COMMISSION OF THE EUROPEAN COMMUNITIES

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Brussels, 7 January 1994

Proposal for a

COUNCIL DIRECTIVE

amending and updating Directive 64/432/EEC
on health problems affecting intra-Community trade
in bovine animals and swine

(presented by the Commission)

EXPLANATORY MEMORANDUM

Recently, Community legislation has been adopted to control Foot and Mouth disease, Exotic diseases, and African Swine Fever. It is therefore no longer appropriate to retain control provisions for these diseases in Directive 64/432/EEC which deals with intra-Community trade in live pigs and bovines. It is necessary to remove these sections from Directive 64/432/EEC and make reference to the relevant control Directive.

In the light of the Single Market, it is necessary to remove the requirement that animals undergo a minimum residency period of six months in a Member State prior to each movement. In addition, calves aged under 15 days should be brought within the scope of the Directive and references to frontier posts should be removed.

The requirement to carry out premovement tests on animals moving from countries or regions recognised as free of Tuberculosis, Brucellosis and Enzootic Bovine Leukosis and to carry out mastitis tests on dairy cows should also be removed as a further step towards the Single Market.

The Directive has been amended on over forty occasions since 1964 and it is now appropriate that it be updated. The opportunity has also been taken to simplify and clarify the provisions of the Directive.

The attached proposal is designed to accomplish these objectives.

There are no financial repercussions on the Community budget involved.

Proposal

for a

Council Directive

of

amending and updating Directive 64/432/EEC

on health problems affecting intra-Community trade

in bovine animals and swine

THE COUNCIL OF THE EUROPEAN UNION,

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

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 harmonisation of the veterinary field; in particular the Council has adopted Directive 90/425/EEC of 26 June 1990 concerning veterinary and zootechnical checks applicable in intracommunity 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 organisation of veterinary checks on animals entering the Community from third countries[5], Directive 85/511/EEC of 18 November 1985 introducing Community measures for the control of foot and mouth disease[6] and Directive 92/117/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];

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1 OJ No C

2 OJ No C

3 OJ No C

4 OJ No L 224, 18.08.1990, p.29

5 OJ No L 268, 24.09.1991, p.56

6 OJ No L 315, 26.11.1985, p.11

7 OJ No L 62, 15.03.1993, p.69

Whereas it is necessary, in the light of this situation, to modify Council Directive 64/432/EEC[8] of 26 June 1964 on health problems affecting intra-Community trade in bovine animals and swine, as last amended by Council Directive 92/102/EEC[9] of 5 December 1992, in particular concerning the period of residence in a Member State prior to movement, rules for trade in animals aged under 15 days and rules for control of certain diseases;

Whereas Directive 64/432/EEC has been substantially amended on several occasions; that it is thus advisable for the sake of clarity and rationality to bring the Directive up-to-date.

HAS ADOPTED THIS DIRECTIVE:

Article 1

Directive 64/432/EEC is hereby replaced by the text in Annex I to this Directive.

Article 2

Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with this Directive not later than 1 July 1994. They shall forthwith inform the Commission thereof.

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

Article 3

This directive is addressed to the Member States.

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8 OJ No L 121, 29.07.1964, 1977/64

9 OJ No L 355, 5.12.1992, p.32

ANNEX I

Article 1

This directive shall apply to intra-community trade in bovine animals and swine.

Article 2

For the purposes of this directive :

(a) **holding** : shall mean a holding as defined in Article 2 of Council Directive 90/425/EEC.

(b) **animal for slaughter** :
means a bovine animal (including the species Bubalus bubalus) or swine intended to be taken to a slaughterhouse or market from which it may only move to slaughter;

(c) **animals for breeding or production** :
means bovine animals (including the species Bubalus bubalus) and swine other than those referred to in (b), including those intended for breeding, milk or meat production, or draft purposes;

(d) **officially tuberculosis-free bovine holding** :
means a bovine holding which satisfies the conditions laid down in Annex A.I 1,2 and 3;

(e) **officially tuberculosis-free Member State or part of a Member State** :
means a Member State or part of a Member State which satisfies the conditions laid down in Annex A.I 4,5 and 6;

(f) **officially brucellosis-free bovine holding** :
means a bovine holding which satisfies the conditions laid down in Annex A II 1,2 and 3.;

(g) **officially brucellosis-free Region** :
means a part of a Member State which satisfies the conditions laid down in Annex A II 7,8 and 9.;

(h) **officially brucellosis-free Member State** :
means a Member State which satisfies the conditions laid down in Annex A II 10,11 and 12.;

(i) **brucellosis-free bovine holding** :
means a bovine holding which satisfies the conditions laid down in Annex A II 4,5 and 6;

(j) **Enzootic bovine leucosis free holding** :
means a holding which satisfies the conditions laid down in Annex D, Chapter 1, Sections A and B.

(k) **enzootic bovine 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 designated by the competent central authority of the Member State;

Article 3

1. Each Member State shall ensure that only animals that fulfil the conditions laid down in this Directive, where applicable, 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 a health examination and identity check 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 affecting the species involved in accordance with Community or National legislation.

(c) be identified as provided for in Council Directive 92/102/EEC;

(d) not be animals which are to be slaughtered under a contagious or infectious disease eradication programme of a Member State.

