COUNCIL DIRECTIVE 98/46/EC

of 24 June 1998

amending Annexes A, D (Chapter I) and F to 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 Council Directive 64/432/EEC of 26 June 1964 on health problems affecting intra-Community trade in bovine animals and swine [1], and in particular Article 16(1)(a) thereof,

Having regard to the proposal from the Commission [2],

Having regard to the opinion of the European Parliament [3],

Whereas in Article 16 of Directive 64/432/EEC the Commission has been requested to make proposals to amend Annexes A, D (Chapter I) and F to the said Directive, in particular with regard to their adaptation to technological developments;

Whereas in the same Article it is stipulated that the Council is to decide on these proposals by a qualified majority before 1 January 1998;

Whereas in recent times the development of veterinary administrative procedures regarding herd management, animal movement control, animal identification and information handling in relation to disease control requires amendments to be made to certain Annexes to Directive 64/432/EEC,

HAS ADOPTED THIS DIRECTIVE:

Article 1

Annexes A, D (Chapter I) and F to Directive 64/432/EEC are hereby replaced by the Annexes 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 1999. 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 reference shall be laid down by 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 Luxembourg, 24 June 1998.

For the Council

The President

J. CUNNINGHAM

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[1] OJ 121, 29. 7. 1964, p. 1977/64. Directive as last amended by Directive 97/12/EC (OJ L 109, 25. 4. 1997, p. 1).
[2] OJ C 266, 3. 9. 1997, p. 4, and OJ C 337, 7. 11. 1997, p. 1.
[3] OJ C 14, 19. 1. 1998, p. 58.

ANNEX I

'ANNEX A

I. **Officially tuberculosis-free bovine herd**

For the purposes of this section 'bovine animals' means all bovine animals with the exception of animals taking part in cultural or sporting events.

1. A bovine herd is officially tuberculosis-free if:

   (a) all the animals are free from clinical signs of tuberculosis;

   (b) all the bovine 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; in the latter case the animal(s) must be isolated physically from the other animals of the herd in a way to avoid any direct or indirect contact with the other animals until proven negative.

   However, the competent authority may not require this test to be carried out for movements of animals on its own territory if the animal is from an officially tuberculosis-free herd, except in a Member State where, on 1 January 1998 and until the status of officially tuberculosis-free region is obtained, the competent authority required such tests to be carried out for animals moving between herds participating in a network system as referred to in Article 14.

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 on 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 competent authority of a Member State may, for the Member State or part of the Member State where all the bovine herds are subject to an official programme to combat tuberculosis, alter the frequency of the routine tests as follows:

   — if the average — determined at 31 December of each year — of the annual percentages of bovine herds confirmed as infected with tuberculosis is not more than 1 % of all herds within the defined area during the two most recent annual supervisory periods, the interval between routine herd tests may be increased to two years and male animals for fattening within an isolated epidemiological unit may be exempted from tuberculin testing provided that they come from officially tuberculosis-free herds and that the competent authority guarantees that the males for fattening will not be used for breeding and will go direct for slaughter,

   — if the average — determined at 31 December of each year — of the annual percentages of bovine herds confirmed as infected with tuberculosis is not more than 0,2 % of all herds within the defined area during the two most recent biennial supervisory periods, the interval between routine tests may be increased to three years and/or the age at which animals have to undergo these tests may be increased to 24 months,

   — if the average — determined at 31 December of each year — of the annual percentages of bovine herds confirmed as infected with tuberculosis is not more than 0,1 % of all herds within the defined area during the two most recent supervisory triennial periods, the interval

between routine tests may be increased to four years, or, providing the following conditions are met, the competent authority may dispense with tuberculin testing of the herds:

(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 histopathological and bacteriological examination for evidence of tuberculosis.

The competent authority may also, in respect of the Member State or a part thereof, increase the frequency of tuberculin testing if the level of the disease has increased.

3A. The officially tuberculosis-free status of a herd is to be suspended if:

(a) the conditions detailed in paragraph 2 are no longer fulfilled;

or

(b) one or more animals are deemed to have given a positive reaction to a tuberculin test, or a case of tuberculosis is suspected at post-mortem examination.

