12. 1988, p. 36).
- Council Directive 89/361/EEC of 30 May 1989 concerning pure-bred breeding sheep and goats (OJ No L 153, 8. 6. 1989, p. 30).
- Council Directive 90/427/EEC of 26 June 1990 on the zootechnical and genealogical conditions governing intra-Community trade in equidae (OJ No L 224, 18. 8. 1990, p. 55).
- Council Directive 91/174/EEC of 25 March 1991 laying down zootechnical and pedigree requirements for the marketing of pure-bred animals (OJ No L 85, 5. 4. 1991, p. 37).

ANNEX B

ANIMALS AND PRODUCTS NOT SUBJECT TO HARMONIZATION BUT TRADE IN WHICH WILL BE SUBJECT TO THE CHECKS PROVIDED FOR IN THIS DIRECTIVE

CHAPTER I

Veterinary legislation — other live animals not listed in Annex A, Chapter I.

CHAPTER II

Veterinary legislation — semen, ova and embryos not listed in Annex A, Chapter I.'

COUNCIL DIRECTIVE 92/119/EEC

of 17 December 1992

introducing general Community measures for the control of certain animal diseases and specific measures relating to swine vesicular disease

THE COUNCIL OF THE EUROPEAN COMMUNITIES,

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

Having regard to the proposal from the Commission (1),

Having regard to the opinion of the European Parliament (2),

Having regard to the opinion of the Economic and Social Committee (3),

Whereas live animals are listed in Annex II to the Treaty; whereas the marketing of live animals constitutes an important source of revenue for the agricultural population;

Whereas it is necessary to establish at Community level the control measures to be taken in the event of outbreaks of disease, in order to ensure rational development of the farming sector and to contribute to the protection of animal health in the Community;

Whereas an outbreak of disease can quickly take on epizootic proportions, causing mortality and disturbances which may severely compromise the profitability of stock farming;

Whereas control measures must be taken as soon as the presence of a disease is suspected so that immediate and effective action can be implemented as soon as its presence is confirmed;

Whereas the measures to be taken must allow the spread of the disease to be prevented, in particular by carefully controlling movements of animals and products liable to spread the infection;

Whereas the prevention of diseases in the Community should normally be based on a non-vaccination policy; whereas, however, it is important to make provision for vaccination where a serious situation demands such action;

Whereas in order to ensure that all vaccinated animals are recognizable, it is necessary for these animals to be identified; whereas in order to give the necessary guarantees, the potency of the vaccine must be approved by a reference laboratory designated by the Community;

Whereas a thorough epidemiological enquiry is essential to prevent any spread of diseases; whereas the Member States must establish special units for this purpose; Whereas in order to ensure the effectiveness of the system of control, diagnosis of the diseases must be harmonized and must be carried out under the auspices of responsible laboratories, the coordination of which may be carried out by a reference laboratory designated by the Community;

Whereas Article 3 of Council Decision 90/424/EEC of 26 June 1990 on expenditure in the veterinary field (4) applies in the event of an outbreak of one of the diseases listed in Annex I;

Whereas common measures for the control of these diseases form a basis for maintaining a uniform standard of animal health;

Whereas specific provisions should also be laid down for each individual disease and, initially, for swine vesicular disease,

HAS ADOPTED THIS DIRECTIVE:

Article 1

This Directive defines the general Community control measures to be applied in the event of an outbreak of one of the diseases listed in Annex I.

Article 2

For the purposes of this Directive, the following definitions shall apply:

- 1. holding: any establishment (agricultural or other), situated in the territory of a Member State, in which animals are kept or bred;
- 2. animal: any domestic animal of a species liable to be directly affected by the disease in question, or any wild vertebrate animal likely to participate in the epidemiology of the disease, by acting as a carrier or reservoir of infection;
- 3. *vector:* any wild vertebrate or invertebrate animal which, by mechanical or biological means, is liable to transmit and spread the agent of the disease in question;
- 4. owner or keeper: any person or persons, either natural or legal, having ownership of the animals, or charged with keeping the said animals, whether or not for financial reward;
- 5. incubation period: the period of time likely to elapse between exposure to the agent of the disease and the

⁽¹) OJ No C 148, 7. 6. 1991, p. 12.

⁽²⁾ OJ No C 280, 28. 4. 1992, p. 124.

⁽³⁾ OJ No C 339, 31. 12. 1991, p. 12.

⁽⁴⁾ OJ No L 224, 18. 8. 1990, p. 19. Decision as amended by Decision 91/133/EEC (OJ No L 66, 13. 3. 1991, p. 18).

onset of clinical symptoms. The duration of this period shall be that indicated in Annex I for the disease in question;

- 6. confirmation of infection: the declaration by the competent authority of the presence of any of the diseases listed in Annex I based on laboratory results; however, in the event of an epidemic, the competent authority may also confirm the presence of the disease on the basis of clinical and/or epidemiological results;
- 7. competent authority: the central authority of a Member State responsible for carrying out veterinary checks or any veterinary authority to which it has delegated that responsibility;
- 8. official veterinarian: the veterinarian appointed by the competent authority.

Article 3

Member States shall ensure that it is compulsory for the suspected presence of any of the diseases referred to in Annex I to be notified immediately to the competent authority.

Article 4

- 1. When animals on a holding are suspected of being infected or contaminated with one of the diseases listed in Annex I, Member States shall ensure that the official veterinarian immediately activates official investigation arrangements to confirm or rule out the presence of the disease in question and, in particular, must take or have taken the samples necessary for laboratory examination. To that end the animals in question may be transported to the laboratories under the supervision of the competent authority, which shall take appropriate steps to prevent the disease from spreading.
- 2. As soon as the suspected presence of the disease is notified, the competent authority shall have the holding placed under official surveillance and shall in particular require that:
- (a) a census be made of all categories of animals of susceptible species and that, in respect of each of these categories, the number of animals already dead, infected or liable to be infected or contaminated be recorded; the census must be kept up to date to take account of animals born or dying during the period of suspicion; the information in the census must be kept up to date and produced on request and may be checked at each visit;
- (b) all animals of susceptible species on the holding be kept in their living quarters or confined in some other place where they can be isolated taking into account the possible role of vectors, where appropriate;

- (c) no animals of susceptible species enter or leave the holding;
- (d) all movement:
 - of persons, animals of other species not susceptible to the disease and vehicles to or from the holding,
 - of meat or animal carcases, or of animal feed, equipment, waste, droppings, litter, manure, or anything liable to transmit the disease in question
- (e) be subject to authorization by the competent authority, which shall lay down the conditions for preventing any risk of the disease spreeding; appropriate means of disinfection be installed at the entrances and exits of buildings or places housing animals of susceptible species and of the holding itself;
- (f) an epizootiological inquiry be carried out in accordance with Article 8.
- 3. Until such time as the official measures laid down in paragraph 2 are enforced, the owner or keeper of any animal in which disease is suspected shall take every appropriate measure to ensure compliance with paragraph 2, except for subparagraph (f) thereof.
- 4. The competent authority may apply any of the measures provided for in paragraph 2 to other holdings should their location, their configuration or contacts with the holding where the disease is suspected give reason to suspect possible contamination.
- 5. The measures referred to in paragraphs 1 and 2 shall not be withdrawn until the suspicion of the presence of the disease has been ruled out by the official veterinarian.