(e) comply with the provisions of Article 4 and Article 5.

Article 4

1. Bovine animals and swine covered by this directive must not, at any time from leaving the holding of origin to arrival at the destination in another Member State, come in contact with cloven hoofed animals other than animals that fulfil the conditions for intracommunity trade.

2. Bovine animals and swine covered by this directive must be transported in means of transport which have first been cleansed and disinfected with a disinfectant officially authorized in the Member State of Origin. The transport vehicles must be so arranged that the animals' faeces, litter or fodder cannot flow or fall out of the vehicle during transportation.

3. Rules for the approval of sites where disinfection may be carried out and the procedures necessary to ensure and verify compliance with the requirements of paragraph 3 above shall be determined in accordance with the provisions of Article 12.

Article 5

1. Bovine animals and swine covered by this directive must be accompanied during transportation to the destination by a health certificate conforming to Annex F. The certificate shall consist of a single sheet and shall contain a serial number. It shall be drawn up on the day of the health examination, 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. However, where the health examination takes place after leaving the holding of origin, as provided for in paragraph 2 below, the certificate shall be valid for 10 days after leaving the holding of origin.

2. The health examination and the issuing of the health certificate for a consignment of animals may be carried out in the holding of origin or at the point of loading. In the latter case, the certifying official veterinarian must have been provided with the evidence issued by the official veterinarian for the holding of origin either comprising an official document containing the necessary information or in the form of the certificate contained in Annex F with Sections A and B duly completed and certified. The address of any interim location such as an approved market or approved assembly point (part C) must also be completed by the official veterinarian responsible for the holding of origin.

3. The official veterinarian responsible for the interim location shall certify arrival of the animals there and where applicable complete the final intracommunity certification (Annex F, Part D). Where animals do not enter an interim location the final intracommunity certification shall be completed by the official veterinarian responsible for the holding of origin.

4. The official veterinarian completing Annex F, part D shall be responsible for registering the movement on the ANIMO system.

5. Interim locations used in intracommunity trade such as markets or assembly centres must;

a. be supervised by an official veterinarian who shall ensure that, in particular, the provisions of Article 4.1 and Article 4.2 are complied with and who shall provide the necessary certification referred to above. The official veterinarian's duties may be further specified by a decision taken under the procedure in Article 12

b. be located in an area which is not subject to prohibition in accordance with Community legislation

c. be cleaned before use and disinfected, as required by the official veterinarian responsible for the premises.

d. be designated as approved markets and assembly centres by the Member State of origin. Such approval may be limited to a particular species or to animals for breeding and production or to animals for slaughter. The Member State shall notify the competent central authorities of the other Member States and the Commission as to which markets or assembly centres are approved.

6. The interim location may also be an officially approved market located in a Member State which is not 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 market shall provide certification to the animals 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 or to a copy of the original certificate.

Article 6

1. Animals for breeding or production must, in addition to the requirements in Articles 3,4 and 5:

   - have remained in the holding of origin for a period of 30 days prior to loading or since birth where the animals are aged less than 30 days. The official veterinarian must, on the basis of the official identification provided for in Article 3.2c and official records be satisfied that the animals have complied with this condition and furthermore that the animals have originated in the Community or been imported from a Third Country in compliance with Community animal health legislation.

   - Animals imported from a third country into a Member State which is not that of ultimate destination, must be transported to the Member State of destination as quickly as practicable under cover of certification issued under Article 7 of Council Directive 91/496/EEC. Upon arrival at the destination, such animals must, as regards any further movements submit to the requirements of this directive and in particular to the residency requirement in the first indent.

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 holding 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 recognised as Officially Tuberculosis Free.

(b) in the case of non castrated animals come from an officially brucellosis-free bovine holding and if more than 12 months old, have shown a brucella count lower than 30 international units of agglutination per millilitre when given a sero-agglutination test carried out during the 30 days prior to leaving the herd of origin and complying with the provisions of Annex C paragraph A;

This seroagglutination test is not required if the animals originate in a Member State or part of a Member State recognised as Officially Brucellosis Free.

(c) come from an enzootic bovine leucosis free holding within the meaning of Article 2 (g);

(d) not, at any time from leaving the holding of origin to arrival at the destination, come in contact with animals which only meet the requirements in Article 6.3 below.

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, enzootic bovine leucosis free and in the case of uncastrated bovines, from herds that are officially brucellosis free.

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, in accordance with animal health requirements.

Animals for slaughter which have been taken on arrival in the Member State of destination to a market, under whose rules all animals must be removed after the market to a slaughterhouse approved for this purpose by the competent central authority, must be slaughtered at that slaughterhouse not later than five days after arriving at the market.

Article 8

Any person or persons suspecting the presence of one of the diseases listed in Annex E(I) shall notify the competent authority and, where appropriate, inform the owner or keeper of the animals as soon as possible.

Each Member State shall forward to the Commission by 31 May each year details of the occurrence of tuberculosis, brucellosis and enzootic bovine leucosis in its territory in the previous calender year and details of the numbers of herds in each status category for each disease along with information on the monitoring or eradication programmes in operation in each region. The content and format of the information required shall be determined by the Commission. The Commission shall present this information to the Member States in the framework of the Standing Veterinary Committee and in particular may utilise it in relation to the decisions mentioned in Annex A and Annex D.

