COUNCIL DIRECTIVE

of 22 January 1980

amending Directive 64/432/EEC as regards tuberculosis and brucellosis

(80/219/EEC)

THE COUNCIL OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Economic Community, and in particular Articles 43 and 100 thereof,

Having regard to the proposal from the Commission (1),

Having regard to the opinion of the European Parliament (2),

Having regard to the opinion of the Economic and Social Committee (3),

Whereas bovine tuberculosis has virtually disappeared from certain regions of the Community; whereas it is necessary to reduce the cost of routine testing for tuberculosis in those regions;

Whereas, in order to reduce the time taken to restore officially tuberculosis-free status to herds in which tuberculosis has been found, the necessary methods of control must be adopted;

Whereas under Article 104 (3) of the Act of Accession, Denmark, Ireland and the United Kingdom were authorized to retain, until 31 December 1977, their national provisions for declaring a herd of cattle officially free of tuberculosis or free of brucellosis; whereas these authorizations were extended on three occasions (4) (5) (6) in the case of tuberculosis and, in the case of Ireland and the United Kingdom, on two occasions (4) (5) as regards brucellosis-free status within the meaning of Article 2 of Directive 64/432/EEC (7), as last amended by Directive 77/98/EEC (8);

Whereas these derogations were instituted and extended because of the time required to provide solutions to basic technical problems;

Whereas, for the same reasons, these derogations apart from that affecting traditional trade in live animals between Ireland and the United Kingdom should be extended for a further period of one year;

Whereas, in order to facilitate trade in certain bovine animals and until such time as the Community accelerated disease-eradication programme is completed, it is necessary to amend and to prolong certain derogations relating to brucellosis which were provided for in Article 7 (1) (C) of Directive 64/432/EEC,

HAS ADOPTED THIS DIRECTIVE:

Article 1

Directive 64/432/EEC is hereby amended as follows:

1. The following paragraph shall be added to Article 3:

'14. By way of derogation from Annex A (I) (b), a decision may be taken in accordance with the procedure laid down in Article 12 that in a Member State or part of a Member State composed of several adjacent regions where at least 99·9 % of the bovine herds have been declared officially tuberculosis-free within the meaning of Article 2 (d) for at least 10 years, and where every year for at least six years bovine tuberculosis has not been found to be present in more than one herd per 10 000 herds in that Member State or part thereof, it being understood that all cattle which have reacted positively to a tuberculin test, and all cattle slaughtered within the territory of that Member State, must have been submitted to a post mortem examination by an official veterinarian and if necessary a bacteriological examination, the inspections for determining whether the status is to be retained may be carried out in a manner and in parts of the Member State to be decided in accordance with the same procedure.

(1) OJ No C 268, 23. 10. 1979, p. 2.
(2) OJ No C 34, 11. 2. 1980, p. 109.
(3) Opinion delivered on 21 November 1979 (not yet published in the Official Journal)
(4) OJ No L 15, 19. 1. 1978, p. 32.
(5) OJ No L 29, 3. 2. 1979, p. 27.
(6) OJ No L 158, 26. 6. 1979, p. 17.
(7) OJ No 121, 29. 7. 1964, p. 1977/64.
(8) OJ No L 26, 31. 1. 1977, p. 81.

If one of the conditions provided for in the first subparagraph ceases to be fulfilled, the Commission, after assessing the circumstances of the recrudecence of tuberculosis, and if its assessment gives grounds for so doing, shall adopt a decision in accordance with the same procedure to rescind the derogation decision taken in respect of that Member State or part of that Member State composed of several adjacent regions.'

2. In Annex A (I):

(i) under (b):

— in the second sentence, the words 'or in a region of a Member State' shall be added after the words 'Member State',

— the following sentence shall be added:

'If the percentage infected bovine herds does not exceed 0·1% during two successive supervisory periods separated by an interval of three years, the interval between subsequent tuberculin tests may be increased to four years and/or the age at which animals have to undergo these tests may be increased to 24 months.'