When an animal is considered to be a positive reactor it will be removed from the herd and slaughtered. Appropriate post-mortem, laboratory and epidemiological examinations shall be carried out on the positive reactor or the carcase of the suspect animal. The status of the herd will remain suspended until such time as all laboratory examinations have been completed. If the presence of tuberculosis is not confirmed, the suspension of the officially tuberculosis-free status may be lifted following a test of all animals over six weeks of age with negative results at least 42 days after the removal of the reactor animal(s);

or

(c) the herd contains animals of unresolved status as described in Annex B. In this case, the status of the herd is to remain suspended until the animals' status has been clarified. Such animals must be isolated from the other animals of the herd until their status has been clarified, either by a further test after 42 days or by post-mortem and laboratory examination;

(d) however, by way of derogation from the requirements of paragraph (c), in a Member State where the competent authority carries out routine herd testing using the comparative tuberculin test described in Annex B, and in the case of a herd where no confirmed reactor animals have been disclosed for at least three years, the competent authority may decide not to restrict the movement of other animals in the herd, provided that the status of any inconclusive reactors is resolved by a further test after 42 days and that no animals from the holding are allowed to enter into intra-Community trade until the status of any inconclusive reactors has been resolved. If at this further test any animal either gives a positive reaction or continues to give an inconclusive reaction, then the conditions of paragraph (b) apply. If the presence of disease is subsequently confirmed, all animals leaving the holding since the time of the last clear herd test must be traced and tested.

3B. The officially tuberculosis-free status of the herd is to be withdrawn if the presence of tuberculosis is confirmed by the isolation of *M. bovis* on laboratory examination.

The competent authority may withdraw status if:

(a) the conditions detailed in point 2 are no longer fulfilled, or

(b) classical lesions of tuberculosis are seen at post-mortem examination, or

(c) an epidemiological enquiry establishes the likelihood of infection,

(d) or for any other reasons considered necessary for the purpose of controlling bovine tuberculosis.

Tracing and checking is to be undertaken by the competent authority of any herd considered to be epidemiologically related. The officially tuberculosis-free status of a herd is to remain withdrawn until cleansing and disinfection of the premises and utensils has been completed and all animals over six weeks of age have reacted negatively to at least two consecutive tuberculin tests, the first no less than 60 days and the second no less than four months and no more than 12 months after the removal of the last positive reactor.

4. On the basis of information supplied in accordance with Article 8, 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 bovine herds confirmed as infected with tuberculosis has not exceeded 0,1 % per year of all herds for six consecutive years and at least 99,9 % of herds have achieved officially tuberculosis-free status each year for six consecutive years, the calculation of this latter percentage to take place on 31 December each calendar year;

(b) an identification system making it possible to identify the herds of origin and transit for each bovine animal is in existence in accordance with Regulation (EC) No 820/97 [1];

(c) all bovine animals slaughtered are subjected to an official post-mortem examination;

(d) the procedures for suspension and withdrawal of officially tuberculosis-free status are complied with.

5. The Member State or part of a Member State will retain officially tuberculosis-free status if the conditions 4(a) to (d) continue to be met. However, 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 the procedure laid down in Article 17, take a Decision suspending or revoking the status until the requirements of the Decision have been fulfilled.

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 for fattening provided that they come from officially brucellosis-free herds and that the competent authority guarantees that the males for fattening will not be used for breeding and will go direct for slaughter.

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 serological tests specified in paragraph 10 at an interval of more than three months and less than 12 months;

(ii) three tests on milk samples at three-monthly intervals followed at least six weeks later by a serological test specified in paragraph 10;

(d) any bovine animal entering the herd comes from a herd of officially brucellosis-free status and, in the case of bovine animals over 12 months old, has shown a brucella titre of less than 30 IU of agglutination per ml when given a serum agglutination test in accordance with Annex C or has reacted negatively to any other test approved in accordance with the procedure at Article 17 during the 30 days prior to or the 30 days after the date of its introduction into the herd: in the latter case, the animal(s) must be isolated physically from the other animals of the herd in such a way as to avoid direct or indirect contact with the other animals until proven negative.

