Council Directive 97/12/EC of 17 March 1997 amending and updating Directive 64/432/EEC on health problems affecting intra-Community trade in bovine animals and swine

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THE COUNCIL OF THE EUROPEAN UNION,
Having regard to the Treaty establishing the European Community, and in particular Article 43 thereof,
Having regard to the proposal from the Commission (1),
Having regard to the opinion of the European Parliament (2),
Having regard to the opinion of the Economic and Social Committee (3),
Whereas important progress has been made in the harmonization of the veterinary field, in particular through the adoption by the Council of Directive 90/425/EEC of 26 June 1990 concerning veterinary and zootechnical checks applicable in intra-Community trade in certain live animals and products with a view to the completion of the internal market (4), Directive 91/496/EEC 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 (5), Directive 85/511/EEC of 18 November 1985 introducing Community measures for the control of foot-and-mouth disease (6), and 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 (7);
Whereas the Council in its resolution 94/C 16/01 of 22 December 1993 on the strengthening of veterinary epidemiological surveillance measures (8) agreed to do everything in its power to ensure rapid implementation of the principles of that resolution in the context of the amendment of Directive 64/432/EEC of 26 June 1964 on health problems affecting intra-Community trade in bovine animals and swine (9);
Whereas it is necessary, in the light of this situation, to amend Directive 64/432/EEC in particular as regards the period of residence in a Member State prior to movement, rules for trade in animals under 15 days old, rules for control of certain diseases and rules applicable to assembly centres, transporters and dealers;
Whereas for the purpose of rapid and accurate tracing of animals for animal health reasons each Member State should create a computerized database which shall record the identity of the animals, all holdings on their territory and the movements of the animals;
Whereas Directive 64/432/EEC has been substantially amended on a number of occasions; whereas for the sake of clarity that Directive should be updated,
HAS ADOPTED THIS DIRECTIVE:

Article 1
As from 1 July 1998 the Articles and the Annexes to Directive 64/432/EEC are hereby replaced by the text annexed to this Directive.

Article 2
1. Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with this Directive not later than 1 July 1998. 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

domestic law which they adopt in the field governed by this Directive.

Article 3
This Directive shall enter into force on the day of its publication in the Official Journal of the European Communities.

Article 4
This Directive is addressed to the Member States.

Done at Brussels, 17 March 1997.
For the Council
The President
J. VAN AARTSEN

ANNEX

DIRECTIVE 64/432/EEC (amendment and updating of the Articles and the Annexes)

Article 1
This Directive shall apply to intra-Community trade in bovine animals and swine with the exception of feral pigs as defined in Article 2 (e) of Directive 80/217/EEC (1) without prejudice to the provisions laid down in Directives 80/215/EEC (2), 85/511/EEC, 88/407/EEC (3), 89/608/EEC (4), 90/425/EEC, 90/429/EEC (5), 90/667EEC (6), 91/496/EEC, 91/628/EEC (7), 92/102/EEC (8), 92/119/EEC and Decision 90/424/EEC (9).

Article 2
1. The definitions given in Article 2 of Directive 90/425/EEC and Article 2 of Directive 91/628/EEC shall apply.
2. In addition the following definitions apply for the purposes of this Directive:
(a) herd means an animal or group of animals kept on a holding (within the meaning of Article 2 (b) of Directive 92/102/EEC) as an epidemiological unit; if more than one herd is kept on a holding, each of these herds shall form a distinct unit and shall have the same health status;
(b) animal for slaughter means a bovine animal (including the species Bison bison and Bubalus bubalus) or swine intended to be taken to a slaughterhouse or assembly centre from which it may only move to slaughter;
(c) animals for breeding or production means bovine animals (including the species Bison bison and Bubalus bubalus) and swine other than those referred to in (b), including those intended for breeding, milk or meat production, or draft purposes, shows or exhibition with the exception of animals taking part in cultural and sporting events;
(d) officially tuberculosis-free bovine herd means a bovine herd which satisfies the conditions laid down in Annex A.I, paragraphs 1, 2 and 3;
(e) officially tuberculosis-free Member State or region of a Member State means a Member State or part of a Member State which satisfies the conditions laid down in Annex A.I, paragraphs 4, 5 and 6;
(f) officially brucellosis-free bovine herd means a bovine herd which satisfies the conditions laid down in Annex A.II, paragraphs 1, 2 and 3;
(g) officially brucellosis-free region means a region of a Member State which satisfies the conditions laid down in Annex A.II, paragraphs 7, 8 and 9;
(h) officially brucellosis-free Member State means a Member State which satisfies the conditions laid down in Annex A.II, paragraphs 10, 11 and 12;
(i) brucellosis-free bovine herd means a bovine herd which satisfies the conditions laid down in

Annex A.II, paragraphs 4, 5 and 6;
(j) officially enzootic-bovine-leukosis-free herd means a herd which satisfies the conditions laid down in Annex D, Chapter I, Sections A and B;
(k) officially enzootic-bovine-leukosis-free Member State or region means a region or Member State which meets the requirements laid down in Annex D, Chapter I, Sections E, F and G;
(l) official veterinarian means the veterinarian appointed by the competent authority of the Member State;
(m) approved veterinarian means any veterinarian approved by the competent authority in accordance with the provisions of Article 14 (3) (B);
(n) compulsorily notifiable diseases means the diseases listed in Annex E (I);
(o) assembly centre means holdings, collection centres and markets, at which bovine animals or swine originating from different holdings are grouped together to form consignments of animals intended for trade. These assembly centres must be approved for trading purposes and meet the requirements laid down in Article 11;
(p) region means that part of a Member State's territory which is at least 2 000 km² in area and which is subject to inspection by the competent authorities and includes at least one of the following administrative regions:
>TABLE missing
(q) dealer means any natural or legal person who buys and sells animals commercially either directly or indirectly, who has a regular turnover of these animals and who within a maximum of 30 days of purchasing animals resells them or relocates them from the first premises to other premises not within his ownership and meets the conditions laid down in Article 13.

Article 3
1. Each Member State shall ensure that only animals that fulfil the relevant conditions laid down in this Directive are sent from its territory to that of another Member State.
2. Bovine animals and swine covered by this Directive must:
(a) be subjected:
- to an identity check, and
- to a clinical inspection within 24 hours of departure by an official veterinarian and show no clinical sign of disease;
(b) not have been obtained from a holding or an area which for health reasons is subject to prohibition or restriction affecting the species involved in accordance with Community and/or national legislation;
(c) be identified as provided for in Directive 92/102/EEC;
(d) not be animals which are to be slaughtered and not be restricted under a contagious or infectious disease eradication programme of a Member State or region;
(e) comply with the provisions of Articles 4 and 5.

Article 4
1. Bovine animals and swine covered by this Directive must at no time between leaving the holding of origin and arriving at destination come into contact with cloven-hoofed animals other than animals that have the same health status.
2. Bovine animals and swine covered by this Directive must be transported in means of transport meeting the requirements of Directive 91/628/EEC and in addition the requirements of Article 12.
3. Rules for the approval of sites where cleansing and disinfection may be carried out shall be determined in accordance with the procedure set out in Article 17.

Article 5
1. Bovine animals and swine covered by this Directive must be accompanied during

transportation to destination by a health certificate conforming to the model set out in Annex F. The certificate shall consist of a single sheet or, where more than one page is required, shall be in such a form that any two or more pages are part of an integrated whole and indivisible and shall contain a serial number. It shall be drawn up on the day of the health inspection, in one of the official languages of the country of destination at least. The certificate shall be valid for 10 days from the date of the health examination.
2. The health inspection for the issuing of the health certificate (including additional guarantees) for a consignment of animals may be carried out in the holding of origin or of an assembly centre. For this purpose the competent authority shall ensure that any health certificate is drawn up by the official veterinarian after inspections, visits and controls as provided by this Directive. However as regards:
(a) animals coming from approved assembly centres, such certification shall be:
- on the basis of an official document containing the necessary information completed by the official veterinarian for the holding of origin, or
- in the form of the certificate contained in Annex F with Sections A and B duly completed and certified by the official veterinarian for the holding of origin;
(b) animals coming from an approved holding which is participating in the surveillance network provided for in Article 14, such certification shall be:
- on the basis of an official document containing the necessary information completed by the approved veterinarian for the holding of origin, or
- in the form of the certificate contained in Annex F with Sections A and B duly completed and certified by the approved veterinarian for the holding of origin.
For this purpose, the official veterinarian will ensure where appropriate that the additional guarantees provided for in Community legislation are fulfilled.
3. The official veterinarian for the assembly centre shall carry out all necessary checks on animals arriving there.
4. The official veterinarian completing Part D of the certificate the model of which appears in Annex F, shall ensure that the movement is registered on the Animo system on the day the certificate is issued.
5. The animals covered by this Directive may transit through an assembly centre which is located in one other Member State before being consigned to the Member State of destination. In this case, the certificate in Annex F (including Section D) must be completed by the official veterinarian responsible in the Member State where the animals originate. The official veterinarian responsible for the assembly centre of transit shall provide certification to the Member State of destination by completing a second certificate, as in Annex F, endorsing it with the serial number of the original and attaching it to the original certificate or to an officially endorsed copy thereof. In this case the combined validity of the certificates shall not exceed that provided for in paragraph 1.

Article 6
1. Animals for breeding or production must, in addition to the requirements of Articles 3, 4 and 5:
- have remained in a single holding of origin for a period of 30 days prior to loading, or since birth in the holding of origin where the animals are less than 30 days old. The official veterinarian must, on the basis of the official identification provided for in Article 3 (2) (c) and official records, be satisfied that the animals have complied with this condition and furthermore that the animals have originated in the Community or have been imported from a third country in compliance with Community animal health legislation.
However, in the case of animals transiting through an approved assembly centre in the Member State of origin, the period during which the assembly of these animals takes place outside the holding of origin shall not exceed six days,

- with regard to animals imported from a third country into a Member State which is not that of ultimate destination, be transported to the Member State of destination as quickly as practicable under cover of a certificate issued under Article 7 of Directive 91/496/EEC,
- with regard to animals imported from a third country upon arrival at destination and before any further movements satisfy the requirements of this Directive, and in particular the residency requirement in the first indent, and may not be brought into the herd until the veterinarian responsible for that holding has ascertained that the animals in question are not likely to jeopardize the health status of the holding.

If an animal from a third country is introduced into a holding no animal from the holding may be traded for 30 days following introduction unless the imported animal is isolated from all other animals on the holding.

2. Bovine animals for breeding and production must, in addition to the requirements in Articles 3, 4 and 5:

(a) come from an officially tuberculosis-free bovine herd, and in the case of animals more than six weeks old, have reacted negatively to an intradermal tuberculin test carried out during the 30 days prior to leaving the herd of origin, in accordance with the provisions of Annex B point 32 (d).