(ii) the following subparagraph shall be added:

'If in an officially tuberculosis-free herd, an animal is deemed to have reacted positively to a routine tuberculin test, or a clinical case of tuberculosis has been diagnosed at routine post mortem examination of an animal from an officially tuberculosis-free herd, the officially tuberculosis-free status of the herd must be suspended until such time as all the remaining animals over six weeks of age have reacted negatively to at least two official intradermal tuberculin tests in accordance with Annex B, the first one carried out at least two months after elimination of the animal from the herd and the second one at least 42 days after the first.'

3. Annex B shall be replaced by the Annex to this Directive.

4. In Article 7 (1):

(a) under C:

— in the second sentence, the words 'if over 30 days old' shall be inserted between the words 'animals' and 'must',

— in the second subparagraph the date '31 December 1979' shall be replaced by '31 December 1981';

(b) the following point shall be added:

'E. Bovine animals which have not undergone the sero-agglutination test prescribed in C and D above, provided that they satisfy the following conditions:

(i) in the case of bovine animals intended for meat production:

— they are less than 42 days of age, or have been castrated before the age of four months,

— they are moved under supervision, if necessary via a weaning unit, to an approved fattening holding and do not leave that holding except to go for slaughter;

(ii) in the case of bovine animals for slaughter, they are moved under official supervision directly to the slaughterhouse.

These provisions shall apply until 31 December 1981.'

5. In Annex A (II) (A), the following paragraph shall be added:

'7. The tests provided for in paragraphs 1 to 6 shall not be required for male animals castrated before the age of four months.'

Article 2

For the purpose of testing tuberculins known as 'synthetic' tuberculins, a Member State which, at the date of adoption of this Directive, makes use of a standard tuberculin conforming with the international standard for old tuberculin may, by way of derogation from Annex B (1) to Directive 64/432/EEC, continue to apply this method until more advanced international standards are introduced.

Article 3

The Council, acting on a proposal from the Commission, and before 1 January 1984, shall designate the Community laboratories and the manner of their operation in accordance with Annex B (27) to Directive 64/432/EEC.

Under the procedure laid down in Article 12 of Directive 64/432/EEC the Standing Veterinary Committee shall designate the tuberculins to be tested and the examinations to be carried out, and may amend the list of laboratories where these examinations must be carried out.

Article 4

This Directive shall apply:

— from 1 January 1980 as regards Article 1 (4),

— by 31 December 1980 at the latest as regards the other provisions.

Article 5

1. Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with this Directive.

They shall forthwith inform the Commission thereof.

2. Until the date on which they are able to comply with this Directive, and until 31 December 1980 at the latest:

— Denmark, Ireland and the United Kingdom are hereby authorized to retain the methods applied in their territory whereby a herd of cattle becomes considered to be officially tuberculosis-free within the meaning of Article 2 of Directive 64/432/EEC,

— Ireland and the United Kingdom are hereby authorized to retain the methods applied in their territory whereby a herd of cattle becomes considered to be brucellosis-free within the meaning of Article 2 of Directive 64/432/EEC subject to the application of the provisions of that Directive relating to the presence of animals vaccinated against brucellosis.

The provisions relating to the tests laid down for animals traded within the Community shall continue to apply.

Article 6

This Directive is addressed to the Member States.

Done at Brussels, 22 January 1980.

For the Council

The President

G. MARCORA

ANNEX

'ANNEX B

Standards for the manufacture and use of bovine and avian tuberculins

1. Officially supervised tuberculin tests must be carried out with PPD or HCSM tuberculins.

2. Manufacturers' working standards for the control of bovine PPD and HCSM tuberculins must be calibrated in Community tuberculin units (CTU) following biological assay against the appropriate EEC standard tuberculin.

3. Manufacturers' working standards for the control of avian tuberculins must be calibrated in international units following biological assay against the EEC standard for PPD of avian tuberculin.

