

[<sup>F1</sup>]<sup>F2</sup> ANNEX A**Textual Amendments**

- F1** Substituted by [Council Directive 97/12/EC of 17 March 1997 amending and updating Directive 64/432/EEC on health problems affecting intra-Community trade in bovine animals and swine.](#)
- F2** Substituted by [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.](#)

**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

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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;
 

[<sup>F3</sup>or]
  - (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.

#### Textual Amendments

- F3** Inserted by [Directive 2000/20/EC of the European Parliament and of the Council of 16 May 2000 amending Council Directive 64/432/EEC on animal health problems affecting intra-Community trade in bovine animals and swine.](#)

- 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 carcass 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

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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) [<sup>F4</sup>each bovine animal is identified in accordance with Community legislation, and]

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- (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.

#### **Textual Amendments**

**F4** Substituted by [Directive 2000/20/EC of the European Parliament and of the Council of 16 May 2000 amending Council Directive 64/432/EEC on animal health problems affecting intra-Community trade in bovine animals and swine.](#)

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.

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

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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.

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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) [<sup>F4</sup>each bovine animal is identified in accordance with Community legislation, 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.]]