2. A bovine herd will retain officially brucellosis-free status if:

(a) one of the following test regimes is carried out annually with negative results in accordance with Annex C:

(i) three milk 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 milk ring tests carried out at an interval of at least three months followed at least six weeks later by a serological test referred to in paragraph 10;

(iv) two milk ELISAs carried out at an interval of at least three months followed at least six weeks later by a serological test referred to in paragraph 10;

(v) two serological tests carried out at an interval of at least three months and not more than 12 months.

[1] Council Regulation (EC) No 820/97 of 21 April 1997 establishing a system for the identification and registration of bovine animals and regarding the labelling of beef and beef products (OJ L 117, 7. 5. 1997, p. 1).

However, the competent authority of a Member State may, for the Member State or part of the Member State which is not officially brucellosis-free but where all the bovine herds are subject to an official programme 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 milk 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 recognised as officially brucellosis-free for at least four years, the interval between checks may be extended to two years if all animals over 12 months of age are tested, or testing may be restricted to animals over 24 months of age if herds continue to be tested each year. The checks must be carried out using one of the serological tests referred to in paragraph 10;

(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 titre of less than 30 IU of agglutination per ml when given a serum agglutination test in accordance with Annex C or have reacted negatively to any other test approved in accordance with the procedure at Article 17 during the 30 days prior to or the 30 days after the date of their introduction into the herd; in the latter case, the animal(s) must be isolated physically from the other animals of the herd in such a way as to avoid direct or indirect contact with the other animals until proven negative.

However, the 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 officially 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 titre lower than 30 IU of agglutination per ml and a negative result when given a complement fixation test, or other test approved under the procedure set out in Article 17.

If, however, a female bovine animal from a brucellosis-free herd is introduced into an officially brucellosis-free herd, under the provisions of the above paragraph, that herd shall be considered to be brucellosis-free for two years from the date on which the last vaccinated animal was introduced.

3A. The officially brucellosis-free status of a herd is to be suspended if:

(a) the conditions detailed in paragraphs 1 and 2 are no longer fulfilled; or

(b) as a result of laboratory tests or on clinical grounds one or more bovine animals is suspected of having brucellosis and the suspect animals have been slaughtered or isolated in a way to avoid any direct or indirect contact with the other animals.

Where the animal has been slaughtered and is no longer available for testing, 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 titre 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 from the animals in the herd, it may be reintroduced into the herd and the status of the herd may be restored following:

(a) a serum agglutination test which has shown a titre lower than 30 IU of agglutination per ml and has given a negative result to a complement fixation test, or

(b) a negative result to any other combination of tests approved for that purpose under the procedure set out in Article 17.

3B. The officially brucellosis-free status of the herd is to be withdrawn if, as a result of laboratory tests or epidemiological investigations, brucella infection has been confirmed in the herd.

The status of the herd is not to be restored until either all bovine animals present in the herd at the time of the outbreak have been slaughtered, or the herd has been subject to check testing and all animals over 12 months of age have given negative results to two consecutive tests at 60-day intervals, the first being carried out not less than 30 days after removal of the positive animal(s).

In the case of bovine animals which were pregnant at the time of the outbreak, the final check must be carried out at least 21 days after the last animal pregnant at the time of the outbreak has calved.

4. A bovine herd is brucellosis-free if it complies with the conditions in 1(b) and (c) and when vaccination has been carried out as follows:

(i) female bovine animals have been vaccinated:

— before the age of six months old with live strain 19 vaccine, or

— before the age of 15 months old with killed 45/20 adjuvant vaccine which has been officially inspected and approved, or

— with other vaccines approved under the procedure laid down in Article 17;

(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.

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 or in isolation after introduction into the herd, less than 30 IU of agglutination per ml when given a serum agglutination test and a negative result to a 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 if they 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.