This intradermal tuberculin test is not required if the animals originate in a Member State or part of a Member State recognized as officially tuberculosis free or in a Member State or part of a Member State with an approved surveillance network;

(b) in the case of uncastrated animals which come from an officially brucellosis-free bovine herd and more than 12 months old, have shown a brucella count lower that 30 international units (IU) of agglutination per millilitre when given a serum agglutination test (or any test approved by Standing Veterinary Committee (SVC) procedure following the adoption of the relevant protocols) carried out during the 30 days prior the leaving the herd of origin and complying with the provisions of Annex C Section A.

This serum agglutination test (or any test approved by SVC procedure following the adoption of the relevant protocols) is not required if the animals originate in a Member State or part of a Member State recognized as officially brucellosis free or in a Member State or part of a Member State with an approved surveillance network;

(c) come from an officially enzootic-bovine-leukosis-free herd and, if more than 12 months old, have reacted negatively to an individual test carried out during the 30 days prior to leaving the herd of origin and complying with the provisions of Annex D.

The test is not required if the animals originate in a Member State or part of a Member State recognized as officially enzootic-bovine-leukosis free or in a Member State or part of a Member State with an approved surveillance network;

(d) at no time between leaving the holding of origin and arriving at destination come into contact with bovine animals which meet only the requirements in paragraph 3.

3. Bovine animals for slaughter must, in addition to the requirements in Articles 3, 4 and 5, come from herds that are officially tuberculosis free, officially enzootic-bovine-leukosis free and in the case of uncastrated bovines, from herds that are officially brucellosis free.

However, until 31 December 1999, the destination countries may grant to Spain general or limited licences to introduce into their territories animals for slaughter from herds which are not officially free of tuberculosis, enzootic bovine leukosis and brucellosis, provided such animals:
- have in the 30 days prior to embarkation undergone the appropriate tests laid down in Annexes B, C and D, with negative results,
- are taken on arrival in the country of destination directly to a slaughterhouse and are slaughtered there as soon as possible but at least within 72 hours of arrival, in accordance with animal health requirements.

Article 7

Animals for slaughter which have been taken on arrival in the country of destination:
- to a slaughterhouse, must be slaughtered there as soon as possible but at least within 72 hours of arrival, in accordance with animal health requirements, or
- to an approved assembly centre, must be removed after the market directly to a slaughterhouse to be slaughtered as soon as possible but at the latest within three working days of arrival at the assembly centre, in accordance with animal health requirements. At no time, between their arrival at the assembly centre and their arrival at the slaughterhouse, may they come into contact with cloven-hoofed animals other than animals that fulfil the conditions laid down in this Directive.

Article 8
Member States shall ensure that the suspected presence of any of the diseases referred to in Annex E (I) is compulsorily and immediately notifiable to the competent authority.
Each Member State shall forward to the Commission by 31 May each year, and for the first time in 1999, details of the occurrence of diseases listed in Annex E (I) and of any other diseases covered by the additional guarantees provided for by Community legislation in its territory in the previous calendar year including details of the monitoring and eradication programmes in operation. This information shall be based on uniform criteria to be established by the procedure provided for in Article 17. The Commission shall present this information to the Member States in the framework of the SVC and in particular may utilize it in relation to the decisions referred to in Annexes A and D.

Article 9
1. A Member State which has a compulsory national control programme for one of the contagious diseases listed in Annex E (II) for all or part of its territory may submit the said programme to the Commission, outlining in particular:
- the distribution of the disease in the Member State,
- the reasons for the programme, taking into consideration the importance of the disease and the programme's likely benefit in relation to its cost,
- the geographical area in which the programme will be implemented,
- the status categories to be applied to the animal establishments, the standards which must be attained in each category, and the test procedures to be used,
- the programme monitoring procedures, the results of which must be supplied at least annually to the Commission,
- the action to be taken if, for any reason, an establishment loses its status,
- the measures to be taken if the results of the tests carried out in accordance with the provisions of the programme are positive.
2. The Commission shall examine the programmes presented by the Member States. Programmes as referred to in paragraph 1 may be approved in compliance with the criteria laid down in paragraph 1 in accordance with the procedure provided for in Article 17. According to the same procedure, the additional guarantees, general or limited, which may be required in intra-Community trade, shall be defined at the same time or at the latest three months after approval of the programmes. Such guarantees must not exceed those which the Member State implements nationally.
3. Programmes submitted by Member States may be amended or supplemented in accordance with the procedure laid down in Article 17. Amendments or additions to programmes which have already been approved or to guarantees which have been defined in accordance with paragraph 2 may be approved under the same procedure.

Article 10
1. Where a Member State considers that its territory or part of its territory is free from one of the

diseases listed in Annex E (II), it shall present to the Commission appropriate supporting documentation, setting out in particular:
- the nature of the disease and the history of its occurrence in its territory,
- the results of surveillance testing based on serological, microbiological, pathological or epidemiological investigation and on the fact that the disease must by law be notified to the competent authorities,
- the period over which the surveillance was carried out,
- where applicable, the period during which vaccination against the disease has been prohibited and the geographical area concerned by the prohibition,
- the arrangements for verifying the absence of the disease.
2. The Commission shall examine documentation submitted by Member States. The additional guarantees, general or specific, which may be required in intra-Community trade may be defined in accordance with the procedure laid down in Article 17. Such guarantees must not exceed those which the Member State implements nationally.
3. The Member State concerned shall notify the Commission of any change in the details specified in paragraph 1 which relate to the disease, in particular regarding any new outbreaks of the disease. The guarantees defined in accordance with paragraph 2 may, in the light of such notification, be amended or withdrawn in accordance with the procedure laid down in Article 17.

Article 11
1. Member States shall ensure that, in order to be approved by the competent authority, assembly centres meet the following conditions at least. They must:
(a) be under the control of an official veterinarian who shall ensure that, in particular, the provisions of Article 4 (1) and (2) are complied with;
(b) be located in an area which is not subject to prohibition or restrictions in accordance with relevant Community legislation and/or national legislation;
(c) be cleaned and disinfected before use, as required by the official veterinarian;
(d) they must have, taking into account the animal capacity of the assembly centre:
- a facility dedicated exclusively for this purpose when used as an assembly centre,
- appropriate facilities for loading, unloading and adequate housing of a suitable standard for the animals, for watering and feeding them, and for giving them any necessary treatment; these facilities must be easy to clean and disinfect,
- appropriate inspection facilities,
- appropriate isolation facilities,
- appropriate equipment for cleaning and disinfecting rooms and trucks,
- an appropriate storage area for fodder, litter and manure,
- an appropriate system for collecting waste water,
- the use of an office for the official veterinarian;
(e) admit only animals that are identified and come from herds that are officially free of tuberculosis, brucellosis and leukosis or slaughter animals meeting the conditions set out in the present Directive and in particular Article 6 (3). To this end, when animals are admitted the owner or person in charge of the centre shall ensure they are properly identified and accompanied by health documents or appropriate certificates for the species and categories involved;
(f) be regularly inspected in order to ascertain that the requirements for approval continue to be fulfilled.
2. The owner or person in charge of the assembly centre shall be required, on the basis either of the accompanying documents for the animals or of the identification numbers or marks of the animals, to record on a register or a data base and retain for a minimum period of three years the following information:
- the name of the owner, the origin, date of entry and exit, number and identification of the

bovine animals or the registration number of the holding of origin or of the herd of origin of the pigs entering the centre and their proposed destination,
- the registration number of the transporter and the licence number of the lorry delivering or collecting animals from the centre.
3. The competent authority shall issue an approval number to each approved assembly centre. Such approval may be limited to a particular species or to animals for breeding and production or to animals for slaughter. The competent authority shall notify the Commission of the list of approved assembly centres and of any updates. The Commission shall present this information to Member States in the framework of the SVC.
4. The competent authority may suspend or withdraw approval in the event of failure to comply with this Article or other appropriate provisions of this Directive or other directives in respect of health restrictions. Approval may be restored when the competent authority is satisfied that that assembly centre is in full compliance with all the appropriate provisions of this Directive.
5. The competent authority shall ensure that when operating assembly centres have sufficient approved veterinarians to carry out all duties.
6. Any detailed rules required for uniform application of this Article shall be adopted in accordance with the procedure provided for in Article 17.

Article 12
1. Member States shall ensure that the transporters referred to in Article 5 of Directive 91/628/EEC meet the following additional conditions:
(a) for the carriage of animals they must use means of transport that are:
- constructed in such a way that the animal faeces, litter or feed cannot leak or fall out of the vehicle,
- cleaned and disinfected immediately after every animal transport operation or that of any product which could affect animal health and if necessary before any new loading of animals, using disinfectants officially authorized by the competent authority;
(b) they must either have appropriate cleaning and disinfection facilities approved by the competent authority, including facilities for storing litter and dung, or they must provide documentary evidence that these operations are performed by a third party approved by the competent authority.
2. The transporter must ensure that for each vehicle used for the transport of animals a register is kept containing the following information at least which shall be retained for a minimum period of three years:
(i) places and dates of pick-up, and the name or business name and address of the holding or assembly centre where the animals are picked up;
(ii) places and dates of delivery, and the name or business name and address of the consignee(s);
(iii) species and number of animals carried;
(iv) date and place of disinfection;
(v) details of accompanying documentation (serial number, etc.).
3. Transporters shall ensure that the consignment of animals do not at any time, between leaving the holdings or the assembly centre of origin and arriving at their destination, come into contact with animals of a lower health status.
4. Member States shall ensure that transporters give a written undertaking stating in particular that:
- all the measures necessary to comply with this Directive shall be taken and in particular the provisions laid down in this Article and relating to the appropriate documentation that must accompany the animals,
- the transport of animals is entrusted to staff who possess the necessary ability, professional competence and knowledge.
5. In the event of failure to comply with the provisions of this Article the requirements of Article

18 of Directive 91/628/EEC shall apply mutatis mutandis relating to animal health.

Article 13

1. Member States shall ensure that all dealers are registered, approved and issued with an approval number by the competent authority and that they comply with the following conditions at least:

(a) they must deal only in animals that are identified and come from herds that are officially free of tuberculosis, brucellosis and leukosis or slaughter animals meeting the conditions set out in this Directive and in particular Article 6 (3). To this end, the dealer shall ensure that the animals are properly identified and are accompanied by health documents as appropriate for the species involved.

However, the competent authority may authorize the marketing of identified animals which do not fulfil the conditions laid down in the first paragraph, in so far as they are brought direct to a slaughterhouse in the Member State of origin without passing through their facilities, for slaughter as soon as possible in order to prevent the spreading of diseases. The necessary provisions should be taken to ensure that such animals, when they reach the abattoir, cannot come into contact with other animals and that they are slaughtered apart from other animals;

(b) the dealer shall be required, either on the basis of the document accompanying the animals, or on the basis of identification numbers or marks on the animals, to keep a record or data base and to store the following data for at least three years:

- the name of the owner, origin, date of purchase, categories, number and identification of bovine animals or registration number of the holding of origin or of the herd of origin of pigs purchased,
- the registration number of the transporter and/or the licence number of the lorry delivering and collecting animals,
- the name and address of the purchaser and the destination of the animals,
- copies of route plans and/or serial number of health certificates as applicable;

(c) when the dealer keeps animals on his premises he shall ensure that:

- specific training is given to the staff in charge of the animals in applying the requirements of this Directive and in the care and welfare of the animals,
- controls and tests if necessary on the animals are carried out regularly by the official veterinarian and that all necessary steps are taken to prevent the spread of disease.