4. The EEC standard for PPD of bovine tuberculin is that supplied by the Centraal Diergeneeskundig Instituut, Afdeling Rotterdam, the Netherlands.

5. The EEC standard for bovine HCSM tuberculin is that supplied by the Institut Pasteur, Paris, France.

6. The EEC standard for avian tuberculin is that supplied by the Central Veterinary Laboratory, Weybridge, Surrey, England.

7. Bovine tuberculins must be prepared with one of the mycobacterium bovis strains indicated below:

   (a) AN5;

   (b) Vallee.

8. Avian tuberculins must be prepared with one of the mycobacterium avium strains indicated below:

   (a) D4ER;

   (b) TB56.

9. The pH of tuberculins must be between 6·5 and 7·5.

10. Antimicrobial preservatives or other substances that may be added to a tuberculin shall have been shown, to the satisfaction of the State institute responsible for the official testing of the tuberculin, not to impair the safety and effectiveness of the product.

    The following are the maximum permitted concentrations for phenol and glycerol:

    (a) phenol: 0·5 % M/v;

    (b) glycerol: 10 % v/v.

11. Provided the tuberculins are stored at a temperature between 2 and 8 °C, protected from light, they may be used up to the end of the following periods subsequent to the last satisfactory potency test:

    (a) liquid PPD tuberculins: two years,
    lyophilized PPD tuberculins: eight years;

    (b) HCSM tuberculins diluted: two years.

12. The State institutes listed below shall be responsible for the official testing of tuberculins in their respective countries:

(a) Germany:	Paul-Ehrlich Institut, Frankfurt/Main;
(b) Belgium:	Instituut voor Hygiëne en Epidemiologie, J. Wytsmanstraat 14, B-1050 Brussels;
(c) France:	Laboratoire national des médicaments vétérinaires, Fougères;
(d) Grand Duchy of Luxembourg:	institute of the supplying country;
(e) Italy:	Istituto superiore di sanità, Rome;
(f) Netherlands:	Centraal Diergeneeskundig Instituut, Afdeling Rotterdam;
(g) Denmark:	Statens Veterinære Serumlaboratorium, Copenhagen V;
(h) Ireland:	institute of the supplying country;
(i) United Kingdom:	The Central Veterinary Laboratory, Weybridge, Surrey.

13. Official testing must be carried out on each batch of bottled tuberculins ready for use.

14. Tuberculins shall be tested by biological and chemical methods.

15. Tuberculins must be sterile. Tests for sterility shall be carried out according to the specifications of the European Pharmacopeia.

16. A test for the absence of toxic or irritant properties shall be carried out according to the specifications of the European Pharmacopeia.

17. Tuberculins must be chemically analyzed to determine the concentration of glycerol and/or phenol and also the concentration of any other preservative which may have been added.

18. A test of non-sensitization to tuberculin must be carried out according to the specifications of the European Pharmacopeia.

19. The potency of tuberculins must be assessed by biological methods. These methods must be used for HCSM and PPD tuberculins; they are based on the comparison with standard tuberculins of the tuberculins to be tested.

20. The protein content of PPD tuberculin must be estimated by the Kjeldahl method. The nitrogen is converted into tuberculo-protein content by multiplying by a factor of 6·25.

21. The EEC standard for bovine HCSM has a potency of 65 000 Community tuberculin units (CTU) per ml and is dispensed in ampoules containing 5 ml of tuberculin.

22. The EEC standard for bovine PPD has a potency of 50 000 Community tuberculin units (CTU) per mg of PPD and is dispensed lyophilized in ampoules containing 1·8 mg of PPD, i.e. 0·00002 mg PPD has a potency equal to one Community tuberculin unit.

23. The EEC standard for avian PPD has a potency of 50 000 international units (i.u.) per mg of the dried material of the purified protein derivative and is dispensed in the lyophilized in ampoules containing 10 mg of PPD plus 26·3 mg of salts, i.e. 0·0000726 mg of the standard has a potency equal to one international unit.