Article 9

1. A Member State which proposes 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 12. 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 12. 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 12. 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 as laid down in paragraph 2 may, in the light of such notification, be amended or withdrawn in accordance with the procedure laid down in Article 12.

Article 11

The Annexes to this Directive may be modified in accordance with the procedure detailed in Article 12

In derogation to the provisions of this Directive, specific conditions for trade in animals for special purposes, and in particular for show purposes, may be determined in accordance with the procedure in Article 12.

Article 12

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

2. Within the committee the votes of Member States shall be weighted as provided in Article 148(2) of the treaty. The chairman shall not vote.

3. The representative of the Commission shall submit a draft of the measures to be adopted. The committee shall deliver its opinion on such measures within a time limit set by the chairman according to the urgency of the matters concerned. Opinions shall be delivered by a majority of 54 votes.

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

The Council shall adopt the measures by a qualified majority.

If, within three months from the date on which the proposal was submitted to it, the Council has not adopted any measures, the Commission shall adopt the proposed measures and apply them immediately.

Article 13

1. Where the procedure laid down in this Article is to be used, matters shall without delay be referred by the chairman, either on his own initiative or at the request of a Member State, to the standing veterinary committee (hereinafter called the " committee ") set up by the Council decision of 15 October 1968.

2. Within the committee the votes of the Member States shall be weighted as provided in Article 148 (2) of the treaty. The chairman shall not vote.

3. The representative of the Commission shall submit a draft of the measures to be adopted. The committee shall deliver its opinion on such measures within two days. Opinions shall be delivered by a majority of 54 votes.

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

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

Article 14

The rules laid down in Council Directive 90/425/EEC of 26 June 1990 concerning veterinary and zootechnical checks in intra-Community trade in certain live animals and products with a view to the completion of the internal market, as last amended by Council Directive 92/60/EEC of 30 June 1992[10] 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 15

This directive is addressed to the Member States.

10 OJ No L 268 24.09.92 p 75

ANNEX A

I. OFFICIALLY TUBERCULOSIS-FREE BOVINE HOLDING

1. **A bovine holding 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 holding and the second six months later or in the case 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 mentioned in (b) above, no bovine animal aged over six weeks has been introduced into the holding 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 it's introduction into the holding.

This test shall not be necessary in Member States where the percentage of bovine holdings infected with tuberculosis is less than 0.2% and where the animal originates in an Officially Tuberculosis Free holding.

2. **A bovine holding will retain Officially Tuberculosis Free status if**:

(a) the conditions detailed in 1.(a) and 1.(c) continue to apply

(b) all animals entering the holding come from holdings of the Officially Tuberculosis Free status.

(c) all animals in the holding, with the exception of calves aged under six weeks 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 12, may, for a Member State or part of a Member State where all the bovine holdings are subject to official operations to combat tuberculosis, alter the frequency of the routine tests as follows;

if the percentage of bovine holdings infected with tuberculosis is not more than 1% on average during the two most recent annual supervisory periods, the interval between routine holding tests may be increased to two years;

if the percentage of infected bovine holdings 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 holdings 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 13, take a decision increasing the frequency of routine tuberculin testing if the level of disease appears to have increased.

3. The Officially Tuberculosis free status of a holding shall be suspended if;

(a) the conditions detailed in 2 above 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 where the routine holding test detailed in 2(c) above has not been performed on time, the status of the holding 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 holding contains animals of unresolved status as described in Annex B point 32. In this case the status of the holding 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 in Article 12 if it meets the following conditions;**

a. the percentage of infected bovine holdings has not been more than 0,01% for 6 consecutive years and at least 99.9% of the holdings 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 4.d above continue to apply

   b. when a case of tuberculosis is confirmed, the officially tuberculosis free status of the holding of origin and transit is withdrawn.

   c. the Officially Tuberculosis free status of holdings 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 recognised as Officially Tuberculosis Free, the Commission may in accordance with Article 13 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.d above.

II. OFFICIALLY BRUCELLOSIS FREE AND BRUCELLOSIS FREE BOVINE HOLDINGS

For the purposes of this Annex A.II "bovine animals" means all bovine animals with the exception of males castrated before the age of four months.

1. **A bovine holding 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 seroagglutination tests at an interval of more than three months and less than twelve months

(ii) three ring tests at three monthly intervals followed at least six weeks later by a seroagglutination test

(iii) two buffered brucella antigen tests at an interval of more than three months and less than twelve months

(iv) two micro-agglutination tests at an interval of more than three months and less than twelve months.

2. **A bovine holding 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 ELISA's 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 ELISA's 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 in Article 12, may, for a Member State or part of a Member State which is not Officially Brucellosis Free but where all the bovine holdings are subject to official operations to combat brucellosis, alter the frequency of the routine tests as follows;

- where not more than 1% of bovine holdings are infected, it may be sufficient to carry out each year two ring tests or two milk Elisa at an interval of at least three months, or one serological test.

- where at least 99.8 % of bovine holdings 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) below.

