## Ι

(Information)

## COUNCIL

# Council Directive of 26 June 1964 on animal health problems affecting intra-Community trade in bovine animals and swine

## I

Council Directive No 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) and the amendments arising out of the acts set out below:

- 1. Directive No 66/600/EEC (OJ No 192, 27. 10. 1966, p. 3294/66);
- 2. Directive No 70/360/EEC (OJ No L 157, 18. 7. 1970, p. 40);
- 3. Directive No 71/285/EEC (OJ No L 179, 9. 8. 1971, p. 1);
- 4. Directive No 72/97/EEC (OJ No L 38, 12. 2. 1972, p. 95);
- 5. Directive No 72/445/EEC (OJ No L 298, 31. 12. 1972, p. 49);
- 6. Act of Accession (OJ, Special Edition, 27. 3. 1972, p. 14) and the Council Decision of the European Communities of 1. 1. 1973, p. 1;
- 7. Directive No 73/150/EEC (OJ No L 172, 5. 6. 1973, p. 18);
- 8. Directive No 75/379/EEC (OJ No L 172, 3. 7. 1975, p. 17);

are hereby coordinated.

This coordination is without legal status. Hence, the preamble has been omitted.

The numbers in brackets at certain Articles correspond to the above numbering and refer to the last amendment of the basic act.

## Π

As regards the implementation of Directive No 64/432/EEC, account has been taken of the following provisions of the Act of Accession:

#### 'Article 104

Directive No 64/432/EEC on veterinary health inspection questions in intra-Community trade in bovine animals and swine shall be applied account being taken of the following provisions:

1. Until 31 December 1977, the new Member States are authorized to retain, in compliance with the general rules of the EEC Treaty, their national rules on

imports of bovine animals and swine for breeding, store and slaughter with the exception, in the case of Denmark, of slaughter cattle.

Adjustments will be sought, within the framework of those national rules, to ensure the progressive development of trade; to this end, those rules will be examined by the Standing Veterinary Committee.

- 2. Until 31 December 1977, the Member States into which cattle are imported shall grant to the Member States from which cattle are exported the derogation provided for in Article 7 (1) (A) (a) of the Directive.
- 3. Until 31 December 1977, the new Member States are authorized to retain the methods applied in their territory for declaring a herd of cattle officially free of tuberculosis or brucellosis within the meaning of Article 2 of the Directive, subject to the application of the provisions of the Directive relating to the presence of animals vaccinated against brucellosis. The provisions relating to the tests laid down for animals traded within the Community shall continue to apply, subject to paragraphs 4 and 6.
- 4. Until 31 December 1977, exports of cattle from Ireland to the United Kingdom may be carried out:
  - (a) by way of derogation from the provisions of the Directive relating to brucellosis; however, the provisions relating to the test laid down for animals traded within the Community shall continue to apply to exports of uncastrated cattle;
  - (b) by way of derogation from the provisions of the Directive relating to tuberculosis, provided that, at the time of export, a declaration is made certifying that the exported animal comes from a herd declared officially free of tuberculosis according to the methods in force in Ireland;
  - (c) by way of derogation from the provisions of the Directive relating to the obligation to separate breeding and store cattle on the one hand and slaughter cattle on the other.
- 5. Until 31 December 1975, Denmark is authorized to use 'alttuberculin' by way of derogation from the provisions in Annex B to the Directive.
- 6. Until the implementation of the Community provisions concerning trade within the Member States, in respect of the matters governed by the Directive, Ireland and the United Kingdom are authorized to retain their national rules governing trade between Ireland and Northern Ireland.

The Member States concerned may take appropriate measures in order to limit this derogation exclusively to the trade referred to above.

## Article 106

Before the expiry of the time limits referred to in Articles 104 and 105, a review of the situation in the Community as a whole and in its various parts will be carried out in the light of developments in the veterinary field.

By 1 July 1976 at the latest, the Commission shall submit a report to the Council and, in so far as is necessary, appropriate proposals taking account of these developments.'

#### COUNCIL DIRECTIVE

#### of 26 June 1964

#### on animal health problems affecting intra-Community trade in bovine animals and swine

#### (64/432/EEC)

## Article 1

This Directive shall apply to intra-Community trade in bovine animals and swine for breeding, production or slaughter.

## Article 2 (1) (3)

For the purposes of this Directive:

- (a) Holding: means an agricultural establishment or officially supervised dealer's premises situated in the territory of a Member State, in which animals for breeding, production or slaughter are regularly kept or bred;
- (b) Animal for slaughter: means a bovine animal or swine intended to be taken on arrival in the country of destination direct to a slaughterhouse or market;
- (c) Animals for breeding or production: means bovine animals and swine other than those referred to in (b), including those intended for breeding, milk or meat production, or draft purposes;
- (d) Officially tuberculosis-free bovine herd: means a bovine herd which satisfies the conditions laid down in Annex A (1);
- (e) Officially brucellosis-free bovine herd: means a bovine herd which satisfies the conditions laid down in Annex A (II) (A) (1);
- (f) Brucellosis-free bovine herd: means a bovine herd which satisfies the conditions laid down in Annex A (II) (A) (2);
- (g) Brucellosis-free swine: means swine which satisfy the conditions laid down in Annex A (II) (B) (1);
- (h) Officially brucellosis-free swine herd: means a swine herd which satisfies the conditions laid down in Annex A (II) (B) (2);
- (i) *Epizootic free area:* means an area 20 km in diameter in which, according to official findings, for at least 30 days prior to loading there has been:
  - (i) no incidence of foot-and-mouth disease, in the case of bovine animals;

- (ii) no incidence of foot-and-mouth disease, swine fever or contagious swine paralysis (Teschen disease) in the case of swine;
- (k) Compulsorily notifiable diseases: means the diseases listed in Annex E;
- (l) Official veterinarian: means the veterinarian designated by the competent central authority of the Member State;
- (m) *Exporting country:* means the Member State from which bovine animals and swine are sent to another Member State;
- (n) Country of destination: means the Member State to which bovine animals and swine are sent from another Member State.

## Article 3 (1) (3)

1. Each Member State shall ensure that only bovine animals and swine which fulfil the general conditions laid down in paragraph 2, account being taken where appropriate of the provisions of paragraph 7, and also the special conditions fixed for certain categories of bovine animals and swine in paragraphs 2 to 6, are sent from its territory to that of another Member State.

2. Bovine animals and swine covered by this Directive must:

- (a) show no clinical sign of disease on the day of loading;
- (b) not have been obtained either from a holding which for health reasons is subject to prohibition as a result of the outbreak of the following diseases to which the animals in question are susceptible: foot-and-mouth disease, swine fever, contagious swine paralysis, bovine brucellosis, swine brucellosis or anthrax, or from an area in which the measures referred to under (ii) are applied, it being understood that:
  - (i) if all the animals of species susceptible to the disease have not been slaughtered and the premises disinfected, the period of prohibition must be at least 30 days from the

date of the last recorded case in the case of foot-and-mouth disease, at least 40 days in the case of swine fever or contagious swine paralysis, at least six weeks in the case of bovine or swine brucellosis and at least 15 days in the case of anthrax;

(ii) in cases of swine fever, foot-and-mouth disease or contagious swine paralysis: if all the animals of species susceptible to the infection have been slaughtered and the premises disinfected, a protective area with a radius of 2 km shall be established around the holding for a period of 15 days; if all the animals of species susceptible to the infection have not been slaughtered, a protective area with a radius of 2 km shall be established around the holding and maintained for as long as the latter is subject to prohibition measures.