Article 5

- 1. Once it has been officially confirmed that one of the diseases listed in Annex I is present on a holding, Member States shall ensure that, in addition to the measures laid down in Article 4 (2), the competent authority requires application of the following measures:
- (a) all animals of susceptible species on the holding shall be killed on the spot, without delay. The animals which have died or been killed shall either be burnt or buried on the spot, if possible, or destroyed in a carcase disposal plant. These operations shall be carried out in such a way as to minimize the risk of disseminating the agent of the disease;
- (b) any substance or waste, such as animal feed, litter, manure or slurry, which is liable to be contaminated, shall be destroyed or treated appropriately. This treatment, carried out in accordance with the instructions of the official veterinarian, must ensure that any agent or vector of the agent of the disease is destroyed;
- (c) after carrying out operations listed in subparagraphs (a) and (b), the buildings used for

housing animals of susceptible species, their surroundings, the vehicles used for transport and all equipment liable to be contaminated shall be cleaned and disinfected in accordance with Article 16;

- (d) an epizootiological inquiry shall be carried out in accordance with Article 8.
- 2. When recourse is had to burial, it must be deep enough to prevent carnivorous animals from digging up the carcases or waste referred to in paragraph 1 (a) and (b) above and must be in suitable ground so as to prevent contamination of water tables or any environmental nuisance.
- 3. The competent authority may extend the measures provided for in paragraph 1 to other neighbouring holdings should their location, their configuration or contacts with the holding where the presence of the disease has been confirmed give reason to suspect possible contamination.
- 4. The restocking of the holding shall be authorized by the competent authority, following the satisfactory inspection by the official veterinarian of the cleaning and disinfection operations carried out in accordance with Article 16.

Article 6

Where animals living in the wild are infected or suspected of being infected, Member States shall ensure that appropriate action is taken. Member States shall inform the Commission and the other Member States, in the Standing Veterinary Committee set up by Decision 68/361/EEC (1), of the measures they have taken.

Article 7

- 1. In the case of holdings which consist of two or more separate production units, the competent authority may derogate from the requirements of Article 5 (1) (a) as regards healthy production units of a holding which is infected, provided that the official veterinarian has confirmed that the structure and size of these units and the operations carried out therein are such that they are completely separate as regards housing, keeping, staff, equipment and feeding, so as to prevent the spread of the agent of the disease from one unit to another.
- 2. Where recourse is had to paragraph 1, the rules laid down in Commission Decision 88/397/EEC (2) shall apply mutatis mutandis. These rules may be amended for the disease in question under the procedure laid down in Article 25 in order to take account of the specific nature of the disease.

Article 8

- 1. The epizootiological enquiry shall deal with:
- (a) the length of time during which the disease may have existed on the holding before being notified or suspected;
- (b) the possible origin of the disease on the holding and the identification of other holdings on which there are animals of susceptible species which may have become infected or contaminated;
- (c) the movement of persons, animals, carcases, vehicles, equipment or any other substances likely to have carried the agent of the disease to or from the holdings in question;
- (d) the presence and distribution of disease vectors as appropriate.
- 2. A crisis unit shall be established in order to provide full coordination of all measures necessary to ensure eradication of the disease as quickly as possible and for the purpose of carrying out the epizootiological enquiry.

The general rules concerning national crisis units and the Community crisis unit shall be laid down by the Council, acting by a qualified majority on a proposal from the Commission.

Article 9

- 1. Where the official veterinarian finds, or considers on the basis of confirmed data, that disease could have been introduced from other holdings onto the holding referred to in Article 4 or from the latter onto other holdings as a result of the movement of persons, animals or vehicles or in any other way, those other holdings shall be placed under official surveillance in accordance with Article 4; this surveillance shall not be lifted until the suspected presence of disease on the holding has been officially ruled out.
- 2. Where the official veterinarian finds, or considers on the basis of confirmed data, that disease could have been introduced from other holdings on to the holding referred to in Article 5 or from the latter onto other holdings as a result of the movement of persons, animals or vehicles or in any other way, those other holdings shall be placed under official surveillance in accordance with Article 4; this surveillance shall not be lifted until the suspected presence of disease on the holding has been officially ruled out.
- 3. When a holding has been subject to the provisions of paragraph 2, the competent authority shall keep the provisions of Article 4 in force on the holding for at least the maximum incubation period pertaining to each disease following the likely time of introduction of infection as established by the epizootiological enquiry carried out in accordance with Article 8.
- 4. Where it considers that conditions permit, the competent authority may limit the measures provided for

⁽¹⁾ OJ No L 255, 18. 10. 1968, p. 23.

⁽²⁾ Commission Decision 88/397/EEC of 12 July 1988 coordinating rules laid down by Member States in application of Article 6 of Council Directive 85/511/EEC (OJ No L 189, 20. 7. 1988, p. 25).

in paragraphs 1 and 2 to a part of the holding and the animals contained therein provided that the holding can satisfy the conditions set out in Article 7, or to animals of susceptible species only.

Article 10

- 1. Once the diagnosis of one of the diseases in question has been officially confirmed, Member States shall ensure that the competent authority establishes around the infected holding a protection zone with a minimum radius of three kilometres, itself contained in a surveillance zone with a minimum radius of 10 kilometres. The establishment of the zones must take account of geographical, administrative, ecological and epizootiological factors relating to the disease in question, and of monitoring facilities.
- 2. Where the zones are situated in the territory of more than one Member State, the competent authorities of the Member States concerned shall cooperate in establishing the zones referred to in paragraph 1. However, if necessary, the protection zone and the surveillance zone shall be established under the procedure provided for in Article 26.
- 3. At the duly substantiated request of a Member State or on the Commission's initiative, it may be decided under the procedure laid down in Article 26, to modify (in particular to reduce or increase, as appropriate) the boundaries of the zones laid down in paragraph 1 or the duration of the restriction measures, taking into account:
- their geographical situation and ecological factors,
- the meteorological conditions,
- the presence, distribution and type of vectors,
- the results of the epizootiological studies carried out in accordance with Article 8,
- the results of laboratory tests,
- control measures actually applied.