(b) all bovine animals entering the holding come from holdings 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 sero-agglutination test in accordance with Annex C during the 30 days prior to introduction into the holding:

However the sero-agglutination test described above need not be required in Member States, or Regions of Member States, where the percentage of bovine holdings infected with brucellosis has not exceeded 0,2 % for at least two years and where the animal comes from an official brucellosis-free bovine holding within that Member State or Region and has not during transportation come into contact with bovine animals of lesser status.

(c) Notwithstanding 2b above, bovine animals from a Brucellosis Free bovine holding may be introduced into an Officially Brucellosis Free holding 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 holding is introduced into an Officially Brucellosis Free bovine holding, under these provisions, that holding 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 holding may be suspended or withdrawn if;**

(a) the conditions detailed in paragraphs 1 and 2 above 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 holding are suspected of having brucellosis, the status of the holding 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 sero-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 holding and the status of the holding may be restored, if it subsequently shows a sero-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 holding, the status of that holding 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 holding is Brucellosis Free if it complies with the conditions in 1a, 1b, and 1c, 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 12 or,
- before the age of 15 months old with killed 45/20 adjuvant vaccine which has been officially inspected and recognised;

(ii) bovine animals aged under 30 months which have been vaccinated with live strain 19 vaccine may give a serum agglutination test result greater than 30 i.u. but less than 80 i.u. 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 holding will retain Brucellosis Free status if**:

(i) it is subject to one of the testing regimes listed in 2(a) above

(ii) bovine animals entering the holding comply with the requirements of 2(b) above or

- come from holdings 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 holding, less than 30 iu of agglutination per ml when given a sero-agglutination test and a negative complement fixation test in accordance with Annex C or,

- come from holdings of Brucellosis Free status, be aged under 30 months and have been vaccinated with live strain 19 vaccine may give a serum agglutination test result greater than 30 i.u. but less than 80 i.u. 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 holding shall be suspended or withdrawn if:

(a) the conditions detailed in paragraph 4 and paragraph 5 above have not been complied with or

(b) as a result of laboratory tests or on clinical grounds one or more bovine animals aged over 30 months are suspected of having brucellosis

If one or more bovine animals, aged over 30 months, in an Brucellosis Free holding are suspected of having brucellosis, the status of the holding 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 sero-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 holding and the status of the holding may be restored, if it subsequently shows a sero-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 holding, the status of that holding 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 in Article 12 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

8. Subject to point 9 below, 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 above 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 in Article 13 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 above.

10. A Member State may be declared Officially Brucellosis Free according to the procedure in Article 12 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 including at least two serological blood tests including the complement fixation test as well as 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 above 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 in Article 13 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 above.

13.(a) For the purposes of this Annex A.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 Centraal Diergeneeskundig Instituut, Afdeling Rotterdam, 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 Central Veterinary Laboratory, Weybridge, Surrey, 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. Antimicrobial 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 enepidemiologie, J.Wytsmanstraat 14, B-1050 Brussels;

(c) France : Laboratoire national des medicaments veterinaires, Fougeres;

(d) Grand Duchy of Luxembourg : Institute of the supplying country;

(e) Italy: Istituto superiore di sanita, Rome;

(f) Netherlands: Centraal diergeneeskundig instituut, afdeling Rotterdam;

(g) Denmark: Statens Veterinaere Serumlaboratorium, Copenhagen V;

(h) Ireland: institute of .he supplying country;

(i) United Kingdom: Central Veterinary Laboratory, Weybridge, Surrey.

(J) Greece :

(k) Spain : Laboratorio de Sanidad y produccion Animal de Granada

(l) Portugal : Laboratorio Nacional de Investigacao Veeterinaria - Lisboa

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 (i.u.) per mg of the dried material of the purified protein derivative and is dispensed in the lyophilized in ampoules containing 10mg 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 pig

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 sensitised 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 2000 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 the procedure in Article 12 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 bovines, 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.WI5

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 calipers 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 pealike 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 increases(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 4mm.

(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 holding status :

positive : a positive bovine reaction which is more than 4mm 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 holding status may be suspended and animals from the holding 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 2mm or the presence of clinical signs is entered into intracommunity trade.

ANNEX C

BRUCELLOSIS

A. Serum agglutination tests

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

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

2. The standard serum must be that supplied by the Bundesgesundheitsamt, Berlin.

3. The degree of brucella agglutination in a serum must be expressed in iu per ml (i.e. Serum x = 80 iu/ml).

4. Readings of slow sero-agglutination in tubes must be taken at 50 or at 75% agglutination, the antigen used having been titrated under identical conditions against the standard serum.

5. The agglutinating value of various antigens in relation to standard serum must be within the following limits :

   - if the reading is made at 50 % : between 1/600 and 1/1000,

   - if the reading is made at 75 % : between 1/500 and 1/750.

6. Weybridge strain no 99 and USDA 1119 or any other strain of equivalent sensitivity must be used for preparing the antigen for use in tube agglutination (slow method).

7. The culture media used for keeping the strain in the laboratory and for producing the antigen must be such that they do not encourage bacterial dissociation (s minus r); potato agar should preferably be used.