Member States shall ensure that animals of species susceptible to the disease recorded in the protective area can leave that area only if they are being taken to a slaughterhouse under official control for immediate slaughter;

- (c) in the case of animals for breeding or production, have been obtained from a holding which officially fulfils the following conditions:
  - (i) it shall be situated in the centre of an epizootic free area;
  - (ii) it shall, for at least three months prior to consignment, have been free from foot-and-mouth disease and bovine brucellosis in the case of bovine animals and from foot-and-mouth disease, bovine and porcine brucellosis, swine fever and contagious porcine paralysis (Teschen disease) in the case of swine;
  - (iii) it shall, for at least 30 days prior to consignment, have been free from all other compulsorily notifiable diseases which are contagious or infectious for the animal species in question;
- (d) in the case of animals for breeding and production, have remained on the holding referred to in 2 (c) during the 30 days preceding loading or since birth. The official veterinarian may certify that the animals have remained on the holding during the 30 days preceding loading or since birth, in the case of animals identified in the manner provided in subparagraph (e) and placed under official veterinary supervision, it being thus possible to certify that they belong to the holding;
- (e) be identified by an official or officially approved mark or, in the case of swine, by a permanent identification stamp;

- (f) be sent direct from the holding to the actual place of loading:
  - (i) without coming into contact with cloven-hoofed animals other than bovine animals and swine which fulfil the conditions laid down for intra-Community trade;
  - (ii) segregated into animals for breeding or production and animals for slaughter;
  - (iii) in transport vehicles or containers which have first been cleansed and disinfected with a disinfectant officially authorized in the exporting country;
- (g) be loaded for transportation to the country of destination in accordance with the conditions set out in subparagraph (f) at a specific place at the centre of an epizootic free area; transport vehicles must be so arranged that the animals' faeces, litter or fodder cannot flow or fall out of the vehicle during transportation;
- (h) after loading be sent direct and as quickly as possible to the frontier post of the exporting country;
- (i) be accompanied during transportation to the country of destination by a health certificate conforming to Annex F (Models I to IV) which shall be drawn up on the day of loading, in the language of the country of destination at least, and be valid for 10 days. The certificate shall consist of a single sheet.

3. Bovine animals for breeding or production must moreover:

- (a) in the case of animals more than four months old, have been vaccinated at least 15 days and not more than four months before loading against types A, O and C of the foot-and-mouth disease virus using an inactivated virus vaccine approved and controlled by the competent authority of the exporting country;
- (b) come from an officially tuberculosis-free bovine herd and in particular, in the case of animals more than six weeks old, have reacted negatively to an intradermal tuberculin test carried out during the 30 days before loading and in accordance with the provisions of Annex B;
- (c) come from an officially brucellosis-free bovine herd and in particular, in the case of animals more than 12 months old, have shown a brucella count lower than 30 international units of agglutination per millilitre when given a sero-agglutination test carried out during the 30 days before loading and complying with the provisions of Annex C;

(d) in the case of dairy cows, show no clinical evidence of mastitis; in addition, upon analysis complying with the provisions of Annex D their milk must not have shown any sign of a characteristic inflammatory condition or of a specifically pathogenic micro-organism.

4. Swine for breeding or production must moreover come from brucellosis-free stock. If the swine concerned weigh more than 25 kilogrammes they must have shown, in tests carried out during the 30 days before loading

- (i) a brucella count lower than 30 international units
   (IU) of agglutination per ml when given a sero-agglutination test in accordance with the provisions of Annex C;
- (ii) a negative complement fixation reaction when given a serological examination in accordance with the provisions of Annex C.

5. Animals must not moreover be bovine animals or swine which are to be slaughtered under a contagious or infectious disease eradication programme of a Member State.

6. Bovine animals for slaughter, if over four months old, must in addition:

- (a) have been vaccinated not less than 15 days and not more than four months before loading against types A, O and C of the foot-and-mouth disease virus, using an inactivated virus vaccine approved and controlled by the competent authority of the exporting country; however, the period of validity of the vaccination shall be extended to 12 months in the case of bovine animals revaccinated in Member States where such animals are vaccinated annually and where they are systematically slaughtered when they contract foot-and-mouth disease;
- (b) if they do not come from an officially tuberculosis-free bovine herd, have reacted negatively to an intradermal tuberculin test carried out during the 30 days before loading and in accordance with the provisions of Annex B;
- (c) if they do not come from an officially brucellosis-free bovine herd nor from a brucellosis-free bovine herd, have shown a brucella count lower than 30 IU of agglutination per ml when given a sero-agglutination test carried out during the 30 days before loading and complying with the provisions of Annex C.

7. The following shall also be approved for intra-Community trade: animals for breeding or production or animals for slaughter acquired on an

officially approved market for consignment to another Member State, provided such market fulfils the following conditions:

- (a) it is supervised by an official veterinarian;
- (b) it is situated in the centre of an epizootic free area;
- (c) it is used after disinfection either for animals for breeding or production or for animals for slaughter which meet the requirements of intra-Community trade as laid down in paragraphs 2 to 6 and in Article 4, provided these conditions apply to the animal species in question. The provisions of paragraph 2 (f) must in particular have been complied with when the animals were sent to market. However, the intradermal tuberculin test and the sero-agglutination test required under paragraph 3 (b) and (c) need not necessarily have been carried out before introduction on the market. Before being taken from the holding or market meeting the requirements of this paragraph to the place of loading, these animals may, provided the provisions of Article 2 (f) are respected, be taken to an officially supervised assembly point if the latter satisfies the conditions fixed for markets.

Animals acquired on such markets must be sent direct from the market or the assembly point to the actual place of loading in such manner that the provisions of paragraph 2 (f) and (h) are satisfied, and be exported to the country of destination.

The period during which the assembling of these animals takes place outside the holding of origin, in particular at the market, assembly point or actual place of loading may be counted in the 30 days prescribed in paragraph 2 (d) but shall not exceed six days.

8. The exporting country shall designate those markets referred to in paragraph 7 which are approved for animals for breeding or production and for animals for slaughter. It shall notify the competent central authorities of the other Member States and the Commission as to which markets are approved.

9. The exporting country shall determine the procedure for official supervision of the markets and assembly points referred to in paragraph 7 and shall ensure that this supervision is carried out.

10. In the case provided for in paragraph 7, corresponding entries must be made on the health

certificates, in accordance with Annex F (Models I to IV).

11. The exporting country shall determine the procedure for official supervision of dealers' premises and shall ensure that this supervision is carried out.

12. If a holding or the area in which it is situated is the subject of official restrictions following the outbreak of a disease which is contagious or infectious for the animal species in question, the time limits set in paragraph 2 (c) (ii) and (iii) and Article 2 (i) shall take effect from the date on which these prohibition restrictions were officially lifted.

## Article 4

1. All animals intended for intra-Community trade must have remained in the territory of the exporting Member State before the day of loading:

- (a) for not less than six months in the case of animals for breeding or production;
- (b) for not less than three months in the case of animals for slaughter.

If such animals are respectively less than six or three months old they must have remained in the territory of the exporting Member State since birth.

2. In all cases to which paragraph 1 applies, appropriate entries must be made in the health certificates, as required by Annex F (Models I to IV).

#### Article 5 (3)

If the vaccines referred to in Article 3 (3) (a) and (6) (a) are not manufactured in a Member State, they shall be obtained from another Member State, except where new scientific data or the absence of vaccines which up to that time have been considered suitable makes it necessary to obtain vaccines from outside the European Economic Community. In the event of outbreaks of foot-and-mouth disease other than types A, O and C or variants of these types, against which the vaccines currently used afford inadequate protection or none at all, each Member State may take the necessary emergency measures to adapt the vaccine formulae and to use them accordingly. At the same time it shall inform the other Member States and the Commission thereof. If it proves necessary to adopt Community measures these shall be decided upon in the light of the national measures referred to above in accordance with the procedure laid down in Article 13.

#### Article 6(1)

1. Each Member State shall communicate to the other Member States and the Commission the list of frontier posts to be used for the introduction of bovine animals and swine into its territory.

Subject to observance of the provisions relating to animal health, marketing channels and all means of transport available for use shall be taken into account in determining which frontier posts are to be used.

2. Each country of destination may require the consignor or his representative to notify it in advance of the entry into its territory of a consignment of bovine animals or swine, and of the type, nature and number of animals, the frontier post and the anticipated time of arrival. It may not, however, require this notification to be made more than 48 hours before the arrival of the consignment in its territory.

3. Each country of destination may prohibit the introduction of bovine animals and swine into its territory if an examination made at the frontier post by an official veterinarian reveals:

- (a) that the animals are affected by, or suspected of being affected by, or of being contaminated by a contagious or infectious disease;
- (b) that the provisions of Articles 3 and 4 have not been observed as regards these animals.

The country of destination may take the necessary measures, including quarantine, to ascertain the position as regards animals suspected of being affected by or of being contaminated by a contagious or infectious disease or which might spread such disease.

Decisions taken under the first or second sentence must, at the request of the consignor or his representative, authorize the return of the animals, provided this is not contrary to considerations of health.