Article 11

- 1. Member States shall ensure that the following measures are applied in the protection zone:
- (a) all holdings within the zone having animals of susceptible species shall be identified;
- (b) there shall be periodic visits to holdings having animals of susceptible species, a clinical examination of those animals including, if necessary, the collection of samples for laboratory examination; a record of visits and findings must be kept, with the frequency of visits being proportional to the seriousness of the epizootic on those holdings at greatest risk;

- (c) the movement and transport of animals of susceptible species on public or private roads, excluding the service roads of holdings, shall be prohibited; the competent authority may, however, grant a derogation from that prohibition for the transit of animals by road or rail without unloading or stopping;
- (d) animals of susceptible species must remain on the holding on which they are being kept, except to be transported under official supervision directly to a slaughterhouse located in that zone for emergency slaughter or, if that zone has no slaughterhouse under veterinary supervision, to a slaughterhouse in the surveillance zone designated by the competent authority. Such transport may be authorized by the competent authority only after the official veterinarian has carried out an examination of all the animals of susceptible species on the holding and confirmed that none of the animals is suspected of being infected. The competent authority responsible for the slaughterhouse shall be informed of the intention to send animals to it.
- 2. The measures applied in the protection zone shall be kept in force for at least the maximum incubation period pertaining to the disease in question after animals from the infected holding have been disposed of in accordance with Article 5 and cleaning and disinfection operations have been carried out in accordance with Article 16. However, where the disease is transmitted by an insect vector, the competent authority may fix the duration of the measures and lay down provisions for the possible introduction of sentinel animals. Member States shall forthwith inform the Commission and the other Member States, within the Standing Veterinary Committee, of the measures they have taken.

On expiry of the period referred to in the first subparagraph, the rules applied to the surveillance zone shall also apply to the protection zone.

Article 12

- 1. Member States shall ensure that the following measures are applied in the surveillance zone:
- (a) all holdings having animals of susceptible species shall be identified;
- (b) the movement of animals of susceptible species on public roads shall be prohibited except for the purpose of leading them to pasture or animal buildings; the competent authority may, however, grant a derogation from that prohibition for the transit of animals by road or rail without unloading or stopping;
- (c) the transport of animals of susceptible species within the surveillance zone shall be subject to authorization by the competent authority;
- (d) animals of susceptible species must remain inside the surveillance zone for a maximum incubation period after the most recent recorded case of disease. Thereafter, animals may be removed from that zone

to be transported under official supervision directly to a slaughterhouse designated by the competent authority for emergency slaugther. Such transport may be authorized by the competent authority only after the official veterinarian has carried out an examination of all the animals of the susceptible species on the holding and confirmed that none of the animals is suspected of being infected. The competent authority responsible for the slaughterhouse shall be informed of the intention to send animals to it.

2. The measures applied in the surveillance zone shall be kept in force for a period at least equal to the maximum incubation period after animals from the holding have been disposed of in accordance with Article 5 and cleaning and disinfection operations have been carried out in accordance with Article 16. However, where the disease is transmitted by an insect vector, the competent authority may fix the duration of the measures and lay down provisions for the possible introduction of sentinel animals. Member States shall forthwith inform the Commission and the other Member States, within the Standing Veterinary Committee, of the measures they have taken.

Article 13

Where the prohibitions provided for in Articles 11 (1) (d) and 12 (1) (d) are maintained beyond 30 days because of the occurrence of further cases of the disease and as a result problems arise in keeping the animals, the competent authority may, following an application by the owner explaining the rounds for such application, by the owner explaining the grounds for such applications authorize the removal of the animals from a holding within the protection zone or the surveillance zone, provided that:

- (a) the official veterinarian has verified the facts;
- (b) an inspection of all animals on the holding has been carried out;
- (c) the animals to be transported have undergone a clinical examination, with negative result;
- (d) each animal has been marked by ear marking or has been identified by any other approved method;
- (e) the holding of destination is located either in the protection zone or within the surveillance zone.

All the necessary precautions must be taken, in particular by cleaning and disinfecting lorries after transport, to avoid the risk of spreading the agent of the disease in the course of such transport.

Article 14

- 1. Member States shall ensure that the competent authority takes all the necessary measures to keep at least persons established in the protection and surveillance zones informed of the restrictions in force and makes all necessary arrangements for the appropriate implementation of those measures.
- 2. Where, in a given region, the epizootic in question is exceptionally serious, all the additional measures to be

taken by the Member States concerned shall be adopted under the procedure laid down in Article 26.

Article 15

By way of derogation from the general provisions laid down in this Directive, specific provisions relating to the control and eradication measures for each respective disease:

- are, for swine vesicular disease, set out in Annex II for swine vesicular disease,
- are, for each of the other diseases listed in Annex I, adopted by the Council, acting by a qualified majority on a proposal from the Commission.

Article 16

- 1. Member States shall ensure that:
- (a) the disinfectants and insecticides to be used and, where appropriate, their concentrations, are officially approved by the competent authority;
- (b) the cleaning, disinfection and disinsectization operations are carried out under official supervision:
 - in accordance with the instructions given by the official veterinarian,

and

- in such a way as to eliminate any risk of spread or survival of the agent of the disease;
- (c) on completion of the operations in (b), the official veterinarian makes sure that the measures have been carried out properly and that an appropriate period, of not less than 21 days, has elapsed to ensure that the disease in question has been completely eliminated before animals of susceptible species are re-introduced.
- 2. The procedures for cleaning and disinfecting an infected holding:
- are, for swine vesicular disease, those set out in Annex II,
- are determined, in the context of preparation of the specific measures for each disease listed in Annex I, in accordance with the procedure laid down in the second indent of Article 15.

Article 17

- 1. Member States shall ensure that in each Member State there is designated:
- (a) a national laboratory with facilities and expert personnel enabling it to show at all times, and especially when the disease in question first appears, the type, sub-type and variant of the relevant virus

- and to confirm results obtained in regional diagnostic laboratories;
- (b) a national laboratory at which reagents used in regional diagnostic laboratories are tested.
- 2. The national laboratories designated for each of the diseases referred to shall be responsible for coordinating diagnostic standards and methods, and for the use of reagents.
- 3. The national laboratories designated for each of the diseases referred to shall be responsible for coordinating the diagnostic standards and methods laid down by each laboratory for diagnosis of the disease in question within the Member State. To this end, they:
- (a) may provide diagnostic reagents to national laboratories;
- (b) shall control the quality of all diagnostic reagents used in the Member State;
- (c) shall periodically arrange comparative tests;
- (d) shall hold isolates of the virus of the disease in question from cases confirmed in the Member State;
- (e) shall ensure the confirmation of positive results obtained in regional diagnostic laboratories.
- 4. However, by way of derogation from paragraph 1, Member States which do not have a national laboratory competent as regards the disease in question, may use the services of a national laboratory with competence in the matter of another Member State.
- 5. The list of national laboratories for swine vesicular disease is set out in Annex II.
- 6. The national laboratories designated for each of the diseases referred to shall cooperate with the respective Community reference laboratories referred to in Article 18.
- 7. The detailed rules for implementing this Article shall be adopted by the Commission under the procedure laid down in Article 25.