8. The bacterial emulsion must be made from physiological saline (NaCl 8,5%) phenolized at 5 %. Formol must not be used.

9. The official institutes indicated below must be made responsible for the official testing of antigens :

(a) Germany: Bundesgesundheitsamt, Berlin;

(b) Belgium: Institut national de recherches veterinaires, Brussels;

(c) France: Laboratoire central de recherches veterinaires, Alfort;

(d) Grand Duchy of Luxembourg : Institute of the supplying country;

(e) Italy: Istituto superiore di sanita, Rome;

(f) Netherlands : Centraal Diergeneeskundig Instituut, Afdeling, Rotterdam

(g) Denmark: Statens Veterinaere Serumlaboratorium, Copenhagen v.;

(h) Ireland: Veterinary Research Laboratory, Department of Agriculture and Food, Dublin;

(i) United Kingdom :

- Great Britain : the Central Veterinary Laboratory, Weybridge,Surrey, England,
- Northern Ireland : Veterinary Research Laboratory, Stormont,Belfast.

(j) Greece :

(k) Spain : Centro Nacional de brucelosis de Murcia

(l) Portugal: Laboratoria Nacional de Investigacao Veterinaria - Lisboa

10. Antigens may be delivered in the concentrated state provided the dilution factor to be used is indicated on the bottle label.

11. In order to carry out a sero-agglutination test, at least three dilutions must be prepared for each serum. Dilutions of suspect serum must be made in such a way that the reading of the reaction at the infection limit is made in the median tube. If there is a positive reaction in this tube, the suspect serum contains at least 30 iu of agglutination per ml.

B. Complement fixation reaction test

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 paragraph a.9 (a) to (j). It is recommended that the antigens should 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 are used the test must be carried out within the following 14 days after 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 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 Central Veterinary Laboratory, Weybridge, Surrey, 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 more or less 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 Annex C (a) (9).

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 having been inhibited by the addition of edta, should be centrifuged for three 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 % sero-agglutination, which corresponds to a dilution of 1 : 20 for sero-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 points 6, 7 and 8 of Annex C (a) and shall be titrated as described under point 5 of Annex C (a). 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 point 1 of Annex C (a). 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) one takes 0,025 ml of each serum and transfers them 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. There should be included in the test, controls with negative and positive serum diluted so as to contain 30 international units of agglutination per ml.

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 12 after receiving the opinion of the Scientific Veterinary Committee.

The brucellosis Elisa standards shall be as specified in Annex C, A. 1 and A.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

ENZOOTIC BOVINE LEUCOSIS FREE HOLDINGS, MEMBER STATES AND REGIONS

A. A holding is an Enzootic Bovine Leucosis Free holding if:

(i) there is no evidence, either clinical or as a result of a laboratory test, of any case of enzootic bovine leucosis in the holding 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 enzootic bovine leucosis free Member State or region.

B. An individual holding shall retain Enzootic Bovine Leucosis Free status if:

(i) the condition in paragraph A(i) continues to be fulfilled.

(ii) any animals introduced into the holding must come from an enzootic bovine leucosis free holding

(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 Leucosis Free Status of a holding shall be suspended if the conditions detailed in B above have not been complied with.

D. The status shall remain suspended until the following requirements are complied with:

1. If a single animal in an enzootic bovine leucosis free holding 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 holding 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 enquiry must be conducted and the holdings linked epidemiologically to the infected holding 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) below.

2. Where more than one animal from an Enzootic Bovine Leucosis Free holding has reacted positively or where infection has been confirmed in a holding:

(i) the animals which have reacted positively and their calves, in the case of cows, 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 4 months and less 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) above.

(iv) an epidemiological enquiry must be conducted, and the holdings linked epidemiologically to the infected holding must be subjected to the measures laid down in (ii) above.

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 Enzootic Bovine Leucosis Free status of a holding has been suspended for any other reason, all animals in the holding 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 12, the Commission may propose that a Member State or Region of a Member State may become Enzootic Bovine Leucosis Free if:

(a) at least 99,8 % of the bovine holdings are enzootic bovine leucosis free holdings within the meaning of A above,

or

(b) no case of enzootic bovine leucosis 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 Enzootic Bovine Leucosis 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 holdings 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 leucosis has been recorded in the Member State or Region in a proportion of one holding out of 10 000 for at least three years, a decision may be taken in accordance with Article 12 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 leucosis in the area affected by the decision to the Commission. The Commission may according to the procedure in Article 12 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 holding remains subject to restrictions until re-establishment of its status pursuant to Annex D, Chapter I, D.

G. (i) The Enzootic Bovine Leucosis Free status of a Member State or Region of a Member State shall be suspended, in accordance with the procedure in Article 12, if enzootic bovine leucosis is detected and confirmed in more than 0.2% of holdings in the region or Member State.

(ii) The Enzootic Bovine Leucosis Free status may be restored, in accordance with the procedure in Article 12, if;

a. in addition to the measures provided for in paragraphs D.1 and D.2 above, at least 20% of the other holdings, 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 not less than 0.2% of holdings are infected.

ANNEX D

CHAPTER II

TESTS FOR ENZOOTIC BOVINE LEUCOSIS

Tests for enzootic bovine leucosis shall be carried out by the immune-diffusion test under the conditions described in points A and B below or by the enzyme-linked immunosorbent assay (Elisa) under the conditions described in point C below. 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 leucosis

1. The antigen to be used in the test must contain bovine leucosis virus glycoproteins. The antigen must be standardized against a standard serum (EI 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 (EI serum) provided by the State Veterinary Serum Laboratory, Copenhagen.