4. If the introduction of animals has been prohibited on any of the grounds set out in paragraph 3 (a) and the exporting country or the transit country, as the case may be, does not within eight hours authorize the return of them, the competent authority of the country of destination may order the animals to be slaughtered or destroyed.

5. Animals for slaughter which have been taken on arrival in the country of destination direct to a

slaughterhouse must be slaughtered there, as considerations of animal health require, as soon as possible. Animals for slaughter which have been sent direct on arrival in the country of destination to a market adjoining a slaughterhouse under whose rules all animals may be removed, in particular after the market, only to a slaughterhouse approved for this purpose by the competent central authority must be slaughtered at that slaughterhouse not later than 72 hours after arriving at the market.

By way of derogation from the above provision and in specific cases Member States of destination may allow animals for slaughter to be sent to a market which does not adjoin a slaughterhouse.

The competent authority of the country of destination may in the light of considerations of animal health designate the slaughterhouse to which these animals must be sent.

6. If, after the introduction into the territory of the country of destination of animals for breeding or production, facts come to light which would have justified the application of the first sentence of paragraph 3, the competent central authority of the exporting country must, at the request of the competent central authority of the country of destination, make the necessary investigations and notify that authority without delay of the outcome of such investigations.

7. The decisions taken by the competent authority under paragraphs 3 to 5 must be communicated to the consignor or his representative, together with the reasons for such decisions. These reasoned decisions must on request, be communicated to him forthwith in writing with an indication of what appeals against them are open under current legislation and the form and time in which they must be commenced. The decisions must also be communicated to the competent central authority of the exporting country.

## Article 7 (3) (4)

1. Countries of destination may grant to one or more exporting country general authorizations or authorizations restricted to specific cases for the introduction into their territory of:

- A. In the case of bovine animals for breeding, production or slaughter:
  - (a) those animals which, by way of derogation from Article 3 (3) (a) or (6) (a), have not been vaccinated against foot-and-mouth disease, if no case of foot-and-mouth disease has been officially recorded in the exporting country

and in the transit countries concerned for at least six months from the date of loading;

- (b) those animals which, by way of derogation from Article 3 (3) (a) or (6) (a), have received anti-foot-and-mouth disease serum treatment not more than ten days before loading with anti-foot-and-mouth disease serum approved and controlled by the competent authority of the exporting country and authorized by the competent authority of the country of destination.
- B. In the case of bovine animals for breeding or production:
  - (a) those animals which, by way of derogation from Article 3 (3) (a), have been revaccinated during the preceding twelve months against types A, O and C of the foot-and-mouth disease virus, if they come from Member States in which such animals are vaccinated yearly and systematically slaughtered if there is an outbreak of foot-and-mouth disease and in which no case of foot-and-mouth disease has been officially recorded for at least six months from the date of loading;
  - (b) those animals which, by way of derogation from Article 3 (3) (c), come from a brucellosis-free herd.
- C. In the case of bovine animals for meat production: those animals under 30 months old which, by way of derogation from Article 3 (3) (c), do not come from an officially brucellosis-free or brucellosisfree herd. However, these animals must have shown a brucella count of less than 30 IU of when agglutination per ml given а sero-agglutination test carried out during the 30 days before loading and in accordance with the provisions of Annex C. They must bear a special identification mark. The Member State of destination shall take all necessary measures to prevent contamination of indigenous herds.

This provision shall apply until 31 December 1977, unless otherwise decided by the Council acting by a qualified majority on a proposal from the Commission.

D. In the case of bovine animals for slaughter: those animals which, by way of derogation from Article 3 (6) (c), showed a brucella count equal to or higher than 30 IU of agglutination per ml when given a sero-agglutination test in accordance with the provisions of Annex C.

2. When a country of destination grants a general authorization under paragraph 1, it shall forthwith inform the other Member States and the Commission thereof.

3. When a country of destination grants any authorization under paragraph 1, a corresponding authorization must, in the case of transit operations, be obtained from the transit countries concerned.

4. The exporting countries shall take all measures neccessary to ensure that the health certificates, specimens of which are given in Annex F (Models I and II), mention that use has been made of one of the possibilities provided in paragraph 1.

## Article 8 (1) (3)

1. Until the entry into force of such provisions as may be adopted by the European Economic Community, this Directive shall not affect the provisions of Member States relating to:

- (a) bovine animals and swine which have been treated with antibiotics, oestrogens or thyreostatics;
- (b) the introduction into their territory for show purposes of animals for breeding or production, or of bulls for breeding for artificial insemination centres, provided that such provisions apply also to trade in such animals within the Member State and without prejudice to the provisions of this Directive relating to such animals;
- (c) bovine animals for breeding or production less than 15 days old.

2. Pending the entry into force of any provisions adopted by the European Economic Community, a Member State may be authorized, under the procedure laid down in Article 12 and the conditions fixed under that procedure, to apply, for intra-Community trade, health guarantees equivalent at most to those required by that Member State within the framework of a national programme for the prevention of a contagious or infectious bovine or swine disease which is not referred to in Annex E of this Directive.

## Article 9 (3)

1. A Member State may, if there is a danger of animal diseases spreading as a result of the introduction of bovine animals or swine into its territory from another Member State, take the following measures:

 (a) in the event of an outbreak of an epizootic disease in the other Member State, temporarily prohibit or restrict the introduction of bovine animals or swine from the affected areas of that Member State; (b) if an epizootic disease becomes widespread or if there is an outbreak of a new serious contagious or infectious animal disease, temporarily prohibit or restrict the introduction of bovine animals or swine from the entire territory of that State.

2. Each Member State must immediately inform the other Member States and the Commission of the outbreak on its territory of any disease referred to in paragraph 1, and of the measures taken to control it. It must also notify them immediately of the elimination of the disease.

3. Measures taken by the Member States under paragraph 1 and the repeal of such measures must be communicated immediately to the other Member States and the Commission together with the reasons therefor.

Under the procedure laid down in Article 13, a decision may be taken to repeal or amend those measures in particular in order to coordinate them with measures adopted by other Member States.

4. If the situation envisaged in paragraph 1 arises and if it appears necessary that other Member States also apply the measures taken under that paragraph, amended, where necessary, pursuant to paragraph 3, appropriate measures shall be adopted under the procedure laid down in Article 13.

#### Article 10

1. Rights of appeal existing under current legislation in the Member States against decisions taken pursuant to this Directive by the competent authorities shall not be affected by this Directive.

2. Each Member State shall grant to consignors in respect of whose bovine animals and swine such measures as are provided for in Article 6 (3) have been taken, the right to obtain, before other measures are taken by the competent authority other than the slaughter or destruction of animals if essential for considerations of animal or public health, the opinion of a veterinary expert to determine whether the conditions of Article 6 (3) have been fulfilled.

The veterinary expert must be a national of a Member State other than the exporting country or country of destination.

The Commission, acting on a proposal from the Member States, shall draw up a panel of veterinary experts who may be instructed to formulate such opinions. After consulting the Member States it shall lay down general rules which are to be applied, in particular as regards the procedure for formulation of these opinions.

#### Article 11

If the Community provisions relating to importation of bovine animals and swine from third countries do not apply at the time when this Directive enters into force, or pending their becoming applicable, national provisions relating to bovine animals and swine imported from those countries shall not be more favourable than those governing intra-Community trade.

#### Article 12 (3) (6)

1. Where the procedure laid down in this Article is to be used, matters shall without delay be referred by the Chairman, either on his own initiative or at the request of a Member State, to the Standing Veterinary Committee (hereinafter called the 'Committee') set up by the Council Decision of 15 October 1968.

2. Within the Committee the votes of Member States shall be weighted as provided 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 such measures within a time limit set by the Chairman according to the urgency of the matters concerned. Opinions shall be delivered by a majority of 41 votes.

4. The Commission shall adopt the measures and shall apply them immediately where they are in accordance with the opinion of the Committee. Where they are not in accordance with the opinion of the Committee or if no opinion is delivered, the Commission shall without delay propose to the Council the measures to be adopted.

The Council shall adopt the measures by a qualified majority.

If, within three months from the date on which the proposal was submitted to it, the Council has not adopted any measures, the Commission shall adopt the proposed measures and apply them immediately, save where the Council has decided by a simple majority against those measures.

