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.