(a) Germany: Bundesforschungsanstalt fur Viruskrankheiten der Tiere, Tubingen

(b) Belgium: Institut national de recherches veterinaires, Bruxelles

(c) France: Laboratoire national de pathologie bovine, Lyon

(d) Grand Duchy of Luxembourg:--

(e) Italy: Istituto Zooprofilattico Spenmentale, Perugia

(f) Netherlands: Centraal Diergeneeskundig Instituut, Afdeling Rotterdam

(g) Denmark: Statens Veterinaere Serum Laboratorium, Copenhagen

(h) Ireland: Veterinary Research Laboratory, Abbotstown, Dublin

(i) United Kingdom:

1. Great Britain: The Central Veterinary Laboratory, Weybridge,England

2. Northern Ireland: The 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 Investigacao Veterinaria, Lisboa

(l) Greece:

3. The standard antigens used in the laboratory must be submitted at least once a year to the EEC reference laboratories listed in paragraph 2 above 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 leucosis 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,

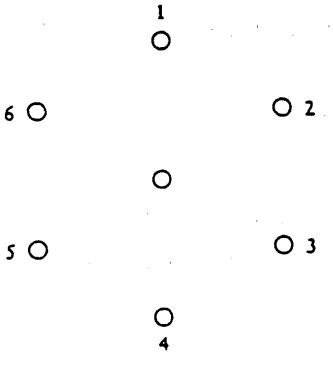
15 ml of this agar must be introduced into a petri dish of 85 mm diameter, resulting in a depth of 2,6 mm of agar.

5. A test pattern of seven moisture-free wells 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.The peripheral wells 1 and 4 (see diagram below) are filled with the known positive serum, the 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 μl
control serum:	73 μl
test serum:	73 μl

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 utilised 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. 10 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 leucosis serum, having antibody only to bovine leucosis 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 leucosis serum, having antibody only to bovine leucosis 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.

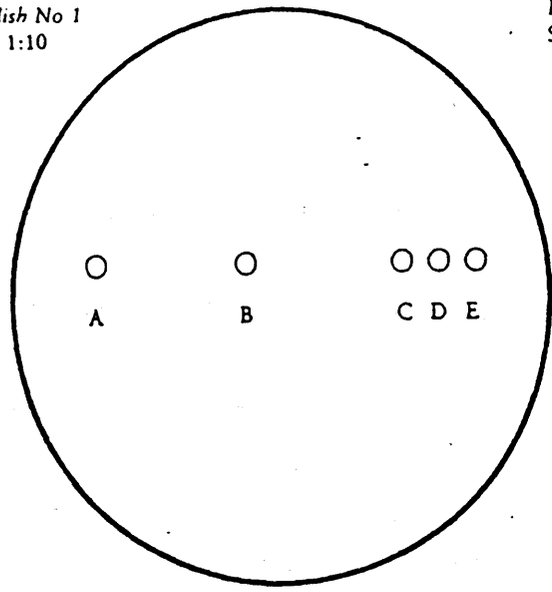
8. A water bath (56 °C).

Procedure:
Dissolve the agarose(1,6%) in the Tris/HCl buffer by carefully heating to 100°C. Place in 56 °C waterbath for approximately one hour. Also, place the bovine leucosis serum dilutions in 56°C water bath.
Now, mix 15 ml of the 56°C agarose solution with the 15ml bovine leucosis serum (1:10),quickly shake and pour 15 ml into each of two petri dishes.

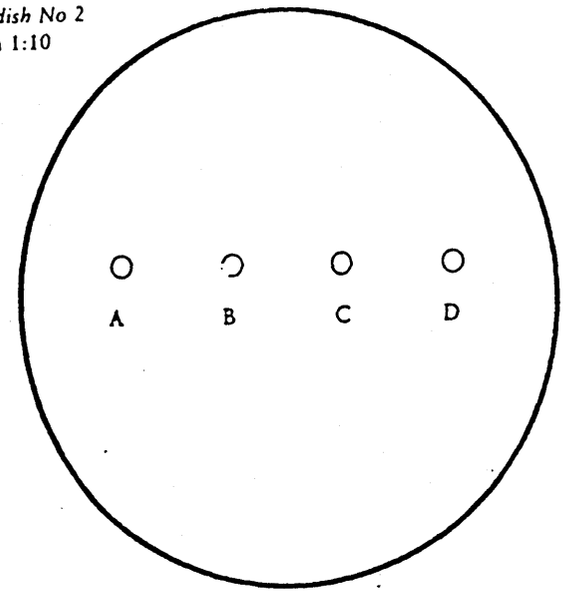
Repeat this procedure with the bovine leucosis serum diluted 1:5.