#### Article 13 (3) (6)

1. Where the procedure laid down in this Article is to be used, matters shall without delay be referred by the Chairman, either on his own initiative or at the request of a Member State, to the Standing Veterinary Committee (hereinafter called the 'Commitee') set up by the Council Decision of 15 October 1968.

2. Within the Committee the votes of the Member States shall be weighted as provided 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 such measures within two days. Opinions shall be delivered by a majority of 41 votes.

4. The Commission shall adopt the measures and shall apply them immediately where they are in accordance with the opinion of the Committee. Where they are not in accordance with the opinion of the Committee or if no opinion is delivered, the Commission shall without delay propose to the Council the measures to be adopted. The Council shall adopt the measures by a qualified majority.

If within 15 days from the date on which the proposal was submitted to it, the Council has not adopted any measures, the Commission shall adopt the proposed measures and apply them immediately, save where the Council has decided by a simple majority against those measures.

## Article 14 (3) (8)

The provisions of Articles 12 and 13 shall apply for 102 months from the date on which a matter was first referred to the Committee either under Article 12 (1) or 13 (1) or under any corresponding rules.

#### Article 15 (3)

The Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with this Directive and its Annexes within 12 months following its notification and shall forthwith inform the Commission thereof.

## Article 16 (3)

This Directive is addressed to the Member States.

## ANNEX A (1) (3)

#### I. TUBERCULOSIS-FREE BOVINE HERD

A bovine herd is considered to be officially tuberculosis-free if:

- (a) all the animals are free from clinical signs of tuberculosis;
- (b) all the animals over six weeks old have reacted negatively to at least two official intradermal tuberculin tests carried out in accordance with Annex B, the first one six months after completion of disinfection of the herd, the second one six months later and the remainder at one-yearly intervals. Where in a Member State all of whose bovine herds are subject to official operations to combat tuberculosis, the percentage of bovine herds infected with tuberculosis is not more than 1 % during two successive supervisory periods separated by an interval of one year, that interval may be increased to two years. If the percentage of infected bovine herds is not more than 0.2 % during two successive supervisory periods separated by an interval of two years, that interval may be increased to three years;
- (c) no bovine animal has been introduced without a certificate from an official veterinarian showing that the animal comes from an officially tuberculosis-free bovine herd and, in the case of animals over six weeks old, that it has reacted negatively to an intradermal tuberculin test assessed according to the criteria set out in Annex B 21 (a);
  - (i) intradermal tuberculin testing shall not, however, be required in Member States in which the percentage of bovine herds infected with tuberculosis is less than 0.2 % and where a certificate from the official veterinarian indicates that the animal:
    - 1. is properly identified;
    - 2. comes from an officially tuberculosis-free bovine herd within that Member State;
    - 3. has not during transportation come into contact with bovine animals which do not come from officially tuberculosis-free bovine herds.
  - (ii) the certificate provided for in (i) need not be required in a Member State where for not less than four years:
    - at least 99.80 % of the bovine herds have been officially recognized as being tuberculosis-free, and where
    - herds which are not officially tuberculosis-free have been under official supervision, the transfer of bovine animals from those herds being prohibited except when they are taken under official supervision for slaughter.

#### II. BRUCELLOSIS-FREE SWINE AND BRUCELLOSIS-FREE BOVINE AND SWINE HERDS

#### A. Bovine herds

- 1. A bovine herd is considered to be officially brucellosis-free if:
  - (a) it contains no bovine animals which have been vaccinated against brucellosis, save females which have been vaccinated at least three years previously;
  - (b) all the bovine animals have been free from clinical signs of brucellosis for at least six months;
  - (c) all the bovine animals over 12 months old:
    - (i) have shown a brucella count lower than 30 IU of agglutination per ml when given two official sero-agglutination tests at intervals of at least three months and at most 12 months complying with Annex C; the first sero-agglutination test may be replaced by three ring-tests carried out at three-monthly intervals provided,

however, that the second sero-agglutination test is carried out not less than six weeks after the third ring-test;

(ii) are checked annually to establish that brucellosis is not present by three ring-tests carried out at intervals of at least three months or two ring-tests at an interval of at least three months and one sero-agglutination test carried out not less than six weeks after the second ring-test. If ring-tests cannot be made, two sero-agglutination tests shall be carried out each year at an interval of at least three months and not more than six months.

Where, in a Member State whose bovine herds are subject to official operations to combat brucellosis, the percentage of bovine herds infected is not more than 1%, it will be sufficient to carry out each year two ring-tests at an interval of at least three months or, if they cannot be made, one sero-agglutination test;

- (d) no bovine animal has been introduced without a certificate from an official veterinarian showing that the animal comes from an officially brucellosis-free bovine herd and, in the case of animals over 12 months old, that it has shown a brucella count of less than 30 IU of agglutination per ml when given a sero-agglutination test in accordance with Annex C during the 30 days before it was taken into the herd:
  - (i) sero-agglutination testing need not, however, be required in Member States where the percentage of bovine herds infected with brucellosis has not exceeded 0.2 % for at least two years and where a certificate from an official veterinarian indicates that the animal:
    - 1. is properly identified;
    - 2. comes from an official brucellosis-free bovine herd within that Member State;
    - 3. has not during transportation come into contact with bovine animals which do not come from officially brucellosis-free bovine herds;
  - (ii) the certificate provided for in (i) need not be required in a Member State where for not less than four years:
    - at least 99.80 % of the bovine herds have been officially recognized as being brucellosis-free, and where
    - herds which are not officially brucellosis-free have been under official supervision, the transfer of bovine animals from those herds being prohibited except when they are taken under official supervision for slaughter.
- 2. A bovine herd is considered to be brucellosis-free if:
  - (a) it contains no male bovine animals which have been vaccinated against brucellosis;
  - (b) all or some of the female bovine animals have been vaccinated at not more than six months old with live Buck 19 vaccine or other vaccines approved under the procedure laid down in Article 12;
  - (c) all the bovine animals satisfy the conditions laid down in 1 (b) and (c), it being understood that the bovine animals which are under 30 months old may show a brucella count equal to or higher than 30 IU of agglutination per ml but lower than 80 IU of agglutination per ml provided they show, when the complement fixation reaction is tested:
    - a count lower than 30 EEC units, in the case of females vaccinated less than 12 months previously,
    - a count lower than 20 EEC units in all other cases;
  - (d) no bovine animal has been introduced without a certificate from an official veterinarian showing either that the conditions laid down in 1 (d) apply to it or that it comes from a bovine herd recognized as brucellosis-free and, in that case, if it is over 12 months old, that it has shown in the 30 days before it was taken into the herd in accordance with Annex C a count lower than 30 IU of agglutination per ml and a negative complement fixation reaction.

However, if the bovine animal concerned has been vaccinated and is under 30 months old, it may show a brucella count equal to or higher than 30 IU of agglutination per ml but less than 80 IU per ml, provided it shows, when the complement fixation reaction is tested:

- a count lower than 30 EEC units, in the case of a female vaccinated less than 12 months previously,

- a count lower than 20 EEC units after the twelfth month following vaccination.

- 3. A brucellosis-free bovine herd may qualify as an officially brucellosis-free bovine herd after a minimum period of three years if:
  - (a) it contains no animal which has been vaccinated against brucellosis within the preceding three years;
  - (b) the conditions laid down in 2 (c) have been fulfilled without interruption during those three years;
  - (c) at the end of the third year, the animals over 12 months old have shown a brucella count lower than 30 IU of agglutination per ml when given a sero-agglutination test and a negative result when given a complement fixation reaction test, these tests being carried out in accordance with Annex C.
- 4. Bovine animals from a brucellosis-free bovine herd may also be introduced into an officially recognized brucellosis-free bovine herd if:
  - they are at least 18 months old at the time they are introduced therein;
  - if they have been vaccinated against brucellosis, the vaccination was effected more than a year previously;
  - during the 30 days before introduction they have shown, in accordance with Annex C, a brucella count lower than 30 IU of agglutination per ml and a negative result when given a complement fixation reaction test.

If, in accordance with the first subparagraph, a bovine animal is introduced into an officially recognized brucellosis-free bovine herd for intra-Community trade, that herd shall be considered to be brucellosis-free for two years from the date on which the animal was introduced.

5. If one or more bovine animals in an officially brucellosis-free herd are suspected of having brucellosis, the qualification of the herd may be provisionally suspended, rather than withdrawn, if the animal or animals are immediately destroyed or isolated.