6A. The brucellosis-free status of a herd is to be suspended 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 is suspected of having brucellosis and the animal(s) under suspicion have been slaughtered, or isolated in a way to avoid any direct or indirect contact with other animals.

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 titre lower than 30 IU of agglutination per ml and has given a negative result to a complement fixation test, or other test approved under the procedure set out in Article 17.

Where the animals have been slaughtered and are no longer available for testing, 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 titre lower than 30 IU of agglutination per ml. The first test is to be carried out at least 30 days after the removal of the animal and the second at least 60 days later.

If the animals to be tested in the previous two subparagraphs are under 30 months old and have been vaccinated with live strain 19 vaccine they may be considered to be negative if they 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.

6B. The brucellosis-free status of the herd is to be withdrawn if, as a result of laboratory tests of epidemiological investigations, brucella infection has been confirmed in a herd. The status of the herd is not to be restored until either all the bovine animals present in the herd at the time of the outbreak have been slaughtered or the herd has been subject to check testing and all unvaccinated animals over 12 months of age have given negative results to two consecutive tests at 60 day intervals, the first being carried out not less than 30 days after removal of the positive animal(s).

If all the animals to be tested referred to in the preceding paragraph are less than 30 months old and have been vaccinated with live strain 19 vaccine, they may be considered negative if they show a brucella titre of more than 30 IU but less than 80 IU of agglutination per ml, provided that in the complement fixation test they show a titre of less than 30 EEC units in the case of females vaccinated less than 12 months previously or a titre of less than 20 EEC units in all other cases.

In the case of bovine animals which were pregnant at the time of the outbreak, the final check must have been carried out at least 21 days after the last animal pregnant at the time of the outbreak has calved.

7. A Member State or 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 and no isolation of *B. abortus* has been recorded for at least three years and at least 99,8 % of herds have achieved officially brucellosis-free status each year for five consecutive years, the calculation of this percentage to take place on 31 December each calendar year. However, where the competent authority adopts a policy of whole herd slaughter, isolated incidents shown by epidemiological enquiry to be due to the introduction of animals from outside the Member State or part of the Member State and herds whose officially brucellosis-free status has been suspended or withdrawn for reasons other than suspicion of disease, is to be disregarded for the purpose of the above calculation provided that the central competent authority of the Member State concerned by these incidents makes an annual record and forwards them to the Commission in accordance with Article 8(2), and

(b) an identification system making it possible to identify the herds of origin and transit for each bovine animal is in existence in accordance with Regulation (EC) No 820/97, and

(c) notification of cases of abortion is mandatory and they are investigated by the competent authority.

8. Subject to paragraph 9, a Member State or a region of a Member State declared officially brucellosis-free is to retain this status if:

(a) the conditions imposed by paragraph 7(a) and (b) are still fulfilled and notification of cases of abortion suspected of being due to brucellosis is mandatory and are investigated by the competent authority;

(b) every year for the first five years after attaining status, all bovine animals over 24 months of age in not less than 20 % of herds have been tested and have reacted negatively to a serological test carried out in accordance with Annex C or, in the case of dairy herds, by examination of milk samples in accordance with Annex C;

(c) every bovine animal suspected of being infected with brucellosis is notified to the competent authority and undergoes official epidemiological investigation for brucellosis comprising at least two serological blood tests, including the complement fixation test, and a microbiological examination of appropriate samples;

(d) during the period of suspicion, which is to continue until negative results have been obtained from the tests provided for in (c), the officially brucellosis-free status of the herd of origin or transit of the suspected bovine animal and of the herds linked epidemiologically to it is to be suspended;

(e) in the event of an outbreak of brucellosis that has spread, all bovine animals have been slaughtered. Animals of the remaining susceptible species will undergo appropriate tests and premises and equipment will be cleaned and disinfected.

9. A Member State or a region of a Member State declared officially brucellosis-free is to report the occurrence of all cases of brucellosis to the Commission. If there is evidence of a significant change in the situation as regards brucellosis in a Member State or part of a Member State which has been recognised as officially brucellosis-free, the Commission may according to the procedure laid down in Article 17 propose that the status be suspended or revoked until the requirements of the Decision have been fulfilled.