Article 18

- 1. The Community reference laboratory for swine vesicular disease is indicated in Annex II.
- 2. The Community reference laboratories for each of the other diseases listed in Annex I shall be designated in accordance with the procedure laid down in the second indent of Article 15 in the context of preparation of the specific measures for each disease.
- 3. Without prejudice to Decision 90/424/EEC, and in particular Article 28 thereof, the functions and duties of the laboratories referred to in paragraphs 1 and 2 of this Article shall be those laid down in Annex III.

Article 19

- 1. Vaccination against the diseases listed in Annex I may not be carried out except as a supplement to control measures taken when the disease in question broke out, in accordance with the following provisions:
- (a) the decision to introduce vaccination as a supplement to control measures shall be taken by the Commission, in cooperation with the Member State concerned, under the procedure laid down in Article 26;
- (b) this decision shall be based on the following criteria in particular:
 - the concentration of animals of the species concerned in the affected zone,
 - the characteristics and composition of each vaccine used,
 - the procedures for supervision of the distribution, storage and use of vaccines,
 - the species and age of the animals which may or must be vaccinated,
 - the areas in which vaccination may or must be carried out,
 - the duration of the vaccination campaign.
- 2. In the case referred to in paragraph 1:
- (a) the vaccination or re-vaccination of animals of susceptible species on the holdings referred to in Article 4 shall be prohibited;
- (b) hyper-immune serum injection shall be prohibited.
- 3. In the event of recourse to vaccination, the following rules shall apply:
- (a) all vaccinated animals must be identified by a clear and legible mark in accordance with a method approved by the procedure laid down in Article 25;
- (b) all vaccinated animals must remain within the vaccination zone unless sent to a slaughterhouse designated by the competent authority for immediate slaughter, in which case the movement of animals may be authorized only after the official veterinarian has carried out an examination of all the susceptible animals on the holding and confirmed that none of the animals is suspected of being infected.
- 4. When the vaccination operations have been completed, movements of animals of susceptible species from the vaccination zone may be permitted under the procedure laid down in Article 26, after a period determined by the same procedure.
- 5. Member States shall inform the Commission on a regular basis, within the Standing Veterinary Committee, of progress as regards the vaccination measures.
- 6. However, by way of derogation from paragraph 1, the decision to introduce emergency vaccination may be taken by the Member State concerned, following notification of the Commission, provided that the fundamental interests of the Community are not affected. That decision, which must in particular take into account

the degree of concentration of the animals in certain regions, of the need to protect individual breeds and of the geographical area in which vaccination is carried out, shall forthwith be re-examined, under the procedure laid down in Article 26, by the Standing Veterinary Committee, which may decide to retain, modify or extend the measures or to bring them to an end.

Article 20

1. Each Member State shall draw up a contingency plan applicable to all the diseases listed in Annex I, specifiying the national measures to be implemented in the event of an outbreak of any of these diseases.

This plan must allow access to facilities, equipment, personnel and all other appropriate materials necessary for the rapid and efficient eradication of the outbreak.

- 2. The general criteria to be applied for drawing up the contingency plans are laid down in points 1 to 5 and 10 of Annex IV, with points 6 to 9 representing criteria to be adapted according to the disease concerned. Member States may however confine themselves to applying the criteria laid down in points 6 to 9 where the criteria in points 1 to 5 and 10 were already adopted when plans were submitted for the application of control measures for another disease.
- 3. Contingency plans drawn up in accordance with the criteria listed in Annex IV shall be submitted to the Commission:
- (i) no later than six months after this Directive is brought into effect as regards swine vesicular disease;
- (ii) no later than six months after implementation of the specific measures for each of the other diseases listed in Annex I.
- 4. The Commission shall examine the contingency plans in order to determine whether they permit the desired objective to be attained and shall suggest to the Member State concerned any amendments required in particular to ensure that they are compatible with those of the other Member States.

The Commission shall approve the plans, if necessary amended, in accordance with the procedure laid down in Article 25.

The plans may subsequently be amended or supplemented, in accordance with the same procedure, to take into account developments in the situation and the specific nature of the disease in question.

Article 21

By way of derogation from the conditions provided for in Articles 19 and 20 as regards the contingency measures to be adopted by the Member States and so as to take account of the natural, geographical constraints particular to the French Overseas Departments, the Azores and

Madeira and their remoteness from the central part of the Community's territory, the Member State concerned shall be authorized to apply particular control measures specific to each of the diseases listed in Annex I to this Directive.

The Member State concerned shall, within the Standing Veterinary Committee, inform the Commission and the other Member States of the measures it has taken in this respect and in particular of the control measures implemented to ensure that animals from the territories in question or products from such animals are not dispatched to the other territories of the Community.

Following the information procedure referred to in the second paragraph, Article 20 shall apply mutatis mutandis.

Article 22

Commission experts may, in collaboration with the competent authorities, and in so far as is necessary to ensure uniform application of this Directive, make on-the-spot checks. In order to do this, they may check a representative percentage of holdings to see whether the competent authorities are checking that these holdings are fulfilling the requirements of this Directive. The Commission shall inform the Member States of the result of the checks carried out.

A Member State in whose territory a check is being carried out shall give all the necessary assistance to the experts in carrying out their duties.

The detailed rules for implementing this Article shall be determined in accordance with the procedure laid down in Article 25.

Article 23

- 1. The conditions governing the Community's financial contribution to the measures connected with the application of this Directive are laid down in Decision 90/424/EEC.
- 2. Article 3 of Decision 90/424/EEC shall be amended as follows:
- (a) the following disease shall be added to the list of diseases specified in paragraph 1:

'haemorrhagic disease of deer';

- (b) the following paragraph shall be added:
 - '2a. The Member State concerned shall also qualify for a Community financial contribution where, on the outbreak of one of the diseases listed in paragraph 1, two or more Member States collaborate closely to control the epidemic, particularly in carrying out an epidemiological survey and disease surveillance measures. Without prejudice to the measures provided for under the common organization of markets concerned, the specific Community financial contribution shall be decided on in accordance with the procedure laid down in Article 41.'