When the agarose has hardened, holes are made in it as follows:

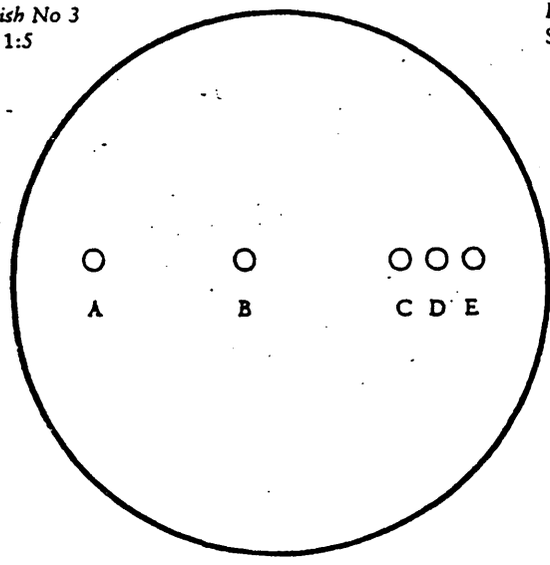
Petri dish No 1
Serum 1:10



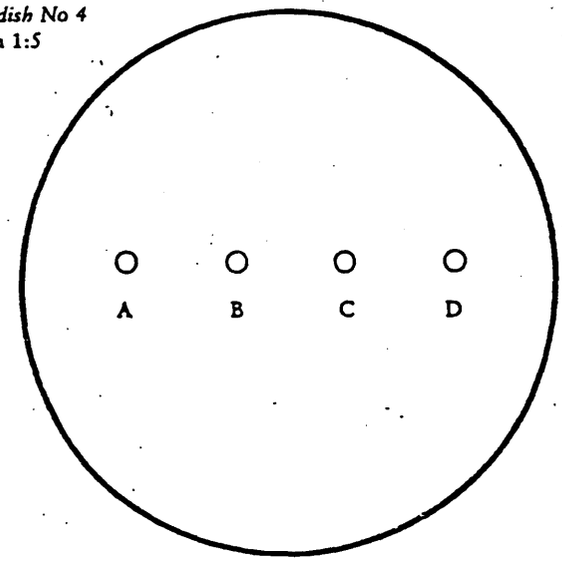
Petri dish No 2
Serum 1:10



Petri dish No 3
Serum 1:5



Petri dish No 4
Serum 1:5



Addition of antigen:

(i). Petri dishes 1 and 3

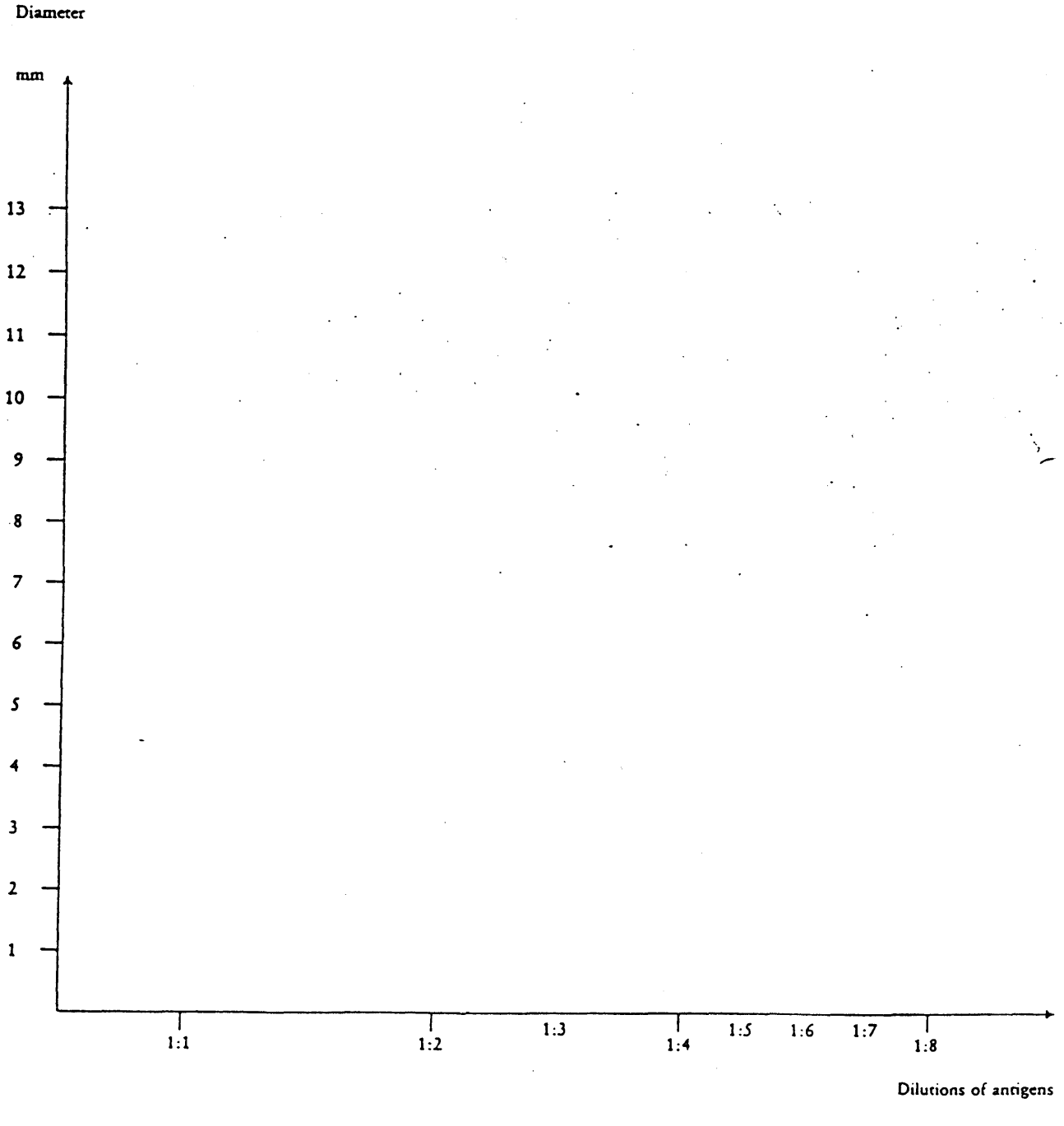
well A - undiluted reference antigen,
well B - 1:2 diluted reference antigen,
wells C and E - reference antigen,
well D - undiluted antigen to be tested.