2. Member States shall ensure that all premises used by a dealer in connection with his business are registered and issued with an approval number by the competent authority and that they comply with the following conditions at least:

(a) they must be under the control of an official veterinarian;

(b) they must be located in an area which is not subject to prohibition or restrictions in accordance with the relevant Community legislation or national legislation;

(c) they must have:

- appropriate facilities of sufficient capacity and in particular inspection facilities and isolation facilities so that all animals can be isolated in the event of an outbreak of a contagious disease,
- appropriate facilities for unloading and where necessary adequate housing of a suitable standard for the animals, for watering and feeding them, and for giving them any necessary treatment; these facilities must be easy to clean and disinfect,
- an appropriate reception area for litter and manure,
- an appropriate system for collecting waste water;

(d) be cleaned and disinfected before use, as required by the official veterinarian.

3. The competent authority may suspend or withdraw approval in the event of failure to comply with this Article or other appropriate provisions of this Directive or other directives in respect of health restrictions. Approval may be restored when the competent authority is satisfied that the dealer is in full compliance with all the appropriate provisions of this Directive.

4. The competent authority must carry out regular inspections in order to ascertain that the

requirements of this Article are fulfilled.

Article 14
1. The competent authority in a Member State may introduce a system of surveillance networks. The surveillance network system must comprise at least the following elements:
- the herds,
- the owner or any other natural or legal person responsible for the holding,
- the approved veterinarian or the official veterinarian responsible for the holding,
- the official veterinary service of the Member State,
- the official veterinary diagnostic laboratories or any other laboratory approved by the competent authority,
- a computer database.
Official veterinarians for the slaughtering establishments and approved assembly centres will be associated with the network system.
2. The main objectives of the surveillance network system are to make the official classification of holdings, to maintain such classification by regular inspection, to collect epidemiological data and to carry out disease monitoring so as to ensure compliance with all the provisions of this Directive and other directives in respect of health restrictions.
This surveillance network system shall be mandatory on all holdings in the territory of the Member State operating such a system. However, the competent authority may authorize the establishment of such a network on part of the territory made up of one or several adjacent regions as defined in Article 2 (2) (p). Where this derogation is accorded, animal movements to that part of the territory from other regions which are not part of the network system shall be subject to the provisions of this Directive.
The competent authority shall lay down the obligations and rights incumbent upon the approved veterinarians, the persons responsible for the holdings or their owners and any other participants in the system including the persons responsible for issuing health certificates.
3. The competent authority shall ensure that the obligations referred to in paragraph 2 at least include the following:
A. Every owner of or person responsible for a holding must:
(i) secure, by contract or legal instrument, the services of a veterinarian approved by the competent authority;
(ii) immediately call in the approved veterinarian for the holding when he suspects the occurrence of an infectious disease or of any notifiable disease;
(iii) notify the approved veterinarian of all arrivals of animals on his holding;
(iv) isolate the animals before introducing them into his holding to enable the approved veterinarian to check, where appropriate by means of the required tests, whether the holding's status may be maintained.
B. The approved veterinarians as provided for by Article 2 (2) (m) shall be under the control of the competent authority and must comply with the following requirements.
They must:
(i) meet the conditions for pursuing the veterinary profession;
(ii) have no financial interest or family links with the owner of or person responsible for the holding;
(iii) possess particular knowledge in the field of animal health as it applies to animals of the species concerned. This means that they must:
- regularly update their knowledge, especially as regards the relevant health regulations,
- meet the requirements laid down by the competent authority to ensure the proper functioning of the network,
- provide the owner of or person responsible for the holding with information and assistance in order that all steps are taken to ensure that the holding's status is maintained, particularly on the

basis of programmes agreed with the competent authority,
- ensure compliance with the requirements concerning:
(i) the identification and health certification of the animals of the herd, the animals introduced and those traded;
(ii) compulsory reporting of infectious animal diseases and any other risk factor for animal health or welfare, and for human health;
(iii) establishing as far as possible the cause of death of animals and where they are to be consigned;
(iv) the hygiene conditions of the herd and of the livestock production units.
If the proper functioning of the system so requires, each Member State may limit the veterinarians' responsibility to a specific number of holdings or to a specific geographical area.
The competent authority shall draw up lists of approved veterinarians and of the approved holdings participating in the network. If the competent authority finds that a participant in the network no longer fulfils the conditions set out above, it shall suspend or withdraw approval, without prejudice to any penalties that may be applied.
C. The computer database must contain at least the following information:
(1) For each animal:
- identification code,
- date of birth,
- sex,
- breed or colour of coat,
- identification code of the mother or, in the case of an animal imported from a third country, the identification number given following inspection under Directive 92/102/EEC and corresponding to the identification number of origin,
- identification number of the holding where born,
- identification numbers of all holdings where the animal has been kept and the dates of each change of holding,
- date of death or slaughter.
(2) For each holding:
- an identification number consisting of not more than 12 figures (apart from the country code),
- name and address of the holder.
(3) The database must be able to supply the following particulars at any time:
- the identification number of all animals of the bovine species present on a holding, or in the case of groups of animals of the porcine species, the registration number of the holding of origin or herd of origin and the number of the health certificate where applicable,
- a list of all changes of holding for each animal of the bovine species starting from the holding of birth, or the holding of importation in the case of animals imported from third countries; and for groups of pigs the registration number of the last holding or last herd and for imported animals from third countries the holding of importation.
These particulars will be held on the database until three consecutive years have elapsed since the death of the bovine animal or until three consecutive years have elapsed since the record was made in the case of records for pigs.
However, only paragraphs 2 and 3 shall be applicable to pigs.
4. All participants in the surveillance network other than those provided for in 3A and B shall be accountable to the competent authority. The competent authority in each Member State shall be responsible for setting up the network and shall carry out regular checks to ensure that it operates properly.
5. Member States which introduce a system of surveillance networks as outlined in paragraphs 1 to 4, operational for a period of at least 12 months, shall apply to the Commission to have it approved under the procedure provided for in Article 17.
For this purpose the Commission shall examine documentation submitted by Member States.

The Commission experts shall validate the systems by means of a system of audits. Where the result of the audit is favourable the Commission shall within 90 days of receipt of the request for approval make a report to the SVC together with appropriate proposals.
Where repeated offences are noted, the approval of the surveillance network system can be suspended according to the procedure laid down in Article 17, at the request of the Commission or of one or more Member States.
6. Member States which have implemented in all their territory a recognized surveillance network system as laid down in this Article shall be authorized not to apply the provision referred to in Article 3 (2) (a), second indent to animal movements referred to by this Directive within their own territory.
7. Not later than 31 December 1999, acting on the basis of a report from the Commission, accompanied by proposals on which it shall act by a qualified majority, the Council shall review the provisions of this Article in the light of experience with a view to amending and updating them and, if appropriate, extending them to all Member States.
8. The financing of the surveillance network system will be covered within the framework of the revision of Annex B to Directive 85/73/EEC (10) in accordance with the provisions laid down in Article 8 of Directive 96/43/EC.

Article 15
1. Member States shall take the appropriate specific measures to penalize any infringement of this Directive whether by a natural or a legal person.
2. If it is confirmed that the provisions of this Directive are not or have not been complied with the competent authority of the place in which such a finding is made shall take all appropriate measures to safeguard animal health and to prevent the spread of disease.
Depending on the circumstances, such action by the competent authority may consist of taking the measures required to:
(a) arrange for the journey to be completed or the animals returned to their place of departure by the most direct route, providing this course of action would not further jeopardize the health or welfare of the animals;
(b) arrange for the animals to be held in suitable accommodation with appropriate care in the event of interruption of the journey;
(c) arrange for the slaughter of the animals. The destination and use of such animals after slaughter shall be regulated:
- in accordance with the provisions of Directive 64/433/EEC (11), or
- in accordance with the provisions of Directive 90/667/EEC where the health status of the animals cannot be established or where they are liable to be a risk to animal health or public health. However, where the provisions of Directive 90/667/EEC should apply, a regularization period may be accorded to the owner or his agent before that final possibility is invoked. In that case, the provisions of paragraph 3 of this Article shall apply.
3. The competent authority of the Member State of destination shall immediately notify the competent authority of the Member State of origin on the establishment of any infringement of this Directive.
In accordance with the provisions established by Directive 89/608/EEC, Member States shall provide mutual assistance to one another in the application of this Directive in order to ensure, in particular, compliance with the provisions laid down in this Article.
4. This Article shall not affect national rules applicable to penal sanctions.

Article 16
1. Annexes A, D (Chapter I), E and F shall be amended by the Council, acting by a qualified majority on a Commission proposal, in particular with regard to their adaptation to technological and scientific developments.

Annexes B, C and D (Chapter II) shall be amended by the Commission in accordance with the procedures provided for in Article 17.
However,
(a) before 1 July 1997, the Commission shall submit to the Council a proposal for the amendment of Annexes A and D (Chapter I), for the purpose of updating them and if necessary it will apply the same procedure to Annex F. The Council shall decide on these proposals by a qualified majority before 1 January 1998;
(b) before 30 June 1998, the Commission, in accordance with the procedure laid down in Article 17 and on the basis of the opinion of the Scientific Veterinary Committee, shall update and if necessary amend Annexes B, C and D (Chapter II) to adapt them to scientific developments.
2. Not later than 31 December 1999, acting on the basis of a report from the Commission, accompanied by suitable proposals on which it shall act by a qualified majority, the Council shall review the provisions of this Directive in the light of experience with a view to amending and updating them so that they comply with the rules laid down for completion of the internal market.

Article 17
Where reference is made to the procedure provided for in this Article, the SVC set up by Decision 68/361/EEC (12) shall act in accordance with the rules laid down in Article 18 of Directive 89/662/EEC (13).

Article 18
Those Member States which have not introduced an approved surveillance network system shall ensure that a computer database complying with the provisions laid down in Article 14 is fully operational from 31 December 1999.

Article 19
The rules laid down in Directive 90/425/EEC shall apply in particular to checks at origin, to the organization of, and follow-up to, the checks to be carried out by the country of destination, and to the safeguard measures to be implemented.

Article 20
This Directive is addressed to the Member States.