Article 24

- 1. Annexes I, III and IV shall be amended, as and when required, by the Council acting by a qualified majority on a proposal from the Commission, in particular in order to take into account developments in research and in diagnostic procedures.
- 2. The Commission may, in accordance with the procedure laid down in Article 25, amend Annex II, in particular in order to take into account technological and scientific developments and diagnostic methods.

Article 25

- 1. Where the procedure laid down in this Article is to be followed, the chairman shall, without delay, refer the matter to the Standing Veterinary Committee, either on his own initiative or at the request of the representative of a Member State.
- 2. The representative of the Commission shall submit to the Committee a draft of the measures to be taken. The Committee shall deliver its opinion on the draft within a time limit which the chairman may lay down according to the urgency of the matter. The opinion shall be delivered by the majority laid down in Article 148 (2) of the Treaty in the case of decisions which the Council is required to adopt on a proposal from the Commission. The votes of the representatives of the Member States within the Committee shall be weighted in the manner set out in that Article. The chairman shall not vote.
- 3. (a) The Commission shall adopt the measures envisaged if they are in accordance with the opinion of the Committee.
 - (b) If the measures envisaged are not in accordance with the opinion of the Committee, or if no opinion is delivered, the Commission shall without delay submit to the Council a proposal relating to the measures to be taken. The Council shall act by a qualified majority.

If, on the expiry of a period of three months from the date of referral to the Council, the Council has not acted, the proposed measures shall be adopted by the Commission, save where the Council has decided against the said measures by a simple majority.

Article 26

- 1. Where the procedure laid down in this Article is to be followed, the matter shall without delay be referred to the Standing Veterinary Committee by its chairman, either on his own initiative or at the request of a Member State.
- 2. Within the Committee, the votes of the Member States shall be weighted as laid down in Article 148 (2) of the Treaty. The chairman shall not vote.

- 3. The representative of the Commission shall submit a draft of the measures to be adopted. The Committee shall deliver its opinion on these measures within two days. Opinions shall be delivered by a majority of 54 votes.
- 4. (a) The Commission shall adopt the measures and shall implement them immediately, where they are in accordance with the opinion of the Committee.
 - (b) Where the measures envisaged are not in accordance with the opinion of the Committee, or if no opinion is delivered, the Commission shall without delay submit a proposal to the Council on the measures to be taken. The Council shall adopt the measures by a qualified majority.

If the Council has not adopted any measures within 15 days of the date on which the matter is referred to it, the Commission shall adopt the proposed measures and shall implement them immediately unless the Council has voted against the measures by a simple majority.

Article 27

1. Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with this Directive before 1 October 1993. They shall forthwith inform the Commission thereof.

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

- 2. Member States shall communicate to the Commission the texts of the main provisions of national law which they adopt in the field governed by this Directive.
- 3. The setting of the deadline for transposition into national law at 1 October 1993 shall be without prejudice to the abolition of veterinary checks at frontiers provided for in Directive 90/425/EEC.

Article 28

This Directive is addressed to the Member States.

Done at Brussels, 17 December 1992.

For the Council
The President
J. GUMMER

ANNEX I

LIST OF COMPULSORILY NOTIFIABLE DISEASES

Disease	Maximum incubation period
Rinderpest	21 days
Peste des petits ruminants	21 days
Swine vesicular disease	28 days
Bluetongue	40 days
Epizootic haemorrhagic disease of deer	40 days
Sheep and goat pox (Capripox)	21 days
Vesicular stomatitis	21 days
Teschen disease	40 days
Lumpy skin disease	28 days
Rift valley fever	30 days

ANNEX II

SPECIFIC MEASURES TO CONTROL CERTAIN DISEASES

In addition to the general provisions laid down in this Directive, the following specific provisions shall be applicable to swine vesicular disease.

1. Description of the disease

A disease of swine that is clinically indistinguishable from foot-and-mouth disease, causing vesicles on the snout, lips, tongue and the coronary bands of the digits. The disease varies considerably in severity and may infect a pig herd without manifesting itself by clinical lesions. The virus is able to survive for long periods outside the body even in fresh meat; it is extremely resistant to normal disinfectants and noted for its persistence and stability over a pH range from 2,5 to 12. Particularly thorough cleaning and disinfection are, therefore, necessary.

2. Incubation period

For the purpose of this Directive, the maximum incubation period shall be considered to be 28 days.

3. Diagnostic procedures for the confirmation and differential diagnosis of swine vesicular disease

The detailed methods for the collection of materials for diagnosis, the laboratory diagnostic tests, detection of antibodies and evaluation of the results of laboratory testing shall be decided in accordance with the procedure laid down in Article 25 before the Directive enters into force.

4. Confirmation of the presence of swine vesicular disease

By way of derogation from Article 2 (6) of this Directive, the presence of the disease shall be confirmed:

- (a) on holdings on which swine vesicular disease virus is isolated either from the pigs or from the environment;
- (b) on holdings containing pigs which are seropositive for swine vesicular disease provided those pigs or others on the holdings show lesions characteristic of swine vesicular disease;
- (c) on holdings containing pigs which show clinical signs of disease or are seropositive, provided there is a direct epidemiological connection with a confirmed outbreak;
- (d) on other herds in which seropositive pigs are detected. In the latter case the competent authority shall, before confirming the presence of the disease, undertake further investigations, in particular resampling and retesting with an interval of 28 days at least between collections of samples. The provisions of Article 4 shall continue to apply until such further investigations are completed. If subsequent investigations show no evidence of the disease, although the pigs are still seropositive, the competent authority shall ensure that the pigs tested are killed and destroyed under its supervision or slaughtered under its supervision in a slaughterhouse it has designated in its national territory.

The competent authority shall ensure that on arrival at the slaughterhouse the pigs are kept and slaughtered separately from other pigs and that their meat is exclusively used on the national market.

5. Diagnostic laboratories

Belgium:

Institut national de recherches vétérinaires,

Groeselenberg 99, B-1180 Bruxelles.

Denmark:

-Statens Veterinære Institut for Virusforskning,

Lindholm.

Germany:

Bundesforschungsanstalt für Viruskrankheiten der Tiere,

Paul-Ehrlich-Straße, 7400 Tübingen.

France:

Laboratoire central de recherche vétérinaire,

Maisons-Alfort.

Greece:

Ινστιτούτο Λοιμωδών και Παρασιτικών Νοσημάτων,

Νεαπόλεως 21, Αγία Παρασκευή:

Ireland:

Institute for Animal Health,

Pirbright, Woking, Surrey.

Italy:

Istituto zooprofilattico sperimentale della Lombardia e dell'Emilia Romagna,

Brescia.

Luxembourg:

Institut national de recherches vétérinaires,

Groeselenberg 99,

B-1180 Bruxelles.