The provisional suspension may be lifted if two sero-agglutination tests, carried out in accordance with Annex C at an interval of six to eight weeks on all the animals over 12 months old, show a count lower than 30 IU of agglutination per ml.

The isolated animals may be reintroduced into the herd if, in the six to eight weeks interval, two sero-agglutination tests have shown a count lower than 30 IU of agglutination per ml and two complement fixation reaction tests have given a negative result, these tests being carried out in accordance with Annex C.

The foregoing provisions also apply to brucellosis-free herds in cases where one or more bovine animals over 30 months old are suspected of the disease.

6. The foregoing provisions relating to a brucellosis-free herd also apply to animals which, before the date of implementation of the provisions of this Directive in each Member State, have been vaccinated between the ages of five and eight months.

#### B. Swine and swine herds

- 1. A swine is considered to be brucellosis-free if:
  - (a) it shows no clinical signs of that disease;
  - (b) weighing more than 25 kg, it shows during serological tests carried out simultaneously and in accordance with Annex C:
    - (i) a brucella count lower than 30 IU of agglutination per ml when given a sero-agglutination test;
    - (ii) a negative result when given a complement fixation reaction test.
- 2. A swine herd is considered to be brucellosis-free if:
  - (a) all the swine have been free from clinical signs of the disease for at least one year;
  - (b) bovine animals kept at the same time on the holding belong to an officially brucellosis-free or brucellosis-free herd.

#### ANNEX B (5)

#### STANDARDS FOR THE MANUFACTURE AND USE OF TUBERCULINS

- 1. Officially supervised tuberculin tests must be carried out with PPD (bovine) tuberculin or a tuberculin prepared on a synthetic medium and heat-concentrated.
- 2. For the control of PPD tuberculin, a standard tuberculin conforming to the international PPD standard of the Statens Seruminstitut in Copenhagen must be used.

Such standard tuberculin must be that supplied by the Centraal Diergeneeskundig Instituut, Afdeling Rotterdam.

- 3. For the control of tuberculins known as 'synthetic' tuberculins, a standard tuberculin conforming with the international standard for old tuberculin of the Staatens Seruminstitut in Copenhagen must be used.
  - Such standard tuberculin must be that supplied by the Paul-Ehrlich-Institut in Frankfurt-am-Main.
- 4. Tuberculins must be prepared with one of the BK stocks of the bovine type indicated below:

(a) An<sub>5</sub>;

- (b) Vallee;
- (c) Behring.
- 5. The pH of tuberculins must be between 6.5 and 7.
- 6. Only phenol with a concentration of 0.5 % may be used as a preservative in tuberculins.
- 7. Provided that tuberculins are preserved at a temperature of about 4 °C, they may be used up to the end of the following periods:
  - (a) liquid PPD tuberculins: six months, lyophilized PPD tuberculins: five years;

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(b) tuberculins known as 'synthetic':

non-diluted: five years,

diluted: two years.

8. The state institutes listed below must be made responsible for the official testing of tuberculins in their respective countries:

(a) Germany:	Paul-Ehrlich-Institut, Frankfurt-am-Main;
(b) Belgium:	Institut national de recherches vétérinaires, Brussels;
(c) France:	Laboratoire central de recherches vétérinaires, Alfort;
(d) Grand Duchy of Luxembourg	Institute of the supplying country;
(e) Italy:	Istituto Superiore di Sanità, Rome;
(f) Netherlands:	Centraal Diergeneeskundig Instituut, Afdeling Rotterdam;
(g) Denmark:	Statens Veterinaere Serumlaboratorium, Copenhagen V;
(h) Ireland:	The Central Veterinary Laboratory, Weybridge, Surrey, England;
(i) United Kingdom:	The Central Veterinary Laboratory, Weybridge, Surrey, England.

- 9. Official testing must be carried out either of bottled tuberculins ready for use, or of a complete consignment of tuberculin before packaging provided it is subsequently bottled in the presence of a representative of the competent authority.
- 10. PPD tuberculin must be tested by biological methods and by the clinical method.

11. Tuberculins must be sterile.

- 12. An innocuity test of the tuberculin, to establish its non-toxicity and the absence of irritant properties, must be carried out as follows:
  - (a) Non-toxicity

Tests must be carried out on mice and guinea-pigs.

Mice

٤,

Injection of 0.5 ml of tuberculin under the skin of two mice weighing 16 to 20 g each. If, within two hours, there are no clear signs of intoxication it may be concluded that the product does not contain excessive phenol.

#### Guinea-pigs

The guinea-pigs must weigh between 350 and 500 g. The amount of tuberculin to be injected must be 1 ml per 100 g live weight. One of the two methods described below must be used:

(aa) Tuberculin is injected into the abdominal skin of two guinea-pigs. The tuberculin may be considered to be satisfactory if the guinea-pigs treated in this way show, for not more than two days, a strong infiltration which is reabsorbed from the third day without having produced necrosis and is no longer visible after six days. If there is necrosis of the abdominal skin, or if the infiltration does not disappear within six days, the tuberculin shall be rejected.

- (bb) The tuberculin is injected intraperitoneally into two guinea-pigs. The animals are observed for six weeks during which there must be no specific symptom or loss of weight. At the end of six weeks the animals are killed and a check made that there is no tubercular lesion; in particular, histological incisions are made in the spleen, liver and lungs. The same procedure is followed for any animal which dies before the end of the time limit.
- (b) Absence of irritant properties

An intradermal inoculation of 2 500 IU of tuberculin in a volume of 0.1 ml is made in the depilated skin of the flank of two guinea-pigs. There must be no reaction after 40 hours.

- 13. Tuberculins must be chemically analysed in order to determine the exact amount of phenol and to establish whether any other preservative is present.
- 14. A test of non-sensitization to tuberculin must be carried out as follows:

Three guinea-pigs which have never been used for scientific tests are given, at five day intervals, three intradermal injections of 500 IU of tuberculin in a volume of 0.1 ml. The guinea-pigs are tested 15 days later by an intradermal injection of the same amount of tuberculin. They must not show a reaction different from that of guinea-pigs of the same weight which have never been used for scientific tests carried out for control purposes with the same amount of tuberculin.

- 15. An activity test must be carried out by the chemical method and by biological methods.
  - (a) Chemical method:

This method can be used for PPD and is based on the precipitation of tuberculo-protein by trichloracetic acid. The nitrogen content is determined by Kjedahl distillation. The conversion factor of the total nitrogen PPD is 6.25.

(b) Biological methods:

These methods can be used for tuberculins prepared on a synthetic medium and for PPD; they are based on the comparison with standard tuberculins of the tuberculins to be tested.

- 16. The international standard for old tuberculin contains 100 000 IU of agglutination per ml.
- 17. The international PPD standard is delivered in the lyophilized state, one IU = 0.00002 mg of tuberculo-protein. The ampoule contains 2 mg of tuberculo-protein.

Tuberculins submitted by manufacturers for testing by the state institutes listed in paragraph 8 must have the same activity as standard tuberculins, i.e. they must contain 100 000 IU per ml.

#### 18. (a) Potency testing on guinea pigs

Albino guinea-pigs weighing between 400 and 600 g must be used. These guinea-pigs must be in good health and checked by palpation to determine whether, at the time of the tuberculin inoculation, their muscular tone has remained normal in spite of prior sensitization.

(aa) Guinea-pigs shall be sensitized by innoculation injection of about 0.5 mg of live tuberculosis bacilli in physiological saline emulsion under the skin of the thigh or the nape of the neck.

The bovine type strain, supplied on request by the Paul-Ehrlich-Institut in Frankfurt-am-Main must be used for this purpose. An excessive dose must be avoided so that the guinea-pigs retain their weight until used;

- (bb) Irrespective of the method of titration used, assessment must always be based on comparison with standard tuberculin of the tuberculin to be tested; the result must be expressed in IU per ml.
- (b) Potency testing on bovine animals

When tests are on bovine animals the reactions obtained on tubercular bovine animals by the tuberculin to be tested must be identical to those produced by the same amounts of standard tuberculin.