(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 leucosis.

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 indicated in point A.2 will be responsible for checking the quality of the Elisa method, and in particular to determine, 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 :

- Rabies,
- Tuberculosis,
- Brucellosis,
- Contagious Bovine Pleuropneumonia,
- Enzootic Bovine Leucosis

(b) swine diseases :

- Rabies,
- Brucellosis

ANNEX E(II)

- Aujeszky's Disease
- Infectious Bovine Rhinotracheitis
- Brucella suis infection

CERT NO _____ SPECIES bovine/swine for slaughter/breeding/production

MEMBER STATE of origin _____ REGION OF ORIGIN _____

A

HOLDING OF ORIGIN

Name _____

ref number _____

address _____

_____

_____

The holding of origin is;

officially tuberculosis free yes/no
officially brucellosis free yes/no
Brucellosis free yes/no
leucosis free. yes/no

DATE OF DEPARTURE ____.___.____

The animals listed below have been tested in compliance with Directive 64/432/EEC as follows;

		TEST DATE
tuberculin test	yes/not required	__.__.__
brucellosis SAT	yes/not required	__.__.__
leucosis test	yes/not required	__.__.__

Signed Official veterinarian, holding of origin

B

ANIMAL IDENTIFICATION total animals _____

Breed	type	age	official identification

C

APPROVED MARKET

Location _____

Address _____

_____

_____

date _____ ref no _____

Signature/stamp

LOADING/ASSEMBLY POINT

Location _____

Address _____

_____

_____

date _____ ref no _____

D

CONSIGNEE _____

Address _____

_____

_____

INTRACOMMUNITY TRADE

Means of transport _____
Identification _____

Following due enquiry, I certify that (1) all applicable provisions of Council Directive 64/432/EEC have been complied with.
(2) The proposed movement has been registered on ANIMO.
(3)The animal(s) listed above comply with the additional guarantees for _____ disease for _____(species/type) destined to _____ (Com. Decision __/___/EEC)

signed _____ date _____

date health examination ____.____.____
expiry date of this cert. ____.____.____

Name block capitals _____

ANNEX II

CORRELATION TABLE

Updated Directive	Directive 64/432/EEC
Article 1	Article 1
Article 2.(a)	---
Article 2.(b)	Article 2.(b)
Article 2.(c)	Article 2.(c)
Article 2.(d)	Article 2.(d)
Article 2.(e)	---
Article 2.(f)	Article 2.(e)
Article 2.(g)	---
Article 2.(h)	---
Article 2.(i)	Article 2.(f)
Article 2.(j)	Article 2.(s)
Article 2.(k)	Article 2.(t)
Article 2.(l)	Article 2.(l)
Article 3.1	Article 3.1
Article 3.2.(a)	Article 3.2.(a)
Article 3.2.(b)	Article 3.2.(b)
Article 3.2.(c)	Article 3.2.(e)
Article 3.2.(d)	Article 3.5
Article 3.2.(e)	---
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Article 4.2	Article 3.2.(g)
Article 4.3.	---
Article 5	---
Article 6.1, first indent	Article 3.2.(d)
Article 6.1, second indent	---
Article 6.2.(a), 1st sub-paragraph	Article 3.3.(a)
Article 6.2.(a), 2nd sub-paragraph	---
Article 6.2.(b), 1st sub-paragraph	Article 3.3.(b)
Article 6.2.(b), 2nd sub-paragraph	---
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Article 6.2.(d)	Article 3.2.(f)(ii)
Article 6.3.	---
Article 7	Article 6
Article 8	---
Article 9	Article 9
Article 10	Article 10
Article 11	---
Article 12.1.	Article 12.1.
Article 12.2.	Article 12.2.
Article 12.3.	Article 12.3.

Updated Directive	Directive 64/432/EEC
Article 12.4., 1st sub-paragraph	Article 12.4., 1st sub-paragraph
Article 12.4., 2nd sub-paragraph	Article 12.4., 2nd sub-paragraph
Article 12.4., 3rd sub-paragraph	---
Article 13.1.	Article 13.1.
Article 13.2.	Article 13.2.
Article 13.3.	Article 13.3.
Article 13.4., 1st sub-paragraph	Article 13.4., 1st sub-paragraph
Article 13.4., 2nd sub-paragraph	---
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