10. For the purposes of section II, a serological test means 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. Any other diagnostic test approved under the procedure laid down in Article 17 and described in Annex C will also be accepted for the purposes of section II. A milk test means a milk ring test or a milk ELISA in accordance with Annex C.

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. A 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;

(iv) breeding animals introduced into a herd and originating from a third country have been imported in accordance with Directive 72/462/EEC.

C. The officially leukosis-free status of a herd is to be suspended if the conditions detailed in B are not fulfilled, or where as a result of laboratory tests or on clinical grounds one or more bovine animals are suspected of having enzootic bovine leukosis and the suspect animal(s) are immediately slaughtered.

D. The status is to 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, or where infection is otherwise suspected in one animal in a herd:

(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) all animals in the herd more than 12 months old have reacted negatively to two serological tests (at least 4 months and less than 12 months apart) 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 has been conducted with negative results and the herds linked epidemiologically to the infected herd have been 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 immediately 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 to one of the tests referred to in Chapter II, or where infection has otherwise been suspected in more than one animal in a herd:

(i) any 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 in the herd aged over 12 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 in the herd must, after identification, remain on the holding until they are aged over 24 months and have been tested in accordance with Chapter II after reaching that age, except that the competent authority may permit such animals to go directly for slaughter under official supervision;

(iv) an epidemiological inquiry has been conducted with negative results and any herd linked epidemiologically to the infected herd has been 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 immediately after calving. In this case, the calf must be made subject to the requirements provided for in 2(iii).

E. In accordance with the procedure in Article 17 and on the basis of information supplied in accordance with Article 8, a Member State or part of a Member State may be considered officially enzootic-bovine-leukosis-free if:

(a) all the conditions of paragraph A are fulfilled and at least 99,8 % of the bovine herds are officially enzootic-bovine-leukosis-free;

or

(b) no case of enzootic bovine leukosis has been confirmed in the Member State or the part of the Member State for the past three years, and the presence of tumours suspected of being due to EBL is compulsorily notifiable, with investigations of cause being carried out, and

in the case of a Member State, all animals aged over 24 months in at least 10 % of the 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 part of a Member State, all animals aged over 24 months have undergone a test provided for in Chapter II with negative results in accordance with Chapter II in the previous 24 months;

or

(c) any other method which demonstrates to a confidence rating of 99 % that less than 0,2 % of herds were infected.

F. A Member State or a region of a Member State is to retain officially enzootic-bovine-leukosis-free status if:

(a) all animals slaughtered within the territory of that Member State or region are submitted to official post-mortem examinations at which all tumours which could be due to the EBL virus are sent for laboratory examination,

(b) the Member State reports to the Commission all cases of enzootic bovine leukosis that occur in the region,

(c) all animals which react positively to any of the tests provided for in Chapter II are slaughtered and their herds remain subject to restrictions until re-establishment of their status in accordance with Section D, and

(d) all animals more than two years old have been tested, either once in the first five years after the status is granted under Chapter II or during the first five years after the grant of the status under any other procedure demonstrating with a certainty level of 99 % that less than 0,2 % of herds have been infected. However, where no case of enzootic bovine leukosis has been recorded in a Member State or in a region of a Member State in a proportion of one herd out of 10 000 for at least three years, a decision may be taken in accordance with the procedure laid down in Article 17 that routine serological tests may be reduced provided that all bovine animals more than 12 months old in at least 1 % of herds, selected at random each year, have been subjected to a test carried out in accordance with Chapter II.

G. The officially enzootic-bovine-leukosis-free status of a Member State or part of a Member State is to be suspended, in accordance with the procedure in Article 17 if, as a result of investigations carried out in accordance with paragraph F above, there is evidence of a significant change in the situation as regards enzootic bovine leukosis in a Member State or part of a Member State which has been recognised as officially enzootic-bovine-leukosis-free.

The officially enzootic-bovine-leukosis-free status may be restored in accordance with the procedure in Article 17 when the criteria laid down by the same procedure are fulfilled.