- 19. Tuberculin tests must be made by a single intradermal injection into either the neck or the shoulder.
- 20. The amount of tuberculin to be injected shall be 5 000 IU of PPD or synthetic tuberculin.
- 21. The result of the intradermal tuberculin test must be read after 72 hours and assessed according to the following method:
  - (a) Negative reaction: if only limited swelling is observed, with an increase of not more than 2 mm in the thickness of the fold of skin without clinical signs such as pasty consistency, exudation, necrosis, pain or inflammation of the lymphatic ducts in that region and of the lymph nodes;
  - (b) Positive reaction: if clinical signs such as mentioned in (a) are observed or if there is an increase of more than 2 mm in the thickness of the skin.

#### ANNEX C (3) (5) (7)

#### BRUCELLOSIS

#### A. Serum agglutination tests

1. The standard agglutinating serum must conform to the standard serum prepared by the Veterinary Laboratory, Weybridge, Surrey, England.

The ampoule must contain 1 000 IU of agglutination obtained by lyophilizing 1 ml of bovine serum.

- 2. The standard serum must be that supplied by the Bundesgesundheitsamt, Berlin.
- 3. The degree of brucella agglutination in a serum must be expressed in IU per ml (i.e. Serum X = 80 IU/ml).
- 4. Readings of slow sero-agglutination in tubes must be taken at 50 or at 75% agglutination, the antigen used having been titrated under identical conditions against the standard serum.
- 5. The agglutinating value of various antigens in relation to standard serum must be within the following limits:
  - if the reading is made at 50 %: between 1/600 and 1/1000,
  - if the reading is made at 75 %: between 1/500 and 1/750.
- 6. Weybridge Strain No 99 and USDA 1119 or any other strain of equivalent sensitivity must be used for preparing the antigen for use in tube agglutination (slow method).
- 7. The culture media used for keeping the strain in the laboratory and for producing the antigen must be such that they do not encourage bacterial dissociation (S minus R); potato agar should preferably be used.

- 8. The bacterial emulsion must be made from physiological saline (NaCl 8.5 %) phenolized at 5 %. Formol must not be used.
- 9. The official institutes indicated below must be made responsible for the official testing of antigens:

(a) Germany:	Bundesgesundheitsamt, Berlin;
(b) Belgium:	Institut national de recherches vétérinaires, Brussels;
(c) France:	Laboratoire central de recherches vétérinaires, Alfort;
(d) Grand Duchy of Luxembourg:	Institute of the supplying country;
(e) Italy:	Istituto Superiore di Sanità, Rome;

Centraal Diergeneeskundig Instituut, Afdeling Rotterdam;

Statens Veterinaere Serumlaboratorium, Copenhagen V.;

- The Veterinary Research Laboratory, Department of Agriculture and Fisheries, Thorndale, Beaumont Road, Dublin 9;
- Great Britain: The Central Veterinary Laboratory, Weybridge, Surrey, England,
- Northern Ireland: The Veterinary Research Laboratory, Stormont, Belfast.
- 10. Antigens may be delivered in, the concentrated state provided the dilution factor to be used is indicated on the bottle label.
- 11. In order to carry out a sero-agglutination test, at least three dilutions must be prepared for each serum. Dilutions of suspect serum must be made in such a way that the reading of the reaction at the infection limit is made in the median tube. If there is a positive reaction in this tube, the suspect serum contains at least 30 IU of agglutination per ml.

#### B. Complement fixation reaction test

(f) Netherlands:

(g) Denmark:

(h) Ireland:

(i) United Kingdom:

- 1. The standard serum is the same as that under A 1 of this Annex. In addition to its content in international agglutinating units, 1 ml of this lyophilized bovine serum must contain 1 000 sensitizing units which fix the complement. These sensitizing units are called EEC sensitizing units.
- 2. The standard serum must be supplied by the Bundesgesundheitsamt, Berlin.
- 3. A serum's level of antibodies which fix the complement must be expressed in EEC sensitizing units (for example: serum X = 60 EEC sensitizing units per ml).
- 4. A serum containing 20 or more EEC sensitizing units (i.e. an activity equal to 20 % of that of the standard serum) per ml, must be considered to be positive.
- 5. Serums must be inactivated as follows:
  - (a) bovine serum: 56 to 60 °C for 30 to 50 minutes;
  - (b) swine serum: 60 °C for 30 to 50 minutes.

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- 6. Weybridge Strain No 99 or USDA Strain 1119 must be used for the preparation of the antigen. The antigen represents a bacterial suspension in a physiological serum at 0.85 % or in a veronal loading solution.
- 7. In order to carry out the reaction test a complementary dose higher than the minimum necessary for total hemolysis should be used.
- 8. In carrying out the complement fixation reaction test, the following controls must be made each time:
  - (a) control of the anti-complementary effect of the serum;
  - (b) control of the antigen;
  - (c) control of sensitized red blood corpuscles;
  - (d) control of the complement;
  - (e) control using a positive serum of sensitivity at the start of the reaction;
  - (f) control of the specificity of the reaction using a negative serum.
- 9. The supervision and official control of standard serums and antigens shall be carried out by the bodies listed in A 9 of this Annex.
- 10. Antigens may be delivered in the concentrated state provided the dilution factor to be used is indicated on the bottle label.

## C. Ring-test

- 1. The ring-test must be made on the contents of each milk churn from the farm.
- 2. The standard antigen to be used must come from one of the institutes listed in paragraph A 9 (a) and (f).
- 3. The antigen may be stained only with hematoxylin or tretrazolium; hematoxylin should preferably be used.
- 4. The reaction test must be carried out in 8 to 10 mm diameter tubes.
- 5. The reaction test must be carried out using 1 ml of milk to which 0.05 ml of one of the stained antigens has been added.
- 6. The mixture of milk and antigen must be incubated at 37 °C for not less than 45 minutes and not more than 60 minutes.
- 7. The reaction test must be carried out approximately 18 hours after milking and assessed according to the following criteria:
  - (a) negative reaction: coloured milk, colourless cream;
  - (b) positive reaction: milk and cream identically coloured or colourless milk and coloured cream.
- 8. Formol must not be added to the sample. The only product which may be added is mercuric chloride in a solution of 0.2 % and, in such case, the ratio between the amount of milk and the solution of mercuric chloride must be 10 to 1.

#### ANNEX D

#### MILK ANALYSIS

- 1. All milk analyses must be carried out in official or officially approved laboratories.
- 2. Milk samples must be taken in accordance with the following conditions:
  - (a) the teats must first be disinfected with 70 % alcohol;
  - (b) tubes must be kept in a sloping position while being filled;
  - (c) milk samples must be taken at the beginning of milking, after eliminating the first streams from each teat;
  - (d) a sample must be taken from each quarter; the milk from these samples must not be mixed;
  - (e) each sample must contain at least 10 ml of milk;
  - (f) if a preservative is required boric acid at 0.5 % must be used;
  - (g) each tube must bear a label giving the following information:
    - the number of the earmark or any other means of identifying the animal,
    - the quarter from which the sample was taken,
    - the date and time of taking the sample.
  - (h) samples must be accompanied by a document giving the following information:
    - the name and address of the official veterinarian,
    - the name and address of the owner,
    - the means of identifying the animal,
    - the stage of lactation.
- 3. Milk analysis must be made not more than 30 days before loading and must always include a bacteriological test and a White Side Test (WST) or California Mastitis Test (CMT). The result of these two tests must be negative, subject as follows:
  - (a) if the result of the bacteriological test is positive although there is no characteristic inflammatory condition but the result of the WST (or the CMT) is negative, a second bacteriological test must be carried out at least 10 days later, within the 30-day limit set above. This second test must establish that:
    - (aa) the pathogenic micro-organisms have disappeared;
    - (bb) there are no antibiotics present.

In addition, the absence of inflammation must be established by a further WST (or a further CMT) which must be negative.

- (b) if the bacteriological test is negative while the WST (or the CMT) is positive, a complete cytological test must be made which must be negative.
- 4. The bacteriological test shall include:
  - (a) the seeding of milk in a Petri dish on blood agar of bovine animals or sheep;
  - (b) the seeding of milk in TKT or Edwards media.

The purpose of the bacteriological test is to identify all pathogenic micro-organisms and it must not be restricted to detecting specific pathogenic streptococci or staphylococci. For this reason, the identification of suspect colonies obtained from seeding in the abovementioned media shall be carried out by traditional methods of bacteriology differentiation such as the use of the Chapman medium to identify staphylococci and of various selective media for the detection of entero-bacteria.