ANNEX A

I. Officially tuberculosis-free bovine herd
1. A bovine herd is 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 six months after the elimination of any infection from the herd and the second six months later or, where the herd has been assembled solely from animals that originate in officially tuberculosis-free herds, the first test shall be carried out at least 60 days after assembly and the second shall not be required;
(c) following the completion of the first test referred to in (b), no bovine animal over six weeks old has been introduced into the herd unless it has reacted negatively to an intradermal tuberculin test performed and assessed according to Annex B and carried out either in the 30 days prior to, or the 30 days after the date of its introduction into the herd.
This test shall not be necessary in Member States or regions of a Member State where the percentage of bovine herds infected with tuberculosis is less than 0,2 % or if the animal originates in an officially tuberculosis-free herd.

2. A bovine herd will retain officially tuberculosis-free status if:
(a) the conditions detailed in 1 (a) and (c) continue to apply;
(b) all animals entering the holding come from herds of officially tuberculosis-free status;
(c) all animals in the holding, with the exception of calves under six weeks old which were born in the holding, are subjected to routine tuberculin testing in accordance with Annex B at yearly intervals.
However, the Commission, in accordance with the procedure in Article 17, may, for a Member State or part of a Member State where all the bovine herds are subject to official operations to combat tuberculosis, alter the frequency of the routine tests as follows:
- if the percentage of bovine herds infected with tuberculosis is not more than 1 % on average during the two most recent annual supervisory periods, the interval between routine herd tests may be increased to two years,
- if the percentage of infected bovine herds is not more than 0,2 % on average during the two most recent biennial supervisory periods, the interval between routine tests may be increased to three years,
- if the percentage of infected bovine herds is not more than 0,1 % on average during the two most recent triennial supervisory periods, the interval between routine tests may be increased to four years and/or the age at which animals have to undergo these tests may be increased to 24 months.
The Commission may also, in accordance with Article 17, take a decision increasing the frequency of routine tuberculin testing if the level of disease appears to have increased.
When a Member State operates a system of identification and registration of bovine animals which provides for identification of herds of origin and transit, if the percentage of infected herds is not greater than 0,1 % on average during the two most recent control periods, it may dispense with the annual tuberculin test of the herds on condition that:
(1) before the introduction into the herd all the bovine animals are subjected to an intradermal tuberculin test with negative results;
(2) all bovine animals slaughtered are examined for lesions of tuberculosis and any such lesions are submitted to a bacteriological examination for evidence of tuberculosis bacteria.
3. The officially tuberculosis-free status of a herd shall be suspended if:
(a) the conditions detailed in 2 have not been complied with;
(b) an animal is deemed to have reacted positively to a routine tuberculin test, or a case of tuberculosis has been diagnosed at routine post-mortem examination.
In these cases, the status shall remain suspended until such time as all the remaining animals over six weeks of age have reacted negatively to at least two official intradermal tuberculin tests in accordance with Annex B, the first one carried out at least two months after elimination of the animal from the holding and the second one at least 42 days after the first.
However, by way of derogation, if during a routine herd test one or more animals react positively to a tuberculin test, and bovine tuberculosis is not considered to be the cause of this reaction, the suspected case(s) of tuberculosis shall be fully investigated, including in particular the tracing and checking of the herd of residence at the time of the test and of any previous herd considered necessary by the competent authority and all examinations including appropriate post-mortem tests and laboratory examinations.
While such examinations take place the officially tuberculosis-free status of the herd referred to shall be suspended until investigations and laboratory examinations or tuberculin tests have ruled out the presence of bovine tuberculosis. If the presence of tuberculosis is not confirmed the status of the herd may be restored.
However, where the routine herd test detailed in 2 (c) has not been performed on time, the status of the herd shall not be suspended provided that the test is carried out not later than 60 days after it was originally due, and provided that subsequent testing takes place according to the original timetable;

(c) the herd contains animals of unresolved status as described in Annex B, point 32. In this case the status of the herd shall remain suspended until the animals' status has been clarified.
4. A Member State or part of a Member State may be declared officially tuberculosis free according to the procedure laid down in Article 17 if it meets the following conditions:
(a) the percentage of infected bovine herds has not been more than 0,01 % for six consecutive years and at least 99,9 % of the herds have been declared officially tuberculosis free for 10 years;
(b) an identification system making it possible to identify the herds of origin and transit for each bovine animal is in existence;
(c) all bovine animals slaughtered must be subjected to a post-mortem examination by an official veterinarian;
(d) all suspected cases of tuberculosis must be fully investigated, including tracing and checking any herds of origin or transit and carrying out all appropriate laboratory examinations. While such examinations take place the officially tuberculosis-free status of the herds of origin or transit shall be suspended until clinical or laboratory examinations or tuberculin tests have ruled out the presence of bovine tuberculosis.
5. The Member State or part of a Member State will retain officially tuberculosis-free status if:
(a) the conditions 4 (a) to (d) continue to apply;
(b) when a case of tuberculosis is confirmed, the officially tuberculosis-free status of the herd of origin and transit is withdrawn;
(c) the officially tuberculosis-free status of herds where tuberculosis has been confirmed remains withdrawn until:
- all the animals that have been deemed to be infected have been slaughtered,
- disinfection of the premises and utensils has taken place,
- all the remaining bovine animals over six weeks of age have reacted negatively to at least two official intradermal tests in accordance with Annex B, the first at least six months after the removal of the infected animals, the second six months after the first.
6. If there is evidence of a significant change in the situation as regards tuberculosis in a Member State or part of a Member State which has been recognized as officially tuberculosis free, the Commission may in accordance with the procedure laid down in Article 17 take a decision suspending or revoking the status and requiring routine tuberculin tests to be carried out in accordance with one of the schedules in 2 (c).

II. Officially brucellosis-free and brucellosis-free bovine herds
For the purposes of this Section 'bovine animals` means all bovine animals with the exception of males castrated before the age of four months.
1. A bovine herd is officially brucellosis free if:
(a) it contains no bovine animals which have been vaccinated against brucellosis, except 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 have been subjected to one of the following test regimes with negative results in accordance with Annex C:
(i) two serum agglutination tests at an interval of more than three months and less than 12 months;
(ii) three ring tests at three-monthly intervals followed at least six weeks later by a serum agglutination test;
(iii) two buffered brucella antigen tests at an interval of more than three months and less than 12 months;
(iv) two micro-agglutination tests at an interval of more than three months and less than 12 months.
2. A bovine herd will retain officially brucellosis-free status if:

(a) one of the following test regimes is carried out annually with negative result in accordance with Annex C:
(i) three ring tests carried out at intervals of at least three months;
(ii) three milk Elisas carried out at intervals of at least three months;
(iii) two ring tests carried out at an interval of at least three months followed at least six weeks later by a serological test;
(iv) two milk Elisas carried out at an interval of at least three months followed at least six weeks later by a serological test;
(v) two serological tests carried out at an interval of at least three months and not more than six months.
However, the Commission, in accordance with the procedure laid down in Article 17, may, for a Member State or part of a Member State which is not officially brucellosis free but where all the bovine herds are subject to official operations to combat brucellosis, alter the frequency of the routine tests as follows:
- where not more than 1 % of bovine herds are infected, it may be sufficient to carry out each year two ring tests or two milk Elisas at an interval of at least three months, or one serological test,
- where at least 99,8 % of bovine herds have been recognized as officially brucellosis free for at least four years, the interval between checks may be extended to two years and the checks must be carried out using one of the serological tests referred to in paragraph 7 (a);
(b) all bovine animals entering the herd come from herds of officially brucellosis-free status and, in the case of bovine animals over 12 months old, have shown a brucella count of less than 30 IU of agglutination per ml when given a serum agglutination test in accordance with Annex C during the 30 days prior to introduction into the herd.
However, the serum agglutination test described in point (b) need not be required in Member States, or regions of Member States, where the percentage of bovine herds infected with brucellosis has not exceeded 0,2 % for at least two years and where the animal comes from an official brucellosis-free bovine herd within that Member State or region and has not during transportation come into contact with bovine animals of lesser status;
(c) notwithstanding point (b), bovine animals from a brucellosis-free bovine herd may be introduced into an officially brucellosis-free herd if they are at least 18 months old and, if vaccinated against brucellosis, the vaccination was carried out more than a year previously. Such animals must have shown, in the 30 days prior to introduction, a brucella count lower than 30 IU of agglutination per ml and a negative result when given a complement fixation test, both in accordance with Annex C.
If, however, a bovine animal from a brucellosis-free herd is introduced into an officially brucellosis-free bovine herd, under these provisions, that herd shall be considered to be brucellosis free for two years from the date on which the animal was introduced.
3. The officially brucellosis-free status of a herd may be suspended or withdrawn if:
(a) the conditions detailed in paragraphs 1 and 2 have not been complied with; or
(b) as a result of laboratory tests or on clinical grounds one or more bovine animals are suspected of having brucellosis.
If one or more bovine animals in an officially brucellosis-free herd are suspected of having brucellosis, the status of the herd may be suspended, rather than withdrawn, if the animal or animals are immediately destroyed or isolated.
Where the animal has been destroyed, the suspension may be lifted if two serum agglutination tests, carried out in accordance with Annex C on all bovine animals in the herd over 12 months old, show a count lower than 30 IU of agglutination per ml. The first test shall be carried out at least 30 days after the removal of the animal and the second at least 60 days later.
Where the animal has been isolated, it may be reintroduced into the herd and the status of the herd may be restored, if it subsequently shows a serum agglutination count lower than 30 IU of

agglutination per ml and has given a negative result to a complement fixation test, these tests being carried out in accordance with Annex C.
Where, as a result of laboratory tests or epidemiological investigations, brucella infection has been confirmed in a herd, the status of that herd shall not be restored until all bovine animals that were pregnant at the time of the outbreak have given negative results to the above tests, the final test having being carried out at least 21 days after calving.
4. A bovine herd is brucellosis free if it complies with the conditions in 1 (a), (b) and (c), except that:
(i) female bovine animals may be vaccinated:
- before the age of six months old with live strain 19 vaccine or other vaccines approved under the procedure laid down in Article 17, or
- before the age of 15 months old with killed 45/20 adjuvant vaccine which has been officially inspected and recognized;
(ii) bovine animals under 30 months old which have been vaccinated with live strain 19 vaccine may give a serum agglutination test result greater than 30 IU but less than 80 IU of agglutination per millilitre provided that, on the complement fixation test, they give a result less than 30 EEC units in the case of females vaccinated less than 12 months previously or less than 20 EEC units in all other cases;
(iii) in addition to those tests listed in 1 (c), the following test regimes will also be approved in order to attain brucellosis-free status;
(a) two buffered brucella antigen tests carried out at an interval of more than three months and less than 12 months;
(b) two micro-agglutination tests carried out at an interval of more than three months and less than 12 months in accordance with the provisions of Annex C.
5. A bovine herd will retain brucellosis-free status if:
(i) it is subject to one of the testing regimes listed in 2 (a);
(ii) bovine animals entering the herd comply with the requirements of 2 (b); or
- come from herds of brucellosis-free status, and in the case of bovine animals over 12 months old, have shown, in the 30 days prior to introduction into the herd, less than 30 IU of agglutination per ml when given a serum agglutination test and a negative complement fixation test in accordance with Annex C, or
- come from herds of brucellosis-free status, are under 30 months old and have been vaccinated with live strain 19 vaccine may give a serum agglutination test result greater than 30 IU but less than 80 IU of agglutination per millilitre provided that, on the complement fixation test, they give a result less than 30 EEC units in the case of females vaccinated less than 12 months previously or less than 20 EEC units in all other cases.
6. The brucellosis-free status of a herd shall be suspended or withdrawn if:
(a) the conditions detailed in paragraphs 4 and 5 have not been complied with; or
(b) as a result of laboratory tests or on clinical grounds one or more bovine animals over 30 months old are suspected of having brucellosis.
If one or more bovine animals, over 30 months old, in a brucellosis-free herd are suspected of having brucellosis, the status of the herd may be suspended, rather than withdrawn, if the animal or animals are immediately destroyed or isolated.
Where the animal has been destroyed, the suspension may be lifted if two serum agglutination tests, carried out in accordance with Annex C on all bovine animals in the holding over 12 months old, show a count lower than 30 IU of agglutination per ml. The first test shall be carried out at least 30 days after the removal of the animal and the second at least 60 days later.
Where the animal has been isolated, it may be reintroduced into the herd and the status of the herd may be restored, if it subsequently shows a serum agglutination count lower than 30 IU of agglutination per ml and has given a negative result to a complement fixation test, these tests being carried out in accordance with Annex C.