ANNEX F

Model 1

HEALTH CERTIFICATE FOR ANIMALS OF THE BOVINE SPECIES FOR SLAUGHTER (1)**/BREEDING** (1)**/PRODUCTION** (1)

Member State of origin: .....

Certificate number (7)

Region of origin: .....

Reference number to original certificate (8)

SECTION A

Name and address of consignor: .....

.....

Name and address of holding of origin: .....

..... (2)

Dealer's approval number: ..... (3)

Address and approval number of assembly centre in the Member State of origin (1) or transit (1):

..... (3)

..... (3)

Health information

I certify that each animal of the consignment described below

1. comes from a holding of origin and an area which, in conformity with Community or national legislation, is not subject to any prohibition or restriction for reasons of animal diseases affecting bovine animals;

2. comes form a herd of origin situated in a Member State or part of its territory

   (a) with a surveillance network approved by: Commission Decision .../.../EC (3)

   (b) which is recognised as being:

   — officially tuberculosis-free Commission Decision .../.../EC (3)

   — officially brucellosis-free Commission Decision .../.../EC (3)

   — officially leukosis-free Commission Decision .../.../EC (3)

3. (3) is an animal for breeding (1) or production (1) that:

   — has been resident, as far as can be ascertained, on the holding of origin during the past 30 days, or since birth if less than 30 days of age, and no animal imported from a third country was introduced into that holding during this period, unless it was isolated from all other animals on the holding,

— comes from a herd which is officially free of tuberculosis, brucellosis and leukosis and had been tested with negative results during the 30 days prior to departure from the holding of origin, in accordance with Article 6(2) of Directive 64/432/EEC, as follows:

Test	Test not required for the following categories of animals	Required Yes/No (4) (5)	Date of testing or sampling
Tuberculin test	Animals less than 6 weeks of age		
Serum agglutination test (6) for brucellosis	Castrated animals and animals less than 12 months of age		
Test of leukosis	Animals less than 12 months of age		

4. (3) is an animal for slaughter coming from an officially tuberculosis and leukosis-free herd and is

— either castrated (3)

or

— uncastrated and comes from an officially brucellosis-free herd (3);

5. (3) is an animal for slaughter originating from a herd which is not officially free of tuberculosis, brucellosis, and leukosis, and is dispatched in accordance with Article 6(3) of Directive 64/432/EEC under licence No ..... from a holding in Spain, and has been tested with negative results during the 30 days prior to departure from the holding of origin, as follows:

Test	Date of testing or sampling
Tuberculin test	
Serum agglutination test (6) for brucellosis	
Test for leukosis	

6. (11) based on the information provided either in an official document or a certificate in which Sections A and B were completed by the official veterinarian or the approved veterinarian responsible for the holding of origin, fulfils the applicable health requirements of points 1 to 5 of Section A which are therefore not detailed in this certificate.

SECTION B

Description of the consignment

Date of departure: .....

Total number of animals:.....

Identification of animal(s):

Number of passport	Number of temporary document (for animals less than 4 weeks old)	Official identification (until 31. 8. 1999 for animals for slaughter in accordance with Article 4(1) of Council Regulation (EC) No 820/97)

Continue if necessary on an attached schedule signed and stamped by the official or approved veterinarian.

Approval number of transporter (if different from transporter stated in Section C and/or if distance of transport exceeds 50 km):.....

Means of transport:..... Registration: .....

Section A and B certification

Official stamp	Place	Date	Signature (*)

Name and capacity in capital letters:

Address of signing veterinarian:

(*) Sections A and B of the certificate must be either stamped and signed by
the **official veterinarian of the holding of origin** if different from the official veterinarian signing Section C,
or
signed by the **approved veterinarian of the holding of origin** where the Member State of dispatch has introduced a surveillance network system approved under Commission Decision .../.../EC,
or
signed by the **official veterinarian responsible for the approved assembly centre** at the date of departure of the animals.

SECTION C ([9])

Name and address of consignee: .....

.....