Netherlands:

Centraal Diergeneeskundig Institut,

Lelystad.

Portugal:

Laboratório Nacional de Investigação Veterinária,

Lisboa.

Spain:

Laboratorio de Alta Seguridad Biológica (INIA),

28130 Madrid.

United Kingdom:

Institute for Animal Health,

Pirbright, Woking, Surrey.

6. Community reference laboratory

AFRC Institute for Animal Health, Pirbright Laboratory, Ash Road, Pirbright, Woking, Surrey GU24 ONF, United Kingdom.

7. Protection zone

- 1. The size of the protection zone shall be as defined in Article 10 of this Directive.
- In the case of swine vesicular disease, by way of derogation, the measures in Article 11 of this Directive shall be replaced by the following:
 - (a) all holdings within the zone having animals of susceptible species shall be identified;
 - (b) there shall be periodic visits to holdings having animals of susceptible species, a clinical examination of those animals including, if necessary, the collection of samples for laboratory examination; a record of visits and findings must be kept; with the frequency of the visits being proportional to the seriousness of the epizootic on those holdings at greatest risk;
 - (c) the movement and transport of animals of susceptible species on public or private roads, excluding the service roads of holdings, shall be prohibited. The competent authority may, however, derogate from this prohibition for the transit of animals by road and rail without unloading or stopping;
 - (d) however, in accordance with the procedure laid down in Article 25, an exemption may be granted for slaughter pigs coming from outside the protection zone and on their way to a slaughterhouse situated in that zone;
 - (e) trucks and other vehicles and equipment which are used within the protection zone to transport pigs or other livestock or material which may be contaminated (e.g. feedingstuff, manure, slurry, etc.) may not leave:
 - (i) a holding situated within the protection zone;
 - (ii) the protection zone;
 - (iii) a slaughterhouse,

without having been cleaned and disinfected in accordance with the procedures laid down by the competent authority. Those procedures shall provide in particular that no truck or vehicle which has been used in the transport of pigs may leave the zone without being inspected by the competent authority;

(f) pigs may not be removed from a holding in which they are kept for 21 days after completion of the preliminary cleaning and disinfection of infected holdings as laid down in Article 16; after 21 days, authorization may be given to remove pigs from the said holding:

- directly to a slaughterhouse designated by the competent authority, preferably within the protection or surveillance zone, provided that:
 - an inspection of all the pigs on the holding has been carried out,
 - a clinical examination of the pigs to be moved to slaughter has been carried out,
 - each pig has been marked by ear marking or has been identified by any other approved method,
 - the pigs are transported in vehicles sealed by the competent authority.

The competent authority responsible for the slaughterhouse shall be informed of the intention to send pigs to it.

On arrival at the slaughterhouse, the pigs shall be kept and slaughtered separately from other pigs. The vehicle and equipment which have been involved in the transport of the pigs shall be cleaned and disinfected before leaving the slaughterhouse.

During the pre-slaughter and *post mortem* inspection carried out at the designated slaughterhouse, the competent authority shall take into account any signs relating to the presence of the swine vesicular disease virus.

In the case of pigs slaughtered under these provisions, a statistically representative sample of bloods shall be collected. In the case of a positive result which leads to the confirmation of swine vesicular disease, the measures in 9 (3) will apply;

- (ii) under exceptional circumstances, directly to other premises located within the protection zone, provided that:
 - an inspection of all the pigs on the holdings has been carried out,
 - a clinical examination of the pigs to be moved has been carried out, with negative results.
 - each pig has been marked by ear marking or has been identified by any other approved method;
- (g) fresh meat from the pigs referred to in point (f) (i) shall be marked in accordance with the Annex to Council Directive 72/461/EEC of 12 December 1972 on health problems affecting intra-Community trade in fresh meat (¹), and subsequently treated in accordance with the rules laid down in Article 4 (1) of Council Directive 80/215/EEC of 22 January 1980 on animal health problems affecting intra-Community trade in meat products (²). This must be done at an establishment designated by the competent authority.

The meat shall be sent to the said establishment on condition that the consignment is sealed before departure and remains sealed throughout the transport.

However, at the request of a Member State, accompanied by appropriate justification and in accordance with the procedure laid down in Article 25 of this Directive, specific solutions may by adopted, in particular with respect to the marking of meat and its subsequent use, and the destination of the processed products.

- 3. The measures in the protection zone shall continue to be applied at least until:
 - (a) all measures laid down in Article 16 of this Directive have been carried out;
 - (b) all the holdings in the zone have undergone:
 - (i) a clinical examination of the pigs which has revealed that they have no signs of disease suggesting the presence of swine vesicular disease; and
 - (ii) a serological examination of a statistical sample of the pigs without the detection of antibodies to swine vesicular disease. The programme for serological screening shall take into account the transmission of swine vesicular disease and the way in which pigs are kept. The programme shall be fixed under the procedure laid down in Article 25 of this Directive before the date of entry on which it is brought into effect.

⁽¹⁾ OJ No L 302, 31. 12. 1972, p. 24. Directive as last amended by Directive 91/687/EEC (OJ No L 377, 31. 12. 1991, p. 16).

⁽²⁾ OJ No L 47, 21. 2. 1980, p. 4. Directive as last amended by Directive 91/687/EEC (OJ No L 377, 31. 12. 1991, p. 16).

The examination and sampling referred to in (i) and (ii) shall not take place before 28 days have elapsed after the completion of preliminary cleaning and disinfection measures at the infected holding.

4. On expiry of the period referred to in point 3, the rules applied to the surveillance zone shall also apply to the protection zone.

8. Surveillance zone

- 1. The size of the surveillance zone shall be as laid down in Article 10.
- 2. In the case of swine vesicular disease, the measures laid down in Article 12 shall be replaced by the following:
 - (a) all holdings having animals of susceptible species shall be identified;
 - (b) any movement of pigs other than direct to a slaughterhouse from a holding in the surveillance zone shall be permitted, provided that no pigs have moved into that holding in the previous 21 days; the owner or the person responsible for the animals must keep a record of all pig movements;
 - (c) the movement of pigs from the surveillance zone may be authorized by the competent authority, provided that:
 - an inspection of all pigs on the holding has been carried out with the 48 hours preceding the movement.
 - a clinical examination of the pigs to be moved has been carried out with negative results in the 48 hours preceding the movement,
 - a serological examination of a statistical sample of the pigs to be moved has been carried out without the detection of antibodies to swine vesicular disease within the 14 days preceding the movement. However, in the case of pigs for slaughter, the serological examination may be carried out on the basis of blood samples taken at the slaughterhouse of destination designated by the competent authority in its territory. In the event of positive results confirming the presence of swine vesicular disease, the measures provided for in point 9 (3) shall be applied,
 - each pig has been marked with an individual eartag or by any other approved method of identification,
 - trucks and other vehicles and equipment used for the transport of the pigs must be cleaned and disinfected after each transport operation;
 - (d) trucks and other vehicles and equipment used for the transport of the pigs or other livestock or material that may be contaminated and which are used within the surveillance zone shall not leave that zone without having been cleaned and disinfected in accordance with the procedures laid down by the competent authority.
- 3. (a) The size of the surveillance zone may be amended in accordance with the provisions laid down in Article 10 (3).
 - (b) The measures in the surveillance zone shall be applied at least until:
 - (i) all the measures laid down in Article 16 have been carried out;
 - (ii) all the measures required in the protection zone have been carried out.