Where, as a result of laboratory tests or epidemiological investigations, brucella infection has been confirmed in a herd, the status of that herd shall not be restored until all bovine animals that were pregnant at the time of the outbreak have given negative results to the above tests, the final test having being carried out at least 21 days after calving.
7. A region of a Member State may be declared officially brucellosis free according to the procedure laid down in Article 17 if it meets the following conditions:
(a) no case of abortion due to brucella infection has been recorded for at least three years and at least 99,8 % of the herd have been declared officially brucellosis free for 10 years;
(b) an identification system making it possible to identify the herds of origin and transit for each bovine animal is in existence.
8. Subject to point 9, a region declared officially brucellosis free shall retain this status if all bovine animals over 24 months old are subjected to either two ring tests or one serological test every three years. In the event of a positive result the provisions of point 6 shall apply.
9. A region declared officially brucellosis free shall report the occurrence of all cases of brucellosis to the Commission. The Commission may according to the procedure laid down in Article 17 propose that the status be suspended or revoked and require that routine brucellosis testing be carried out in accordance with one of the schedules in paragraph 2.
10. A Member State may be declared officially brucellosis free according to the procedure laid down in Article 17 if it meets the following conditions:
(a) no case of abortion due to brucella infection has been recorded for at least three years and at least 99,8 % of the holdings have been declared officially brucellosis free for 10 years;
(b) an identification system making it possible to identify the herds of origin and transit for each bovine animal is in existence.
11. A Member State declared officially brucellosis free shall retain this status if:
- every bovine animal suspected of being infected with brucellosis is notified to the competent authority and undergoes official investigation for brucellosis comprising at least two serological blood tests, including the complement fixation test, and a microbiological examination of appropriate samples taken in the case of an abortion,
- during the period of suspicion, which shall continue until negative results have been obtained from the tests provided for in the first indent, the officially brucellosis-free status of the herd of origin or transit of the suspected bovine shall be suspended,
- in the event of a positive result, the provisions of point 6 apply.
12. A Member State declared officially brucellosis free shall report the occurrence of all cases of brucellosis to the Commission. The Commission may, according to the procedure laid down in Article 17, propose that the status be suspended or revoked and require that routine brucellosis testing be carried out in accordance with one of the schedules in paragraph 2.
13. (a) For the purposes of Section II, a serological test shall mean either a serum agglutination test, buffered brucella antigen test, complement fixation test, plasma agglutination test, plasma ring test, micro-agglutination test or individual blood Elisa, as described in Annex C.
(b) Where ring tests are carried out on bulk tanks, the number of those tests referred to in this Annex shall be doubled and the intervals between the tests shall be halved.

ANNEX B

(STANDARDS FOR THE MANUFACTURE AND USE OF BOVINE AND AVIAN TUBERCULINS)
1. Officially supervised tuberculin tests must be carried out with PPD or HCSM tuberculins.
2. Manufacturers' working standards for the control of bovine PPD and HCSM tuberculins must be calibrated in Community tuberculin units (CTU) following biological assay against the

appropriate EEC standard tuberculin.
3. Manufacturers' working standards for the control of avian tuberculins must be calibrated in international units following biological assay against the EEC standard for PPD of avian tuberculin.
4. The EEC standard for PPD of bovine tuberculin is that supplied by the Instituut voor Dierhouderij en Diergezondheid (ID-DLO), Lelystad, The Netherlands.
5. The EEC standard for bovine HCSM tuberculin is that supplied by the Institut Pasteur, Paris, France.
6. The EEC standard for avian tuberculin is that supplied by the Veterinary Laboratory Agency, Addlestone, Weybridge, England.
7. Bovine tuberculins must be prepared with one of the mycobacterium bovis strains indicated below:
(a) AN5;
(b) Vallee.
8. Avian tuberculins must be prepared with one of the mycobacterium avium strains indicated below:
(a) D4ER;
(b) TB56.
9. The pH of tuberculins must be between 6,5 and 7,5.
10. Anti-microbial preservatives or other substances that may be added to a tuberculin shall have been shown, to the satisfaction of the State institute responsible for the official testing of the tuberculin, not to impair the safety and effectiveness of the product.
The following are the maximum permitted concentrations for phenol and glycerol:
(a) phenol: 0,5 % m/v;
(b) glycerol: 10 % v/v.
11. Provided the tuberculins are stored at a temperature between 2 and 8 °C, protected from light, they may be used up to the end of the following periods subsequent to the last satisfactory potency test:
(a) liquid PPD tuberculins: two years,
lyophilized PPD tuberculins: eight years;
(b) HCSM tuberculins diluted: two years.
12. The State institutes listed below shall be responsible for the official testing of tuberculins in their respective countries:
(a) Germany: Paul-Ehrlich Institut, Frankfurt/Main;
(b) Belgium: Instituut Voor Hygiene en Epidemiologie, J. Wytsmanstraat 14, B-1050 Brussels;
(c) France: Laboratoire national des médicaments vétérinaires, Fougères;
(d) Grand Duchy of Luxembourg: institute of the supplying country;
(e) Italy: Istituto superiore di sanità, Rome;
(f) Netherlands: Instituut voor Dierhouderij en Diergezondheid (ID-DLO), Lelystad;
(g) Denmark: Statens Veterinaere Serumlaboratorium, Copenhagen V;
(h) Ireland: institute of the supplying country;
(i) United Kingdom: Veterinary Laboratory Agency, Addlestone, Weybridge;
(j) Greece: ÊÝíôñï Êôçíéáôñéêþí Éäñõìüôùí Íåáðüëåùò 25, 153 10 ÁèÞíá;
(k) Spain: Laboratorio de Sanidad y producción animal de Granada;
(l) Portugal: Laboratorio Nacional de Investigação Veterinária, Lisbon;
(m) Austria: Bundesanstalt für Tierseuchenbekämpfung, Mödling;
(n) Finland: Eläinlääkintä - ja elintarvikelaitos, Helsinki-anstalten för veterinärmedicin och livsmedel, Helsingfors;
(o) Sweden: Statens veterinärmedicinska anstalt, Uppsala.
13. Official testing must be carried out on each batch of bottled tuberculins ready for use.
14. Tuberculins shall be tested by biological and chemical methods.

15. Tuberculins must be sterile. Tests for sterility shall be carried out according to the specifications of the European pharmacopoeia.
16. A test for the absence of toxic or irritant properties shall be carried out according to the specifications of the European pharmacopoeia.
17. Tuberculins must be chemically analyzed to determine the concentration of glycerol and/or phenol and also the concentration of any other preservative which may have been added.
18. A test of non-sensitization to tuberculin must be carried out according to the specifications of the European pharmacopoeia.
19. The potency of tuberculins must be assessed by biological methods. These methods must be used for HCSM and PPD tuberculins; they are based on the comparison with standard tuberculins of the tuberculins to be tested.
20. The protein content of PPD tuberculin must be estimated by the Kjeldahl method. The nitrogen is converted into tuberculo-protein content by multiplying by a factor of 6,25.
21. The EEC standard for bovine HCSM has a potency of 65 000 Community tuberculin units (CTU) per ml and is dispensed in ampoules containing 5 ml of tuberculin.
22. The EEC standard for bovine PPD has a potency of 50 000 Community tuberculin units (CTU) per mg of PPD and is dispensed lyophilized in ampoules containing 1,8 mg of PPD, i.e. 0,00002 mg PPD has a potency equal to one Community tuberculin unit.
23. The EEC standard for avian PPD has a potency of 50 000 international units (IU) per mg of the dried material of the purified protein derivative and is dispensed lyophilized in ampoules containing 10 mg of PPD plus 26,3 mg of salts, i.e. 0,0000726 mg of the standard has a potency equal to one international unit.
24. Tuberculins submitted by manufacturers for testing by the State institutes listed in paragraph 12 must have been tested for potency by biological assay against the appropriate standards as listed in paragraphs 2 and 3.
25. (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 at the time of injection of the tuberculin. Not less than eight guinea-pigs shall be used for each assay. The assay should be made not less than one month after sensitization.
(aa) For the assay of bovine tuberculins, guinea-pigs shall be sensitized by one of the following methods:
(1) the injection of heat-killed mycobacterium bovis strain AN5 in oil adjuvant;
(2) the injection of living mycobacterium bovis strain AN5 in physiological saline;
(3) the injection of BCG vaccine.
(bb) For the assay of avian tuberculins guinea-pigs shall be sensitized by injection of 2 mg of heat-killed avian-type tubercular bacilli suspended in 0,5 ml of sterile liquid paraffin or by the injection of live avian-type tubercular bacilli in physiological saline. The avian-type strain D4 must be used for this purpose.
(cc) Each tuberculin under test shall be assayed against the appropriate standard tuberculin by an intradermal assay using groups of guinea-pigs suitably sensitized.
The hair shall be clipped from both sides of each guinea-pig. The assay shall be carried out by comparing the reactions induced by a series of intracutaneous injections of doses of not more than 0,2 ml of dilutions of the standard tuberculin in isotonic buffered saline solution containing Tween 80, 0,0005 %, with a corresponding series of injections of the tuberculin under test. Dilutions shall be arranged in geometric series, and injected into guinea-pigs according to a randomized latin square design (four sites on each side of an eight-point assay is used). The diameters of the reactions at each site should be measured and recorded after 24 to 28 hours. For each sample of tuberculin under test, an estimate of relative potency against the appropriate standard and its fiducial limits shall be made by statistical methods, using the diameters of the reactions and the logarithms of the doses as metameters. The bovine tuberculin under test is of acceptable potency if its estimated potency guarantees per bovine dose 2 000 Community