Name and address of holding of destination ([1]) or approved assembly centre in the Member State of destination ([1]) (complete this field in printed characters)

Name: .....

Street: .....

Country/province: .....

Postal code: ..... Member State: .....

Dealer's approval number: ..... ([3])

Approval number of transporter (if distance of transport exceeds 50 km): ..... ([10])

Means of transport: ..... Registration: .....

After inspection as required by regulations, I certify that:

1. the above described animals had been inspected on (insert date) ..... during the 24 hours before scheduled departure and had not shown clinical signs of infectious or contagious disease;
2. the holding of origin and where applicable the approved assembly centre and the area they are situated in are not subject to any prohibitions or restrictions for reasons of animal diseases affecting bovine animals in conformity with Community or national legislation;
3. all applicable provisions of Council Directive 64/432/EEC have been fulfilled;
4. ([3]) the above animals meet the additional guarantees for:
   — Disease: .....
   — In accordance with Commission Decision .../.../EC;
5. the animals did not remain more than six days in the approved assembly centre ([3]).

Section C certification

Official stamp	Place	Date	Signature (*)

Name and capacity in capital letters:

Address of signing veterinarian:

(*) Section C of the certificate must be stamped and signed by the official veterinarian of either the holding of origin,

or

the approved assembly centre situated within the Member State of origin,

or

the approved assembly centre situated within the Member State of transit when completing the certificate for dispatch of animals to the Member State of destination.

Additional information

1. The certificate must be stamped and signed in colour different to the printing.

2. This certificate remains valid for 10 days following the date of the health inspection carried out in the Member State of origin and referred to in Section C.

3. The required details of this certificate have to be entered into the ANIMO system on the day of issuing the certificate and at least within 24 hours thereof.

(1) Delete as appropriate.

(2) Not applicable where animals are from several holdings.

(3) Delete if not applicable.

(4) Not required if a system of surveillance networks is approved by Commission Decision .../.../EC.

(5) Not required if the Member State or the part of the Member State where the herd is situated is recognised as being officially free of the diease concerned.

(6) Or any other test approved in accordance with Article 17 of Directive 64/432/EEC.

(7) To be completed by the official veterinarian of the Member State of origin.

(8) To be completed by the official veterinarian at the approved assembly centre of the Member State of transit.

(9) Delete if certificate is used for movement of animals within Member State of origin and only Sections A and B are completed and signed.

(10) Delete if transporter is not different to transporter identified in Section B.

(11) Point 6 of Section A must be signed by the official veterinarian at the approved assemby centre after documentary and identity checks on animals arriving with an official document or Sections A and B completed certificate, otherwise this point must be deleted.

Model 2

HEALTH CERTIFICATE FOR ANIMALS OF THE PORCINE SPECIES FOR SLAUGHTER (1)**/BREEDING** (1)**/PRODUCTION** (1)

Member State of origin: .....

Certificate number (4)

Region of origin: .....

Reference number to original certificate (5)

SECTION A

Name and address of consignor: .....

.....

Name and address of holding of origin: .....

..... (2)

Dealer's registration number: ..... (3)

Address and approval number of assembly centre in the Member State of origin (1) or transit (1)

..... (3)

..... (3)

Health information

I certify that each animal of the consignment described below

1. comes from a holding of origin and an area which, in conformity with Community or national legislation, is not subject to any prohibition or restriction for reasons of animal diseases affecting porcine animals;
2. (3) is an animal for breeding (1) or production (1) that has been resident, as far as can be ascertained, on the holding of origin during the past 30 days or since birth if less than 30 days of age, and no animal imported from a third country was introduced into that holding during this period, unless it was isolated from all other animals on the holding.

SECTION B

Description of the consignment

Date of departure: .....

Total number of animals: .....

Identification of animal(s):

Breed	Date of birth	Official identification

Continue if necessary on an attached schedule signed and stamped by the official or approved veterinarian.

Approval number of transporter (if different from transporter stated in Section C and/or if distance of transport exceeds 50 km):

.....

Means of transport:..... Registration: .....