5. The complete cytological test is intended to detect, where necessary, a characteristic inflammatory condition independent of any clinical symptom.

The existence of an inflammatory condition is established when the leucocyte count taken according to the Breed method attains 1 million leucocytes per ml and the proportion of mononuclear to polynuclear leucocytes is less than 0.5.

#### ANNEX E

The following diseases are compulsorily notifiable:

- (a) Bovine diseases:
  - rabies,
  - tuberculosis,
  - brucellosis,
  - foot-and-mouth disease,
  - anthrax,
  - cattle plague,
  - pleuro-pneumonia;
- (b) Swine diseases:
  - rabies,
  - brucellosis,
  - Anthrax,
  - foot-and-mouth disease,
  - classical and African swine fever,
  - contagious swine paralysis (Teschen disease).

## ANNEX F (3) (5) (6)

## MODEL I

## HEALTH CERTIFICATE (1)

for trade between Member States of the EEC

- Bovine animals for breeding or production -

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	No:
Exporting country:	
Competent ministry:	••••••
Competent regional authority:	· · · · · · · · · · · · · · · · · · ·
I. Number of animals:	·····

#### II. Identification of animals

Number of animals	Cow, bull, ox, heifer, calf	Breed	Age	Official marks, other marks or brands (state No and position)
			,	
			)	

## III. Origin of animals

The animals have remained in the territory of the exporting Member State for at least six months prior to the date of loading or since birth.

#### IV. Destination of animals

The animals will be sent

## V. Health information

I, the undersigned, certify that the animals described above meet the following requirements:

- (a) they have been examined this day and show no clinical sign of disease;
- (b) (<sup>6</sup>) they have been vaccinated within the prescribed period of not less than 15 days and not more than four months (<sup>5</sup>) against types A, O and C of foot-and-mouth disease virus using an officially approved and tested inactivated vaccine (<sup>2</sup>),
  - they have been revaccinated during the last 12 months (5) against types A, O and C of foot-and-mouth disease virus with an officially approved and tested inactivated vaccine (2),
  - they have not been vaccinated against foot-and-mouth disease (2);
- (c) they come from an officially tuberculosis-free bovine herd.

The result of the intradermal tuberculin test carried out within the prescribed 30-day time limit (5) was negative (2) (7);

- (d) they come from an officially brucellosis-free bovine herd  $(^2)$ ,
  - they come from a brucellosis-free bovine herd  $(^2)$ ,
  - they do not come from an officially brucellosis-free or brucellosis-free bovine herd (\*) (10).

The sero-agglutination test carried out within the prescribed 30-day time limit (5) showed a brucella count of less than 30 IU of agglutination per ml (2) (8).

- (e) they show no clinical sign of mastitis; the analysis/second analysis (2) of the milk carried out within the prescribed 30-day time limit (5) showed no characteristic inflammatory condition, no specific pathogenic micro-organism or, moreover, in the case of a second analysis, the presence of an antibiotic (2) (9);
- (f) they are not animals which are to be destroyed under a national contagious or infectious disease eradication programme;
- (g) they have remained during the last 30 days (5) on a holding situated in the territory of the exporting Member State where, during that period, no compulsorily notifiable contagious or infectious bovine animal disease within the meaning of the provisions applicable to intra-Community trade has been officially recorded.

In addition, the holding is situated in the centre of an epizootic-free area and according to official findings has for the last three months (5) been free from foot-and-mouth disease and bovine brucellosis;

- (h) they were obtained:
  - from a holding (2),
- (i) they were transported direct, passing/without passing (2), through an assembly point:
  - from the holding  $(^2)$ ,
  - from the holding to the market and thence (2),
  - to the actual place of loading without coming into contact with cloven-hoofed animals other than bovine animals or swine for breeding or production meeting the requirements for intra-Community trade, by transport vehicles and containers which had first been cleansed and disinfected with an officially authorized disinfectant.

The actual place of loading is situated in the centre of an epizootic-free area.

- VI. The necessary authorization as regards:
  - point V (b), second alternative (2),
  - point V (b), third alternative  $\binom{2}{2}$ ,

- point V (d), second alternative (2),
- point V (d), third alternative (2),

was given by:

- the country of destination (2),
- the country of destination and the countries of transit (2).

VII. This certificate is valid for 10 days from the date of loading.

Done at ...... on ......

(Date of loading)

. . . . . .

Seal

. . . . . . . . (Signature) Name in capital letters and title of signatory (4)

(2) Delete if inappropriate or in case of exemption.

<sup>&</sup>lt;sup>(1)</sup> A health certificate may be issued only in respect of animals transported in a single railway waggon, lorry, aircraft or boat from the same holding to the same consignee.

<sup>(\*)</sup> In case of trucks and lorries, state the registration number, in the case of aircraft the flight number, and in the case of boats the name.

In the case of boats the name.
(4) In Belgium: Inspecteur vétérinaire or Inspecteur Dierenarts; in France: Directeur des services vétérinaires du département; in Germany: Beamteter Tierarzt; in Italy: Veterinario provinciale; in Luxembourg: Inspecteur vétérinaire; in the Netherlands: Inspecteur-Districtshoofd; in Denmark: Autoriseret Dyrlaege; in Ireland: Veterinary Inspector; in the United Kingdom: Veterinary Inspector.

<sup>(5)</sup> This time limit runs from the date of loading.

<sup>(\*)</sup> This information is required only in the case of bovine animals over four months old.

<sup>(7)</sup> This information is required only in the case of bovine animals over six weeks old.

<sup>(8)</sup> This information is required only in the case of bovine animals over 12 months old, except in the case of bovine animals referred to in footnote (19).

<sup>(\*)</sup> This information is required only in the case of dairy cows.

<sup>(10)</sup> This derogation applies only in the case of bovine animals under 30 months old, on condition that they bear a special mark and are specially supervised in the country of destination.

## 20. 8. 75

## MODEL II

#### HEALTH CERTIFICATE (1)

#### for trade between Member States of the EEC

- Bovine animals for slaughter (2) -

No .....

xporting country:	
Competent ministry:	
Competent regional authority:	
I. Number of animals:	

#### II. Identification of animals

Number of animals	Cow, bull, ox, heifer, calf	Official marks, other marks or brands (state No and position)

#### III. Origin of animals

The animals have remained in the territory of the exporting Member State for at least three months prior to the date of loading or since birth.

#### IV. Destination of animals

#### V. Health information

I, the undersigned, certify that the animals described above meet the following requirements:

(a) they have been examined this day and show no clinical sign of disease;

(b) (°) — they have been vaccinated within the prescribed period of not less than 15 days and not more than (7)

-12 months,

-4 months,

against types A, O and C of foot-and-mouth disease virus with an officially approved and tested inactivated vaccine  $(^{8})$ ;

- they have not been vaccinated against foot-and-mouth disease (3);
- (c) (6) they come from an officially tuberculosis-free bovine herd (3),
  - they do not come from an officially tuberculosis-free bovine herd; the result of the intradermal tuberculin test carried out within the prescribed 30-day time limit (7) was negative (8);
- (d) ( $^{6}$ ) they come from an officially brucellosis-free or brucellosis-free bovine herd ( $^{3}$ ),
  - they do not come either from a bovine herd officially recognized as brucellosisfree or from a brucellosis-free herd; the sero-agglutination test carried out within the prescribed 30-day time limit (7) showed a brucella count of:
    - lower than 30 IU/ml (<sup>3</sup>),
    - 30 IU/ml or more (<sup>3</sup>);
- (e) they are not animals which are to be destroyed under a national contagious or infectious disease eradication programme;
- (f) they were not obtained from either a holding or an area situated in the territory of the exporting Member State which is subject to prohibition as regards bovine animals for animal health reasons within the meaning of the Council Directive on animal health problems affecting intra-Community trade in bovine animals and swine;
- (g) they were obtained:
  - from a holding (<sup>3</sup>),
- (h) they were transported direct, passing/without passing (3) through an assembly point:
  - from the holding  $(^3)$ ,
  - from the holding to the market and from the market  $(^3)$ ,

to the actual place of loading without coming into contact with cloven-hoofed animals other than bovine animals or swine for slaughter meeting the requirements for intra-Community trade, by transport vehicles and containers which had first been cleansed and disinfected with an officially authorized disinfectant.

The actual place of loading is situated in the centre of an epizootic-free area.