tuberculin units (more or less 25 %) in cattle. The potency of each tuberculin under test shall be expressed as appropriate in Community tuberculin units or international units per ml.
(b) Potency testing on cattle
Periodic potency testing of bovine tuberculins may be carried out on naturally or artificially infected tuberculous cattle. These potency tests, on groups of tuberculous cattle, shall be carried out by intradermal four or six-point assay of the tuberculin under test against the appropriate standard and the potency of the tuberculin shall be estimated by statistical methods as in the guinea-pig assay.
26. The following requirements shall apply to the labelling of tuberculin containers and packages.
The label on the containers and the label on the package shall state:
- the name of the preparation,
- for liquid preparations, the total volume in the container,
- the number of Community or international units per ml or per mg,
- the manufacturer's name,
- the batch number,
- the nature and quantity of the reconstituting liquid for the freeze-dried preparation.
The label on the container or the label on the package shall state:
- the expiry date,
- the conditions of storage,
- the name and, if possible, the proportions of any added substance,
- the strain of bacillus from which the tuberculin has been made.
27. Community laboratories designated in accordance with Article 17 will be made responsible for the additional examination of routine issue field tuberculins used in the Member States to ensure that the potency of each of these tuberculins is adequate in relation to the appropriate Community standard tuberculin. These examinations must be carried out, in tuberculous bovine animals, in suitably sensitized guinea-pigs and by appropriate chemical tests.
28. The following shall be recognized as official intradermal tuberculin tests:
(a) the single intradermal test - this test requires a single injection of bovine tuberculin;
(b) the intradermal comparative test - this test requires one injection of bovine tuberculin and one injection of avian tuberculin given simultaneously.
29. The dose of tuberculin injected shall be:
(1) Not less than 2 000 CTU of bovine tuberculin;
(2) Not less than 2 000 IU of avian tuberculin W15;
The volume of each injection dose shall not exceed 0,2 ml.
30. Tuberculin tests shall be carried out by injecting tuberculin(s) into the skin of the neck. The injection sites shall be situated at the border of the anterior and middle thirds of the neck. When both avian and bovine tuberculins are injected in the same animal, the site for injection of avian tuberculins shall be about 10 cm from the crest of the neck and the site for the injection of bovine tuberculin about 12,5 cm lower on a line roughly parallel with the line of the shoulder or on different sides of the neck; in young animals in which there is not room to separate the sites sufficiently on one side of the neck, one injection shall be made on each side of the neck at identical sites in the centre of the middle third of the neck.
31. The technique of tuberculin testing and interpretation of reactions shall be as follows:
(a) Technique
Injection sites shall be clipped and cleansed. A fold of skin within each clipped area shall be taken between the forefinger and thumb and measured with callipers and recorded. A short sterile needle, bevel edge outwards, with graduated syringe charged with tuberculin attached shall be inserted obliquely into the deeper layers of the skin. The dose of tuberculin shall then be injected. A correct injection shall be confirmed by palpating a small pea-like swelling at each site of injection. The skin-fold thickness of each injection site shall be remeasured 72 hours after

injection and recorded.
(b) Interpretation of reactions
The interpretation of reactions shall be based on clinical observations and the recorded increase(s) in skin-fold thickness at the sites of injection 72 hours after injection of tuberculin(s).
(ba) 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 diffuse or extensive oedema, exudation, necrosis, pain or inflammation of the lymphatic ducts in that region or of the lymph nodes.
(bb) Inconclusive reaction: if no clinical signs such as mentioned in (ba) are observed and if the increase in skin-fold thickness is more than 2 mm and less than 4 mm.
(bc) Positive reaction: if clinical signs such as mentioned in (ba) are observed or there is an increase of 4 mm or more in the thickness of the fold of skin at the injection site.
32. The interpretation of official intradermal tuberculin tests shall be as follows:
(a) Single intradermal test:
positive: a positive bovine reaction as defined in paragraph 31 (bc);
inconclusive: an inconclusive reaction as defined in paragraph 31 (bb);
negative: a negative bovine reaction as defined in paragraph 31 (ba).
Animals inconclusive to the single intradermal test shall be subjected to another test after a minimum of 42 days.
Animals which are not negative to this second test shall be deemed to be positive to the test.
Animals positive to the single intradermal test may be subjected to an intradermal comparative test.
(b) Intradermal comparative test for the establishment and maintenance of officially tuberculosis-free herd status:
positive: a positive bovine reaction which is more than 4 mm greater than the avian reaction, or the presence of clinical signs;
inconclusive: a positive or inconclusive bovine reaction which is from 1 to 4 mm greater than the avian reaction, and the absence of clinical signs;
negative: a negative bovine reaction, or a positive or inconclusive bovine reaction but which is equal to or less than a positive or inconclusive avian reaction and the absence of clinical signs in both cases.
Animals inconclusive to the intradermal comparative test shall be subjected to another test after a minimum of 42 days. Animals which are not negative to this second test shall be deemed to be positive to the test.
(c) Officially tuberculosis-free herd status may be suspended and animals from the herd shall not be allowed to enter intra-Community trade until such time as the status of the following animals is resolved:
(1) animals which have been deemed to be inconclusive to the single intradermal tuberculin test;
(2) animals which have been deemed to be positive to the single intradermal tuberculin test but are awaiting retest with an intradermal comparative test;
(3) animals which have been deemed to be inconclusive to the intradermal comparative test.
(d) Where animals are required by Community legislation to be subjected to an intradermal test prior to movement, the test shall be interpreted so that no animal which shows an increase in skin-fold thickness greater than 2 mm or the presence of clinical signs is entered into intra-Community trade.

ANNEX C

BRUCELLOSIS

A. Serum agglutination tests

1. The standard agglutinating serum must conform to the standard serum prepared by the Veterinary Laboratory Agency, Addlestone, Weybridge, 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 serum 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 >600 and 1 000
- if the reading is made at 75 %: between 500 and 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 - R); potato agar should preferably be used.

8. The bacterial emulsion must be made from physiological saline (NaCl 0,85 ‰ phenolized at 0,5 %. 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;
(f) Netherlands: Instituut voor Dierhonderij en Diergezondheid (ID-DLO), Lelystad;
(g) Denmark: Statens Veterinaere Serumlaboratorium, Copenhagen V;
(h) Ireland: Veterinary Research Laboratory, Department of Agriculture and Food, Dublin;
(i) United Kingdom:
- Great Britain: Veterinary Laboratory Agency, Addlestone, Weybridge, England,
- Northern Ireland: Veterinary Research Laboratory, Stormont, Belfast;
(j) Greece: ÊÝíôñï Êôçíéáôñéêþí Éäñõìüôùí Íåáðüëåùò 25, 153 10 ÁèÞíá;
(k) Spain: Centro Nacional de Brucelosis; Laboratorio de Sanidad y Producción Animal de Santa Fé (Granada);
(l) Portugal: Laboratoria Nacional de Investigaçáo Veterinária, Lisbon;
(m) Austria: Bundesanstalt für Tierseuchenbekämpfung, Mödling;
(n) Finland: Eläinlääkintä-ja elintarvikelaitos, Helsinki-anstalten för veterinärmedicin och livsmedel, Helsingfors;
(o) Sweden: Statens veterinärmedicinska anstalt, Uppsala.

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 serum 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

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.
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 haemolysis 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 or on the contents of each bulk tank from the farm.
2. The standard antigen to be used must come from one of the institutes listed in A.9 (a) to (j). It is recommended that the antigens be standardized according to the WHO/FAO recommendations.
3. The antigen may be stained only with haematoxylin or tetrazolium; haematoxylin should preferably be used.
4. If no preservation is used then the reaction test must be carried out between 18 and 24 hours of taking the sample from the cow. If milk is to be tested later than 24 hours after sampling, then preservation must be used; formalin or mercuric chloride may be used as preservatives and if either of these is used the test must be carried out within 14 days of the day of sampling. Formalin may be added to give a final concentration in the milk sample of 0,2 % and, in such cases, the ratio between the amount of milk and the solution of formalin must be at least 10 to 1. A solution of mercuric chloride may be used instead of formalin to give a final concentration in the milk of 0,2 % and, in such cases, the ratio between the amount of milk and the solution of mercuric chloride must be 10 to 1.
5. The reaction must be carried out using one of the following methods:

- on a column of milk at least 25 mm high and on a volume of milk of 1 ml to which 0,03 ml of one of the standardized stained antigens has been added,
- on a column of milk at least 25 mm high and on a volume of milk of 1 ml to which 0,05 ml of one of the standardized stained antigens has been added,
- on a volume of milk of 8 ml to which 0,08 ml of one of the standardized stained antigens has been added,
- on a column of milk at least 25 mm high and on a volume of milk of 2 ml to which 0,05 ml of one of the standardized stained antigens has been added.

6. The mixture of milk and antigens must be incubated at 37 °C for not less than 45 minutes and not more than 60 minutes. The test must be assessed within 15 minutes of removal from the incubator.

7. The reaction must be 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.

D. The buffered brucella antigen test

The buffered brucella antigen test may be carried out using one of the following methods:

(a) Manual test

1. The standard serum shall be the second international standard anti-brucella abortus serum which is supplied by the Veterinary Laboratory Agency, Addlestone, Weybridge, England.

2. The antigen shall be prepared without reference to the cell concentration, but its sensitivity must be standardized in relation to the second international standard anti-brucella abortus serum in such a way that the antigen produces a positive reaction with serum dilution of 1:47,5 and a negative reaction with a dilution of 1:55.

3. The antigen shall be suspended in buffered brucella antigen diluent at a pH of 3,65 ± 0,5 and may have been stained by the use of rose bengal dye.

4. Weybridge strain No 99 or USDA 1119 or any other strain of equivalent sensitivity must be used for preparing the antigen.

5. 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 - R); potato agar medium or continuous culture methods should be used.

6. The antigen shall be tested against eight freeze-dried known positive and negative sera.

7. The official supervision and control of standard serum and antigen shall be carried out by the official bodies listed in A.9 of this Annex.

8. The antigen shall be delivered ready for use.

9. The buffered brucella antigen test shall be carried out in the following manner:

(a) one drop (0,03 ml) of antigen should be placed alongside one drop (0,03 ml) of the serum on a white plate;

(b) they should be mixed with an applicator stick, first in a straight line and then in a circle of about 10 to 12 mm diameter;

(c) the plate should then be rocked back and forth for four minutes (about 30 times per minute);

(d) readings should be taken in a good light; if there is no evidence of agglutination, the test shall be regarded as negative; any degree of agglutination shall be regarded as positive, unless there has been excessive drying round the edges.

(b) Automated method

The automated method must be at least as sensitive and accurate as the manual method.