Section A and B certification

Official stamp	Place	Date	Signature (*)

Name and capacity in capital letters:

Address of signing veterinarian:

(*) Sections A and B of the certificate must be either
stamped and signed by the **official veterinarian of the holding of origin** if different from the official veterinarian signing Section C, or
signed by the **approved veterinarian of the holding of origin** where the Member State of dispatch has introduced a surveillance network system approved under Commission Decision .../.../EC or,
signed by the **official veterinarian responsible for the approved assembly centre** at the date of departure of the animals.

SECTION C ([6])

Name and address of consignee:.....

.....

Name and address of holding of destination (complete this field in printed characters):

Name: .....

Street: .....

Country/province: .....

Postal code:..... Member State: .....

Approval number of transporter (if distance of transport exceeds 50 km): ..... ([7])

Means of transport:..... Registration: .....

After inspection as required by regulations, I certify that:

1. the above described animals had been inspected on (insert date)..... during the 24 hours before scheduled departure and had not shown clinical signs of infectious or contagious disease;

2. the holding of origin and where applicable the approved assembly centre and the area they are situated in are not subject to any prohibitions or restrictions for reasons of animal diseases affecting porcine animals in conformity with Community or national legislation;

3. all applicable provisions of Council Directive 64/432/EEC have been fulfilled;

4. ([3]) the above animals meet the additional guarantees for:

   — disease:.....

   — in accordance with Commission Decision .../.../EC;

5. the animals did not remain more than six days in the approved assembly centre ([3]).

Section C certification

Official stamp	Place	Date	Signature (*)

Name and capacity in capital letters:

Address of signing veterinarian:

(*) Section C of the certificate must be stamped and signed by the official veterinarian of either the holding of origin, or
the approved assembly centre situated within the Member State of origin, or
the approved assembly centre situated within the Member State of transit when completing the certificate for dispatch of animals to the Member State of destination.

Additional information

1. The certificate must be stamped and signed in colour different to the printing.
2. This certificate remains valid for 10 days following the date of the health inspection carried out in the Member State of origin and referred to in Section C.
3. The required details of this certificate have to be entered into the ANIMO system on the day of issuing the certificate and at least within 24 hours thereof.

(1) Delete as appropriate.
(2) Not applicable where animals are from several holdings.
(3) Delete if not applicable.
(4) To be completed by the official veterinarian of the Member State of origin.
(5) To be completed by the official veterinarian at the assembly centre of the Member State of transit.
(6) Delete if certificate is used for movement of animals within Member State of origin and only Sections A and B are completed and signed.
(7) Delete if transporter is not different to transporter identified in Section B.'

ANNEX II

Correlation table

Subject	References to Annexes in Directive 97/12/EC	Related reference points in the Annexes to Directive 97/12/EC as amended by this Directive
Article 2 (definitions)		
Tuberculosis		
Officially free herd	A I 1, 2, 3	A I 1, 2, 3A, 3B
Officially free region/MS	A I 4, 5, 6	A I 4, 5
Brucellosis		
Officially free herd	A II 1, 2, 3	A II 1, 2, 3A, 3B
Officially free region	A II 7, 8, 9	A II 7, 8, 9 (1)
Officially free MS	A II 10, 11, 12	A II 7, 8, 9
Free herd	A II 4, 5, 6	A II 4, 5, 6A, 6B
For the whole chapter on brucellosis		New paragraph 10 on testing
EBL		
Officially free herd	D I A, B	D I A, B (1)
Officially free region/MS	D I E, F, G	D I E, F, G (1)
Article 5 (Certification)		
Article 5(1)	F	F Models 1 and 2
Article 5(2)(a), second indent	F	F Models 1 and 2
Article 5(2)(b), second indent	F	F Models 1 and 2
Article 5(4)	Part D, Annex F	Section C, Annex F, Models 1 and 2
Article 5(5), second sentence	Annex F (including Section D)	Annex F, Models 1 and 2 (including Section C)
Article 5(5), third sentence	Annex F	Annex F, Models 1 and 2

(1) No discrepancy between the text in Directive 97/12/EC and the new Annexes