24. Tuberculins submitted by manufacturers for testing by the State institutes listed in paragraph 12 must have been tested for potency by biological assay against the appropriate standards as listed in paragraphs 2 and 3.

25. (a) Potency testing on guinea pigs

Albino guinea-pigs weighing between 400 and 600 g must be used. These guinea-pigs must be in good health at the time of injection of the tuberculin. Not less than eight guinea-pigs shall be used for each assay. The assay should be made not less than one month after sensitization.

(aa) For the assay of bovine tuberculins, guinea-pigs shall be sensitized by one of the following methods:

1. the injection of heat-killed Mycobacterium bovis strain AN5 in oil adjuvant,

2. the injection of living Mycobacterium bovis strain AN5 in physiological saline,

3. the injection of BCG vaccine.

(bb) For the assay of avian tuberculins guinea-pigs shall be sensitized by injection of 2 mg of heat-killed avian-type tubercular bacilli suspended in 0·5 ml of sterile liquid paraffin or by the injection of live avian-type tubercular bacilli in physiological saline. The avian-type strain D4 must be used for this purpose.

(cc) Each tuberculin under test shall be assayed against the appropriate standard tuberculin by an intradermal assay using groups of guinea-pigs suitably sensitized.

The hair shall be clipped from both sides of each guinea-pig. The assay shall be carried out by comparing the reactions induced by a series of intracutaneous injections of doses of not more than 0·2 ml of dilutions of the standard tuberculin in isotonic buffered saline solution containing Tween 80, 0·0005 %, with a corresponding series of injections of the tuberculin under test. Dilutions shall be arranged in geometric series, and injected into guinea-pigs according to a randomized Latin square design (four sites on each side of an eight-point assay is used). The diameters of the reactions at each site should be measured and recorded after 24 to 28 hours.

For each sample of tuberculin under test, an estimate of relative potency against the appropriate standard and its fiducial limits shall be made by statistical methods, using the diameters of the reactions and the logarithms of the doses as metameters. The bovine tuberculin under test is of acceptable potency if its estimated potency guarantees per bovine dose 2 000 Community tuberculin units (± 25 %) in cattle. The potency of each tuberculin under test shall be expressed as appropriate in Community tuberculin units or international units per ml.

(b) Potency testing on cattle

Periodic potency testing of bovine tuberculins may be carried out on naturally or artificially infected tuberculous cattle. These potency tests, on groups of tuberculous cattle, shall be carried out by intradermal four or six-point assay of the tuberculin under test against the appropriate standard and the potency of the tuberculin shall be estimated by statistical methods as in the guinea-pig assay.

26. The following requirements shall apply to the labelling of tuberculin containers and packages:

The label on the containers and the label on the package shall state:

— the name of the preparation,

— for liquid preparations, the total volume in the container,

— the number of Community or international units per ml or per mg,

— the manufacturer's name,

— the batch number,

— the nature and quantity of the reconstituting liquid for the freeze-dried preparation.

The label on the container or the label on the package shall state:

— the expiry date,

— the conditions of storage,

— the name and, if possible, the proportions of any added substance,

— the strain of bacillus from which the tuberculin has been made.

27. Community laboratories designated in accordance with Article 3 will be made responsible for the additional examination of routine issue field tuberculins used in the Member States to ensure that the potency of each of these tuberculins is adequate in relation to the appropriate Community standard tuberculin. These examinations must be carried out, in tuberculous bovines, in suitably sensitized guinea-pigs and by appropriate chemical tests.

28. The following shall be recognized as official intradermal tuberculin tests:

(a) The single intradermal test — this test requires a single injection of bovine tuberculin.

(b) The intradermal comparative test — this test requires one injection of bovine tuberculin and one injection of avian tuberculin given simultaneously.

29. The dose of tuberculin injected shall be:

1. not less than 2 000 CTU of bovine tuberculin;

2. not less than 2 000 IU of avian tuberculin.

The volume of each injection dose shall not exceed 0·2 ml.