E. Plasma ring test

(a) Extraction of the plasma

The tube containing blood, coagulation of which has been inhibited by the addition of EDTA, should be centrifuged for three minutes at 3 000 r/min and subsequently kept at 37 °C for 12 to 24 hours.
(b) Evaluation
0,2 ml of stabilized plasma should be placed in a tube with 1 ml of untreated milk. After mixing, one drop (0,05 ml) of ABR antigen should be added and the whole again mixed. The antigen should be standardized in relation to a standard antigen supplied by the body referred to in A.9 (a).
Following an incubation period of 45 minutes at 37 °C, a reading should be taken within 15 minutes. The result shall be regarded as positive if the colour of the ring has become the same as, or darker than, that of the milk column.

F. Plasma agglutination
The plasma extracted in accordance with E (a) may be used immediately after centrifuging, no thermal stabilization being necessary. 0,05 ml of plasma should be mixed with 1 ml of antigen for 50 % serum agglutination, which corresponds to a dilution of 1:20 for serum agglutination. A reading should be taken after 18 to 24 hours incubation at 37 °C. 50 % or more agglutination shall be regarded as positive.

G. Micro-agglutination test
1. Diluents are made up of 0,85 % physiological saline solution phenolized at 0,5 %.
2. The antigen shall be prepared as described under A.6, 7 and 8 and shall be titrated as described under A.5. At the moment the antigen is used, safranin O shall be added at 0,02 % (final dilution).
3. The standard serum is the same as that under A.1.
4. The standard serum must be supplied by the Bundesgesundheitsamt, Berlin.
5. The micro-agglutination test shall be carried out on plates bearing wells with conical bottoms of a volume of 0,250 ml. The test shall be carried out as follows:
(a) predilution of the serum: 0,050 ml of each serum to be tested are added to each well containing 0,075 ml of diluent. The mixtures are shaken for 30 seconds;
(b) gradual serum dilution: prepare at least three dilutions for each serum. To this end from the predilutions (1:2,5) 0,025 ml of each serum is taken and transferred to a well containing 0,025 ml of diluent. In this way the first dilution reaches a strength of 1:5 and the following dilutions are carried out by doubling;
(c) addition of antigen: 0,025 ml of antigen is added to each well containing the different serum dilutions. After being shaken for 30 seconds the plates are closed with their respective lids and kept at 37 °C for 20 to 24 hours in a humidified atmosphere;
(d) reading the results: assessment of the aspect of the sedimentation of the antigen is made by examining the bottom of the well reflected in a concave mirror placed above it. If there is a negative reaction, the antigen forms a sediment in the form of a compact button with clear edges and having an intense red colour. If there is a positive reaction on the other hand, a diffused pink veil is formed that is evenly distributed. The different percentages of agglutination are determined by comparison with antigen checks indicating 0, 25, 50, 75 and 100 % agglutination. The title of each serum is expressed in international units of agglutination per ml. Controls with negative and positive serum diluted so as to contain 30 international units of agglutination per ml should be included in the test.

H. Enzyme-linked immunosorbent assay (Elisa) for detecting bovine brucellosis

1. The material and reagents to be used are as follows:
(a) solid-phase microplates, cuvettes or any other solid phase;
(b) the antigen is fixed to the solid phase with or without the aid of polyclonal or monoclonal catching antibodies;
(c) the biological fluid to be tested;
(d) a corresponding positive and negative control;
(e) conjugate;
(f) a substrate adapted to the enzyme used;
(g) a stopping solution, if necessary;
(h) solutions for the dilution of the test samples for preparations of the reagents and for washing;
(i) a reading system appropriate to the substrate used.
2. Standardization and sensitivity of test
(1) Bulk milk samples are classified negative if they give a reaction less than 50 % of that given by a 1 in 10 000 dilution of the second international brucellosis standard serum made up in negative milk.
(2) Individual serum samples are classified negative if they give a reaction less than 10 % of that given by a 1 in 200 dilution of the second international brucellosis standard serum made up in saline solution or in any other recognized dilution, in accordance with the procedure laid down in Article 17 after receiving the opinion of the Scientific Veterinary Committee.
The brucellosis Elisa standards shall be as specified in A.1 and 2 (to be used at the dilutions indicated on the label).
3. Conditions for use of the Elisa test for bovine brucellosis
The Elisa method may be used on a sample of milk or whey taken from the milk collected from a farm with at least 30 % of dairy cows in milk.
If this method is used, measures must be taken to ensure that the samples taken can be identified with the animals from which the milk or sera examined were taken.
ANNEX D

CHAPTER I OFFICIALLY ENZOOTIC-BOVINE-LEUKOSIS-FREE HERDS, MEMBER STATES AND REGIONS
A. Officially enzootic-bovine-leukosis-free herd means a herd in which:
(i) there is no evidence, either clinical or as a result of a laboratory test, of any case of enzootic bovine leukosis in the herd and no such case has been confirmed in the previous two years; and
(ii) all animals over 24 months of age have reacted negatively during the preceding 12 months to two tests carried out in accordance with this Annex, at an interval of at least four months; or
(iii) it meets the requirements of (i) above and is situated in an officially enzootic-bovine-leukosis-free Member State or region.
B. An individual herd shall retain officially enzootic-bovine-leukosis-free status provided:
(i) the condition in A (i) continues to be fulfilled;
(ii) any animals introduced into the herd come from an officially enzootic-bovine-leukosis-free herd;
(iii) all animals over 24 months of age continue to react negatively to a test carried out in accordance with Chapter II at intervals of three years.
C. The officially leukosis-free status of a herd shall be suspended if the conditions detailed in B are not fulfilled.
D. The status shall remain suspended until the following requirements are complied with:
1. If a single animal in an officially enzootic-bovine-leukosis-free herd has reacted positively to one of the tests referred to in Chapter II:
(i) the animal which has reacted positively, and, in the case of a cow, any calf it may have produced, must have left the herd for slaughter under the supervision of the veterinary authorities;

(ii) the remaining animals have reacted negatively to a serological test carried out in accordance with Chapter II three months at least after removal of the positive animal and any possible progeny thereof;
(iii) an epidemiological inquiry must be conducted and the herds linked epidemiologically to the infected herd must be subjected to the measures laid down in (ii).
However, the competent authority may grant a derogation from the obligation to slaughter the calf of an infected cow where it was separated from its mother after calving. In this case, the calf must be made subject to the requirements provided for in 2 (iii).
2. Where more than one animal from an officially enzootic-bovine-leukosis-free herd has reacted positively or where infection has been confirmed in a herd:
(i) the animals which have reacted positively and, in the case of cows, their calves, must be removed for slaughter under the supervision of the veterinary authorities;
(ii) all animals aged over 24 months must react negatively to two tests carried out in accordance with Chapter II at an interval of at least four months and no more than 12 months;
(iii) all other animals must, after identification, remain on the holding until they are aged over 24 months and have satisfied the tests referred to in (ii);
(iv) an epidemiological inquiry must be conducted, and the herds linked epidemiologically to the infected herd must be subjected to the measures laid down in (ii).
However, the competent authority may grant a derogation from the obligation to slaughter the calf of an infected cow where it was separated from its mother after calving. In this case, the calf must be made subject to the requirements provided for in 2 (iii).
3. Where the officially enzootic-bovine-leukosis-free status of a herd has been suspended for any other reason, all animals in the herd aged over 24 months must give a negative reaction to a serological test carried out in accordance with Chapter II.
E. In accordance with the procedure in Article 17, the Commission may propose that a Member State or region of a Member State may become officially enzootic-bovine-leukosis-free if:
(a) at least 99,8 % of the bovine herds are officially enzootic bovine leukosis free herds within the meaning of A;
or
(b) no case of enzootic bovine leukosis has been confirmed in the Member State or region for the past three years and
in the case of a Member State, all animals aged over 24 months in at least 10 % of herds, selected randomly, have been tested with negative results in accordance with Chapter II in the previous 24 months or
in the case of a region or a Member State, all animals aged over 24 months have undergone a test provided for in Chapter II with negative result.
F. A Member State or a region of a Member State shall retain officially enzootic-bovine-leukosis-free status if:
(i) every year either a random sample with a confidence rating of 99 % has established that less than 0,2 % of the herds were infected or not less than 20 % of bovine animals over two years of age have been tested and have reacted negatively to a test carried out in accordance with Chapter II;
or
(ii) where no case of enzootic bovine leukosis has been recorded in the Member State or region in a proportion of one herd out of 10 000 for at least three years, a decision may be taken in accordance with Article 17 to cease routine serological testing provided that:
- all cattle slaughtered within the territory of that Member State or region are submitted to a post-mortem examination by an official veterinarian who must issue notification of all tumours with a view to laboratory examination, and
- the Member State shall report the occurrence of all cases of enzootic bovine leukosis in the region affected by the decision to the Commission. The Commission may, in accordance with the

procedure laid down in Article 17, propose that the decision to cease routine serological testing be suspended or revoked, and
- any cattle which react positively to an immune-diffusion test are slaughtered and the herd remains subject to restrictions until re-establishment of its status pursuant to Chapter I.D.
G. (i) The officially enzootic-bovine-leukosis-free status of a Member State or region of a Member State shall be suspended, in accordance with the procedure in Article 17, if enzootic bovine leukosis is detected and confirmed in more than 0,2 % of holdings in the region or Member State.
(ii) The officially enzootic-bovine-leukosis-free status may be restored, in accordance with the procedure in Article 17, if:
(a) in addition to the measures provided for in paragraphs D.1 and 2, at least 20 % of the other herds, selected randomly, in the region or Member State have, within a 12-month period, undergone one of the tests referred to in Chapter II;
(b) the results of this testing establish, with a confidence rating of 99 %, that less than 0,2 % of herds are infected.

CHAPTER II TESTS FOR ENZOOTIC BOVINE LEUKOSIS

Tests for enzootic bovine leukosis shall be carried out by the immune-diffusion test under the conditions described in A and B or by the enzyme-linked immunosorbent assay (Elisa) under the conditions described in C. The immune-diffusion method may only be used for individual tests. If test results are the subject of a duly-substantiated challenge, an additional check shall be carried out by means of the immune-diffusion test.