- VI. (6) Where appropriate, the necessary authorization as regards:
  - point V (b), second indent (3),
  - point V (d) (brucella count of 30 IU/ml or more) (3).

was given by:

- --- the country of destination (8),
- the country of destination and the countries of transit (3).

. . . . . . . . . . . . . .

(Signature) Name in capital letters and title of signatory (3)

VII. This certificate is valid for 10 days from the date of loading.

Done at, on	(Date of loading)

. . . . . . . . . . . .

Seal

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<sup>(1)</sup> A health certificate may be issued only in respect of animals transported in a single railway waggon, lorry, aircraft or boat from the same holding to the same consignee.

<sup>(\*)</sup> Bovine animals for slaughter: bovine animals intended to be taken immediately on arrival in the country of destination direct to the slaughterhouse or to a market.
(\*) Delete if inappropriate or in case of exemption.

<sup>(4)</sup> In the case of trucks and lorries, state the registration number, in the case of aircraft the flight number, and in the case of boats the name.

 <sup>(5)</sup> In Belgium: Inspecteur vétérinaire or Inspecteur Dierenarts; in France: Directeur des services vétérinaires du département; in Germany: Beamteter Tierarzt; in Italy: Veterinario provinciale; in Luxembourg: Inspecteur vétérinaire; in the Netherlands: Inspecteur Districtshoofd, in Denmark: Autoriset Dyrlaege; in Ireland: Veterinary Inspector; in the United Kingdom: Veterinary Inspector.

<sup>(\*)</sup> The information required in V (b), (c) and (d) of this certificate need not be given in the case of calves under four months old.

<sup>(7)</sup> This time limit runs from the date of loading.

## MODEL III

#### HEALTH CERTIFICATE (1)

for trade between Member States of the EEC

- Swine for breeding or production -

No .....

Exporting country:
Competent ministry:
Competent regional authority:
I. Number of animals:

## II. Identification of animals

Number of animals	Sex	Breed	Age	Official marks, other marks or brands (state No and position)

## III. Origin of animals

The animals have remained in the territory of the exporting Member State for at least six months prior to the date of loading or since birth.

#### IV. Destination of animals

The animals will be sent

from
to
by ( <sup>2</sup> ): railway waggon ( <sup>3</sup> ), lorry ( <sup>3</sup> ), aircraft ( <sup>3</sup> ), boat ( <sup>3</sup> ).
Name and address of consignor:
•••••••••••••••••••••••••••••••••••••••
Name and address of consignee:

## V. Health information

I, the undersigned, certify that the animals described above meet the following requirements:

(a) they have been examined this day and show no clinical sign of disease;

(b) they come from a brucellosis-free swine herd

- within the prescribed 30-day time limit (<sup>5</sup>), they have shown a brucella count of less than 30 IU/ml when given a sero-agglutination test and a negative result when given a complement fixation reaction test (<sup>2</sup>) (<sup>6</sup>);
- (c) they are not animals which are to be destroyed under a national contagious or infectious disease eradication programme;
- (d) they have remained during the last 30 days (<sup>5</sup>) on a holding situated in the territory of the exporting Member State where, during that period, no compulsorily notifiable contagious or infectious swine disease within the meaning of the provisions applicable to intra-Community trade has been officially recorded.

In addition, the holding is situated in the centre of an epizootic-free area and according to official findings has for the last three months ( $^{5}$ ) been free from foot-and-mouth disease, bovine and swine brucellosis, swine fever and contagious swine paralysis (Teschen disease);

- (e) they were obtained:
  - from a holding  $(^2)$ ,
- (f) they were transported direct, passing/without passing (2) through an assembly point:
  - from the holding  $(^2)$ ,
  - from the holding to the market and from the market  $\binom{2}{2}$

to the actual place of loading without coming into contact with cloven-hoofed animals other than bovine animals or swine for breeding or production meeting the requirements for intra-Community trade, by transport vehicles and containers, if any, which had first been cleansed and disinfected with an officially authorized disinfectant.

The actual place of loading is situated in the centre of an epizootic-free area.

VI. This certificate is valid for 10 days from the date of loading.

Done at .....

Seal

(Signature) Name in capital letters and title of signatory (4)

<sup>&</sup>lt;sup>(4)</sup> A health certificate may be issued only in respect of animals transported in a single railway waggon, lorry, aircraft or boat from the same holding to the same consignee.

<sup>(2)</sup> Delete if inappropriate or in case of exemption.

<sup>(\*)</sup> In the case of trucks and lorries, state the registration number, in the case of aircraft the flight number, and in the case of boats the name.

 <sup>(4)</sup> In Belgium: Inspecteur vétérinaire or Inspeteur Dierenarts; in France: Directeur des services vétérinaires du département; in Germany: Beamteter Tierarzt; in Italy: Veterinario provinciale; in Luxembourg: Inspecteur vétérinaire; in the Netherlands: Inspecteur Districtshoofd; in Denmark: Autoriseret Dyrlaege; in Ireland: Veterinary Inspector, in the United Kingdom: Veterinary Inspector.

<sup>(5)</sup> This time limit runs from the day of loading.

<sup>(9)</sup> Sero-agglutination tests and the complement fixation reaction test are carried out only on swine weighing more than 25 kg.

## MODEL IV

## HEALTH CERTIFICATE (1)

for trade between Member States of the EEC

— Swine for slaughter (2) —

	NO		• • • • • • •	• • • • • • •
			N	
Exporting country:	••••	• • • • • •	•••••	•••••
Competent ministry:	• • • • •			
Competent regional authority:	••••	••••	•••••	•••••
I. Number of animals:				••••

## II. Identification of animals

Pigs or piglets	Official marks, other marks or brands (state No and position)
	Pigs or piglets

## III. Origin of animals

The animals have remained in the territory of the exporting Member State for at least three months prior to the date of loading or since birth.

#### IV. Destination of animals

The animals will be sent

from(Place of loading)
to
by (3): waggon (4), lorry (4), aircraft (4), boat (4).
Name and address of consignor:
•••••••••••••••••••••••••••••••••••••••
Name and address of consignee:
· · · · · · · · · · · · · · · · · · ·

V. Health information

I, the undersigned, certify that the animals described above meet the following requirements:

(a) they have been examined this day and show no clinical sign of disease;

- (b) they are not animals which are to be destroyed under a national contagious or infectious disease eradication programme;
- (c) they were not obtained from either a holding or an area situated in the territory of the exporting Member State which is subject to prohibition as regards swine for animal health reasons within the meaning of the Council Directive on animal health problems affecting intra-Community trade in bovine animals and swine;
- (d) they were obtained:
  - from a holding (3),
  - from a market for animals for slaughter which is officially authorized for the export (Name of market)

(e) they were transported direct, passing/without passing through an assembly point:

- from the holding (3),

- from the holding to the market and from the market (8)

to the actual place of loading without coming into contact with cloven-hoofed animals other than bovine animals or swine for slaughter meeting the requirements for intra-Community trade, by transport vehicles and containers, if any, which had first been cleansed and disinfected with an officially authorized disinfectant.

. . . . . . . . . . . . . . . . . .

The actual place of loading is situated in the centre of an epizootic free area.

VI. This certificate is valid for 10 days from the date of loading.

Done at ..... on .....

Seal

. . . . . . (Signature) Name in capital letters and title of signatory (5)

(Date of loading)

<sup>(4)</sup> A health certificate may be issued only in respect of animals transported in a single railway waggon, lorry aircraft or boat from the same holding to the same consignee.

<sup>(\*)</sup> Swine for slaughter: swine intended to be taken immediately on arrival in the country of destination direct to the slaughterhouse or to a market.

<sup>(3)</sup> Delete if inappropriate or in case of exemption.

<sup>(4)</sup> In the case of trucks and lorries, state the registration number, in the case of aircraft the flight number, and in the case of boats the name.

<sup>(\*)</sup> In Belgium: Inspecteur vétérinaire or Inspecteur Dierenarts; in France: Directeur des services vétérinaires du département; in Germany: Beamteter Tierarzt; in Italy: Veterinario provinciale; in Luxembourg: Inspecteur vétérinaire; in the Netherlands: Inspecteur Districtshoofd; in Denmark: Autoriseret Dyrlaege; in Ireland: Veterinary Inspector; in the United Kingdom: Veterinary Inspector.