30. Tuberculin tests shall be carried out by injecting tuberculin(s) into the skin of the neck. The injection sites shall be situated at the border of the anterior and middle thirds of the neck. When both avian and bovine tuberculins are injected in the same animal, the site for injection of avian tuberculins shall be about 10 cm from the crest of the neck and the site for the injection of bovine tuberculin about 12·5 cm lower on a line roughly parallel with the line of the shoulder or on different sides of the neck; in young animals in which there is not room to separate the sites sufficiently on one side of the neck, one injection shall be made on each side of the neck at identical sites in the centre of the middle third of the neck.

31. The technique of tuberculin testing and interpretation of reactions shall be as follows:

(a) Technique:

Injection sites shall be clipped and cleansed. A fold of skin within each clipped area shall be taken between the forefinger and thumb and measured with calipers and recorded. A short sterile needle, bevel edge outwards, with graduated syringe charged with tuberculin attached shall be inserted obliquely into the deeper layers of the skin. The dose of tuberculin shall then be injected. A correct injection shall be confirmed by palpating a small pealike swelling at each site of injection. The skin-fold thickness of each injection site shall be remeasured 72 hours after injection and recorded.

(b) Interpretation of reactions:

The interpretation of reactions shall be based on clinical observations and the recorded increases(s) in skin-fold thickness at the sites of injection 72 hours after injection of tuberculin(s).

(ba) Negative reaction: If only limited swelling is observed, with an increase of not more than 2 mm in the thickness of the fold of skin without clinical signs such as diffuse or extensive oedema, exudation, necrosis, pain or inflammation of the lymphatic ducts in that region or of the lymph nodes.

(bb) Inconclusive reaction: If no clinical signs such as mentioned in (ba) are observed and if the increase in skin-fold thickness is more than 2 mm and less than 4 mm.

(bc) Positive reaction: If clinical signs such as mentioned in (ba) are observed or there is an increase of 4 mm or more in the thickness of the fold of skin at the injection site.

32. The interpretation of official intradermal tuberculin tests shall be as follows:

(a) single intradermal test:

positive: a positive bovine reaction as defined in paragraph 31 (bc);

inconclusive: an inconclusive reaction as defined in paragraph 31 (bb);

negative: a negative bovine reaction as defined in paragraph 31 (ba).

Animals inconclusive to the single intradermal test shall be subjected to another test after a minimum of 42 days.

Animals which are not negative to this second test shall be deemed to be positive to the test.

Animals positive to the single intradermal test may be subjected to an intradermal comparative test;

(b) intradermal comparative test for the establishment and maintenance of officially tuberculosis-free herd status:

positive: a positive bovine reaction which is more than 4 mm greater than the avian reaction, or the presence of clinical signs;

inconclusive: a positive or inconclusive bovine reaction which is from 1 to 4 mm greater than the avian reaction, and the absence of clinical signs;

negative: a negative bovine reaction, or a positive or inconclusive bovine reaction but which is equal to or less than a positive or inconclusive avian reaction and the absence of clinical signs in both cases.

Animals inconclusive to the intradermal comparative test shall be subjected to another test after a minimum of 42 days. Animals which are not negative to this second test shall be deemed to be positive to the test;

(c) officially tuberculosis-free herd status may be suspended until such time as the status of the following animals is resolved:

1. animals which have been deemed to be inconclusive to the single intradermal tuberculin test;
2. animals which have been deemed to be positive to the single intradermal tuberculin test but are awaiting retest with an intradermal comparative test;
3. animals which have been deemed to be inconclusive to the intradermal comparative test.

33. Animals destined for intra-Community trade must be subjected to a single intradermal test within 30 days prior to movement. Any animal which shows an increase in skin-fold thickness greater than 2 mm or the presence of clinical signs must not be entered into intra-Community trade.

Animals from herds referred to in 32 (c) shall not be permitted to enter intra-Community trade until such time as the health status of the animals referred to therein has been clarified.'