A. Agar gel immune-diffusion test for enzootic bovine leukosis
1. The antigen to be used in the test must contain bovine leukosis virus glycoproteins. The antigen must be standardized against a standard serum (El serum) supplied by the State Veterinary Serum Laboratory, Copenhagen.
2. The official institutes indicated below must be made responsible for calibrating the standard working antigen of the laboratory against the official EEC standard serum (El serum) provided by the State Veterinary Serum Laboratory, Copenhagen.
(a) Germany: Bundesforschungsanstalt für Viruskrankheiten der Tiere, Tubingen;
(b) Belgium: Institut national de recherches vétérinaires, Brussels;
(c) France: Laboratoire national de pathologie bovine, Lyon;
(d) Grand Duchy of Luxembourg:
(e) Italy: Istituto zooprofilattico spenmentale, Perugia;
(f) Netherlands: Instituut voor Dierhouderij en Diergezondheid (ID-DLO), Lelystad;
(g) Denmark: Statens Veterinaere Serum Laboratorium, Copenhagen;
(h) Ireland: Veterinary Research Laboratory, Abbotstown, Dublin;
(i) United Kingdom:
(1) Great Britain: Veterinary Laboratory Agency, Addlestone, Weybridge, England;
(2) Northern Ireland: Veterinary Research Laboratory, Stormont, Belfast;
(j) Spain: Subdirreccion general de sanidad animal. Laboratorio de sanidad y produccion animal Algete, Madrid;
(k) Portugal: Laboratorio Nacional de Investigaçáo Veterinária, Lisbon;
(l) Greece: ÊÝíôñï Êôçíéáôñéêþí Éäñõìüôùí Íåáðüëåùò 25, 153 10 ÁèÞíá; ;
(m) Austria: Bundesanstalt für Tierseuchenbekämpfung, Mödling;
(n) Finland: Eläinlääkintä-ja elintarvikelaitos, Helsinki/Anstalten för veterinärmedicin och livsmedel, Helsingfors;
(o) Sweden: Statens veterinärmedicinska anstalt, Uppsala.
3. The standard antigens used in the laboratory must be submitted at least once a year to the EEC

reference laboratories listed in 2 for testing against the official EEC standard serum. Apart from this standardization, the antigen in use can be calibrated in accordance with B.
4. The reagents for the test shall consist of:
(a) antigen: the antigen must contain specific glycoproteins of enzootic bovine leukosis virus which has been standardized against the official EEC serum;
(b) the test serum;
(c) known positive control serum;
(d) agar gel:
0,8 % agar,
8,5 % NaCl,
0,05 M Tris-buffer pH 7,2;
15 ml of this agar must be introduced into a petri dish of 85 mm diameter, resulting in a depth of 2,6 mm of agar.
5. A test pattern of seven moisture-free wells must be cut in the agar to the bottom of the plate; the pattern must consist of one central well and six wells in a circle around it.
Diameter of central well: 4 mm
Diameter of peripheral wells: 6 mm
Distance between central and peripheral wells: 3 mm
6. The central well must be filled with the standard antigen. Peripheral wells 1 and 4 (see diagram below) are filled with the known positive serum, wells 2, 3, 5 and 6 with the test sera. The wells must be filled until the meniscus disappears.
7. This results in the following quantities being obtained:
antigen: 32 ìl
control serum: 73 ìl
test serum: 73 ìl.
8. Incubation must be for 72 hours at room temperature (20 to 27 °C) in a closed humid chamber.
9. The test may be read at 24 and 48 hours but a final result may not be obtained before 72 hours:
(a) a test serum is positive if it forms a specific precipitin line with the BLV antigen and forms a complete line of identity with the control serum;
(b) a test serum is negative if it does not form a specific precipitin line with the BLV antigen and if it does not bend the line of the control serum;
(c) the reaction cannot be considered conclusive if it:
(i) bends the line of the control serum towards the BLV antigen well without forming a visible precipitin line with the antigen;
or
(ii) if it cannot be read either as negative or as positive.
In inconclusive reactions the test may be repeated and concentrated serum utilized.
10. Any other well configuration or pattern may be utilized provided that the E4 serum diluted 1:10 in negative serum can be detected as positive.

B. Method for antigen standardization

Solutions and materials required
1. 40 ml of 1,6 % agarose in 0,05 M Tris/HCl buffer, pH 7,2 with 8,5 % NaCl;
2. 15 ml of a bovine leukosis serum, having antibody only to bovine leukosis virus glycoproteins, diluted 1:10 in 0,05 M Tris/HCl buffer, pH 7,2 with 8,5 % NaCl;
3. 15 ml of a bovine leukosis serum, having antibody only to bovine leukosis virus glycoproteins, diluted 1:5 in 0,05 M Tris/HCl buffer, pH 7,2 with 8,5 % NaCl;
4. four plastic petri dishes with a diameter of 85 mm;
5. a punch with a diameter of 4 to 6 mm;
6. a reference antigen;

7. the antigen which is to be standardized;
8. a water bath (56 °C).

Procedure
Dissolve the agarose (1,6 %) in the Tris/HCl buffer by carefully heating to 100 °C. Place in 56 °C water bath for approximately one hour. Also, place the bovine leukosis serum dilutions in a 56 °C water bath.
Now mix 15 ml of the 56 °C agarose solution with the 15 ml bovine leukosis serum (1:10), quickly shake and pour 15 ml into each of two petri dishes. Repeat this procedure with the bovine leukosis serum diluted 1:5.
When the agarose has hardened, holes are made in it as follows:

Addition of antigen
(i) Petri dishes 1 and 3:
well A - undiluted reference antigen,
well B - 1:2 diluted reference antigen,
wells C and E - reference antigen,
well D - undiluted test antigen.
(ii) Petri dishes 2 and 4:
well A - undiluted test antigen,
well B - 1:2 diluted test antigen,
well C - 1:4 diluted test antigen,
well D - 1:8 diluted test antigen.

Additional instructions
1. The experiment shall be carried out with two serum dilutions (1:5 and 1:10) in order to achieve optimal precipitation
2. If the precipitation diameter is too small with both dilutions, then the serum must be further diluted.
3. If the precipitation diameter in both dilutions is too large and faint, then a lower serum must be chosen.
4. The final concentration of the agarose must be 0,8 %; that of the sera 5 and 10 % respectively.
5. Plot the measured diameters in the following coordinate system. The dilution of the antigen to be tested with the same diameter as the reference antigen is the working dilution.

C. Enzyme-linked immunosorbent assay (Elisa) for detecting enzootic bovine leukosis
1. The material and reagents to be used are as follows:
(a) solid-phase microplates, cuvettes or any other solid phase;
(b) the antigen is fixed to the solid phase with or without the aid of polyclonal or monoclonal catching antibodies. If antigen is coated directly to the solid phase, all test samples giving positive reactions have to be retested against control antigen in the case of EBL. The control antigen should be identical to the antigen except for the BLV antigens. If catching antibodies are coated to the solid phase, the antibodies must not react to antigens other than BLV antigens;
(c) the biological fluid to be tested;
(d) a corresponding positive and negative control;
(e) conjugate;
(f) a substrate adapted to the enzyme used;
(g) a stopping solution, if necessary;
(h) solutions for the dilution of the test samples for preparations of the reagents and for washing;
(i) a reading system appropriate to the substrate used.
2. Standardization and sensitivity of test

The sensitivity of the Elisa assay must be of such a level that E4 serum is scored positive when diluted 10 times (serum samples) or 250 times (milk samples) more than the dilution obtained of individual samples when these are included in pools. In assays where samples (serum and milk) are tested individually E4 serum diluted 1 to 10 (in negative serum) or 1 to 250 (in negative milk) must be scored positive when tested in the same assay dilution as used for the individual test samples. The official institutes listed in A.2 will be responsible for checking the quality of the Elisa method, and in particular for determining, for each production batch, the number of samples to be pooled on the basis of the count obtained for the E4 serum.
The E4 serum will be supplied by the National Veterinary Laboratory, Copenhagen.
3. Conditions for use of the Elisa test for EBL
The Elisa method may be used on a sample of milk or whey taken from the milk collected from a farm with at least 30 % of dairy cows in milk.
If this method is used, measures must be taken to ensure that the samples taken can be identified with the animals from which the milk or sera examined were taken.

ANNEX E (I)

(a) Bovine diseases
- Foot-and-mouth disease
- Rabies
- Tuberculosis
- Brucellosis
- Contagious bovine pleuropneumonia
- Enzootic bovine leukosis
- Anthrax

(b) Swine diseases
- Rabies
- Brucellosis
- Classical swine fever
- African swine fever
- Foot-and-mouth disease
- Swine vesicular disease
- Anthrax

ANNEX E (II)
- Aujeszky's disease
- Infectious bovine rhinotracheitis
- Brucella suis infection
- Transmissible gastro-enteritis

ANNEX F
>START OF GRAPHIC>
BOVINE SPECIES/SWINE FOR SLAUGHTER/BREEDING/PRODUCTION (1)
Certificate No: . Species: . Member State of origin: . Region of origin: .
SECTION A
Name and address of consignor: .

.
Name and address of holding of origin: .
. (2)
Dealer's registration number: . (1)
Health data concerning bovine animals
I certify that the animals listed below are from a herd or herds which is officially tuberculosis, brucellosis and leukosis free and that (3):
- the herd of origin is situated in a Member State or part of the territory of a Member State which is recognized as being:
1. officially tuberculosis free: yes/no Commission Decision . . . /. . . /. . . (1) 2. officially brucellosis free: yes/no Commission Decision . . . /. . . /. . . (1) 3. officially leukosis free: yes/no Commission Decision . . . /. . . /. . . (1) - the Member State or part of the territory of a Member applies a system of surveillance networks:
Commission Decision . . . /. . . /. . . (1)
- the animals listed below have been tested with negative results during the 30 days prior to departure from the holding in accordance with Article 6 (2) of Directive 64/432/EEC, as follows:
Date of test Tuberculin test (animals of over six weeks): yes/not required: . (1) Serum agglutination test for brucellosis (except castrated animals or those under 12 months of age): yes/not required: . (1) Test for leukosis (animals over 12 months of age): yes/not required: . (1)
- are animals for slaughter (1)
- are animals for slaughter from herds which are not officially tuberculosis, brucellosis and leukosis free, originating from a holding in Spain (1) (4); the animals listed below have been tested with negative results during the 30 days before departure from the holding of origin, as follows:
Date of test Tuberculin test: . (1) Serum agglutination test for brucellosis: . (1) Test for leukosis: . (1)
SECTION B
Identification of the animal Total number of animals: . . . . . .
Race: . . . . . Type: . . . . . Age: . . . . . .
. . . . . Official identification: . . . . . .
Date of departure: .
Section A and B certification
Official stamp
ML01 L109/97
Signature of the official veterinarian: . of the holding of origin, or in the case of a Member State which has introduced a surveillance network system, signature of the approved veterinarian of the holding of origin (1): . Name (in capitals): . Date: .
SECTION C
Approved assembly centre (1)
Name of centre: .
Address: .
Registration number: .
Arrival date: .
Departure date: . Signature/stamp
SECTION D
Destination of animals: .
Name and address of consignor: .
.
Name and address of destination holding: .
. (1)
Name and address of transit centre: .

. (1)
Means of transport: . Approval number: . After inspection as required by regulations, I certify that:
1. on . . . . . (date) the animals in question had been inspected during the 24 hours before departure and had shown no clinical signs of infectious or contagious disease;
2. all applicable provisions in Council Directive 64/432/EEC have been fulfilled;
3. the movement proposed has been registered by the Animo system on the day of issue;
4. the above animal(s) meet(s) the additional guarantees for . . . . .