9. General common measures

Additional measures in the case of swine vesicular disease shall be applied as follows:

- 1. in cases where the presence of swine vesicular disease is officially confirmed, Member States shall ensure that, in addition to the measures laid down in Articles 4 (2) and 5 of this Directive, meat of pigs slaughtered during the period between the probable introduction of disease to the holding and the implementation of official measures is, wherever possible, traced and destroyed under official supervision in such a way as to avoid the risk of swine vesicular disease virus spreading;
- when the official veterinarian has reason to suspect that pigs on any holding may have been contaminated as a result of the movement of any person, animal or vehicle or in any other way, pigs

on the holding shall remain under the movement restrictions referred to in Article 9 of this Directive at least until the holding has undergone:

- (a) a clinical examination of the pigs, with negative results;
- (b) a serological examination of a statistical sample of the pigs without the detection of antibodies to swine vesicular disease in accordance with 7 (3) (b) (ii).

The examination referred to in (a) and (b) shall not take place until 28 days have elapsed since the possible contamination of the premises as the result of the movement of persons, animals, or vehicles, or in any other way.

- 3. Should the presence of swine vesicular disease be confirmed in a slaughterhouse, the competent authority shall ensure that:
 - (a) all pigs in the slaughterhouse are slaughtered without delay;
 - (b) the carcases and offal of infected and contaminated pigs are destroyed under official supervision in such a way as to avoid the risk of swine vesicular disease virus spreading;
 - (c) cleaning and disinfection of buildings and equipment, including vehicles, take place under the supervision of the official veterinarian, in accordance with instructions laid down by the competent authority;
 - (d) an epidemiological enquiry is carried out in accordance with Article 8 of the Directive;
 - (e) no pigs are re-introduced for slaughter until at least 24 hours after completion of the cleaning and disinfection operations carried out in accordance with (c).

10. Cleansing and disinfection of infected holdings

In addition to the measures laid down in Article 16 of this Directive, the following measures shall also apply:

- 1. Procedure for preliminary cleaning and disinfection
 - (a) As soon as the carcases of the pigs have been removed for disposal, those parts of the premises in which the pigs have been housed and any other parts of the premises which have been contaminated during slaughter should be sprayed with disinfectant, approved in compliance with Article 16, at the concentration appropriate for swine vesicular disease. The disinfectant used should remain on the surface for at least 24 hours.
 - (b) Any tissue or blood which may have been spilled during slaughter should be carefully collected and disposed of with the carcases (slaughter should always be carried out on an impervious surface).
- 2. Procedure for further cleaning and disinfection
 - (a) All manure, bedding, contaminated food, etc., should be removed from the buildings, stacked and sprayed with an approved disinfectant. Slurry should be treated by a method suitable for killing the virus.
 - (b) All portable fittings should be removed from the premises and cleansed and disinfected separately.
 - (c) Grease and other dirt should be removed from all surfaces by soaking with a degreasing agent and then washing with water under pressure.
 - (d) A further application of disinfectant should then be made by spraying all surfaces.
 - (e) Sealable rooms should be fumigated.
 - (f) Repairs to damaged floors, walls etc. should be agreed following inspection by an official veterinarian, and carried out immediately.
 - (g) Completed repairs should be inspected to ensure that they have been done satisfactorily.
 - (h) All parts of the premises which are completely free of combustible material may be heat-treated using a flame gun.

- (i) All surfaces should be sprayed with an alkaline disinfectant having a pH greater than 12,5 or any other approved disinfectant. The disinfectant should be washed off after 48 hours.
- 3. Procedure for final cleaning and disinfection

Treatment with flame gun or alkaline disinfectant (point 2 (h) or (i)) should be repeated after 14 days.

11. Restocking of infected holdings

In addition to the measures laid down in Article 5 (4) of this Directive, the following measures shall apply:

- 1. Restocking should not commence until four weeks after completion of the first full disinfection of the premises, i.e. step 3 of the cleaning and disinfection procedures.
- The re-introduction of pigs shall take account of the type of farming practised on the holding and must conform to one of the following procedures:
 - (a) in the case of outdoor pig holdings, restocking shall start with the introduction of a limited number of sentinel piglets which have been checked and found negative for the presence of antibodies against swine vesicular disease virus. The sentinel piglets shall be placed, in accordance with the requirements of the competent authority, throughout the infected holding and will be examined clinically 28 days after having been placed on the holding, and sampled for serological testing.

If none of the piglets shows clinical evidence of swine vesicular disease nor has developed antibodies against the virus of the disease, full restocking may take place;

- (b) for all other forms of rearing, the re-introduction of pigs shall take place either in accordance with the measures provided for in paragraph (a) or by full restocking, provided that:
 - all the pigs arrive within a period of eight days and come from holdings situated outside areas restricted as a result of swine vesicular disease, and are seronegative,
 - no pig may leave the holding for a period of 60 days after the arrival of the last pigs,
 - the repopulated herd is subjected to a clinical and serological examination in accordance with the requirements of the competent authority. That examination may be carried out at the earliest 28 days after the arrival of the last pigs.
- 12. By 1 October 1997 at the latest, the Commission shall submit to the Council a report drawn up on the basis of an opinion from the Scientific Veterinary Committee on developments in research and diagnosis procedures as well as technical and scientific developments regarding swine vesicular disease, together with any appropriate proposals in the light of that report's findings. The Council shall act on such proposals by a qualified majority not later than six months after their submission.

ANNEX III

COMMUNITY REFERENCE LABORATORIES FOR THE DISEASES CONCERNED

The functions and duties of the Community reference laboratories for the diseases concerned shall be:

- 1. to coordinate, in consultation with the Commission, the methods employed in the Member States for diagnosing the disease concerned, specifically by:
 - (a) typing, storing and supplying strains of the virus of the relevant disease for serological tests and the preparation of antisera;
 - (b) supplying standard sera and other reference reagents to the national reference laboratories in order to standardize the tests and reagents used in the Member States;
 - (c) building up and retaining a collection of virus strains and isolates of the relevant disease;
 - (d) organizing periodic comparative tests of diagnostic procedures at Community level;
 - (e) collecting and collating data and information on the methods of diagnosis used and the results of tests carried out in the Community;
 - (f) characterizing isolates of the virus of the relevant disease by the most up-to-date methods to allow greater understanding of the epizootiology of the disease;
 - (g) keeping abreast of developments in the surveillance, epizootiology and prevention of the relevant disease throughout the world;
 - (h) retaining expertise on the relevant disease virus and other pertinent viruses to enable rapid differential diagnosis;
 - (i) acquiring a thorough knowledge of the preparation and use of the products of veterinary immunology used to eradicate and control the relevant disease;
- 2. to assist actively in the diagnosis of outbreaks of the relevant disease in Member States by receiving virus isolates for confirmatory diagnosis, characterization and epizootiological studies;
- 3. to facilitate the training or retraining of experts in laboratory diagnosis with a view to the harmonization of diagnostic techniques throughout the Community.

ANNEX IV

MINIMUM CRITERIA FOR THE CONTINGENCY PLANS

Contingency plans shall meet at least the following criteria:

- 1. the establishment of a crisis centre on a national level, which shall coordinate all control measures in the Member State concerned;
- 2. a list shall be provided of local disease control centres with adequate facilities to coordinate the disease control measures at a local level;
- 3. detailed information shall be given on the staff involved in control measures, their skills and their responsibilities;
- 4. each local disease control centre must be able to contact rapidly persons/organizations which are directly or indirectly involved in an outbreak;
- 5. equipment and materials shall be available to carry out the disease control measures properly;
- 6. detailed instructions shall be provided on action to be taken on suspicion and confirmation of infection or contamination, including means of disposal of carcases;
- training programmes shall be established to maintain and develop skills in field and administrative procedures;
- 8. diagnostic laboratories must have facilities for post mortem examination, the necessary capacity for serology, histology, etc., and must maintain the skills for rapid diagnosis. Arrangements must be made for rapid transportation of samples;
- 9. details shall be provided of the quantity of vaccine against the disease in question estimated to be required in the event of recourse to emergency vaccination;
- provisions shall be made to ensure the legal powers necessary for the implementation of the contingency plans.

COUNCIL DIRECTIVE 92/120/EEC

of 17 December 1992

on the conditions for granting temporary and limited derogations from specific Community health rules on the production and marketing of certain products of animal origin

THE COUNCIL OF THE EUROPEAN COMMUNITIES,

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

Having regard to the proposal from the Commission (1),

Having regard to the opinion of the European Parliament (2),

Having regard to the opinion of the Economic and Social Committee (3),

Whereas products of animal origin are included on the list of products in Annex II to the Treaty; whereas their marketing provides an important source of income for the farming population;

Whereas to ensure rational development of the sector, increase productivity and progressively establish the conditions for a single market, health rules applying to production and marketing have been laid down at Community level;

Whereas the Community has adopted measures enabling veterinary checks to be abolished at the frontiers between Member States for the products concerned;

Whereas it is possible that, because of particular circumstances, some establishments will be unable to comply with all the specific rules laid down by 1 January 1993; whereas, in order to take account of local situations and prevent abrupt closures of establishments, arrangements should be made for temporary and limited derogations for establishments in operation before 1 January 1993;

Whereas the Commission has deemed it necessary to obtain the opinion of the Scientific Veterinary Committee for the grant of derogations from the principle of systematic examination for trichinae in pigmeat; whereas since this opinion is not yet available, it is appropriate to make provision for the retention of temporary derogations for pigmeat not intended for Member States carrying out systematic examination for trichinae in pigmeat;

Whereas these derogations must be strictly controlled to forestall any risk of abuse,

HAS ADOPTED THIS DIRECTIVE:

Article 1

- 1. Member States may, until 31 December 1995, authorize establishments manufacturing products of animal origin referred to in Article 2 (b) of Directive 77/99/EEC which, on the date on which this Directive is notified, have not been judged to comply with the requirements laid down by Directive 77/99/EEC for their approval, to derogate from some of the structural requirements laid down in Chapter I of Annex A and in Chapters II (A) and III of Annex C to that Directive provided that animal products from such establishments are still subject to the rules on checks laid down by Article 5 (2) of Directive 89/662/EEC.
- 2. Derogations as referred to in paragraph 1 may be granted only to establishments which have submitted an application for a derogation to the competent national authority. This application must be supplemented, at the request of the competent authority, by a work plan and programme indicating the period within which the establishment will be able to comply with the structural requirements referred to in paragraph 1.

Member States shall notify the Commission and the other Member States within the Standing Veterinary Committee of the establishments which comply with the requirements of that Directive as regards the products of animal origin referred to in Article 2 (b) of Directive 77/99/EEC. The notification must, for each individual establishment, specify the nature of the products manufactured.

3. Where financial assistance is requested from the Community, only requests in respect of projects complying with the requirements of Directive 77/99/EEC can be accepted.

Article 2

1. Member States may, until 31 December 1995, grant derogations from the structural requirements provided for in Chapter IV of Annex I to Directive 64/433/EEC (4) and in Chapter I (1) (a) of Annex B to Directive 77/99/EEC for low-capacity coldstores in which meat and other foodstuffs are stored only if they are packaged and from any obligation to approve such establishments.

⁽¹⁾ OJ No C 84, 2. 4. 1990, p. 100.

⁽²⁾ OJ No C 113, 7. 5. 1990, p. 205. (3) OJ No C 332, 31. 12. 1990, p. 62.

⁽⁴⁾ OJ N L 268, 24. 9. 1991, p. 71 (consolidated version).

2. The provisions concerning the output appearing in the first subparagraph of Article 13 (1) of Directive 64/433/EEC shall apply to the slaughterhouses referred to in Article 4A of the aforementioned Directive until 31 December 1994. Likewise, for cutting plants, the figure appearing in the first subparagraph of Article 4A point 2 of the said Directive shall be five tonnes per week for the same period.

Article 3

Member States may, pending the decision provided for in Article 6 (2) of Directive 64/433/EEC, derogate from the requirement in Article 6 (1) (a) of that Directive for fresh pigmeat intended for marketing in their territories and for that intended for any Member State having recourse to the same derogation.

Member States having recourse to this derogation shall inform the Commission and the other Member States within the Standing Veterinary Committee.

Article 4

Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with this Directive before 1 January 1993. They shall forthwith inform the Commission thereof.

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

Article 5

This Directive is addressed to the Member States.

Done at Brussels, 17 December 1992.

For the Council
The President
J. GUMMER