COMMISSION OF THE EUROPEAN COMMUNITIES

COM(79) 509 final.

Brussels, 2 October 1979

Proposal for a

COUNCIL DIRECTIVE

amending Directive 64/432/EEC as regards

tuberculosis and brucellosis

(submitted to the Council by the Commission)

EXPLANATORY NOTE

By virtue of Article 104 of the Treaty of Accession, Denmark, Ireland and the United Kingdom were authorized to maintain for an interim period, until the end of 1977, their national rules for declaring a herd of cattle officially free of tuberculosis or free of brucellosis, these derogations were subsequently prolonged until the end of 1979.

On the same basis certain derogations from existing Community provisions were granted, to allow for the maintenance of traditional exports of cattle from Ireland and the United Kingdom.

The limiting factors to the dismantling of these derogations were technical problems involving primarily tuberculins and castrates; these technical problems have now been solved thus allowing for harmonization to take place.

The attached proposals allow for a reduction in the amount of routine tuberculosis testing in those regions of the Community where the disease has virtually disappeared, thus reducing the cost and easing trade in bovine animals.

Derogations concerning bovine animals intended for meat production and which are under 30 months of age that were allowed for in the original Council Directive (64/432/EEC Art. 7.I.C), are prolonged for a further two years, that is until the completion of the Community accelerated anti-brucellosis campaign.

It is additionally proposed to suppress the requirement to test for brucellosis animals intended for meat production and which are under 30 days of age because the test below this age is insufficiently precise.

Proposal for a
Council Directive

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

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;

Having regard to the opinion of the European Parliament;

Having regard to the opinion of the Economic and Social Committee;

Whereas bovine tuberculosis has virtually disappeared from certain regions of the Community and 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 reestablish the status of "officially tuberculosis-free" as regards those 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[1][2][3] in the case of tuberculosis or, in the case of Ireland and the United Kingdom, on two occasions[1][2] relating to brucellosis freedom within the meaning of Article 2 of Council Directive 64/432/EEC [4], as last amended by [5];

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

Whereas, for the same reason and in order not to interrupt the traditional trade in live animals between Ireland and the United Kingdom, it was necessary to prolong for the same period certain special derogations granted in respect of such trade;

Whereas these basic technical problems have now been solved, thus allowing for certain technical amendments to Directive 64/432/EEC in order that the abovementioned derogation will no longer be necessary;

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

HAS ADOPTED THIS DIRECTIVE :

(1) OJ No L 15, 19.01.1978, p. 32
(2) OJ No L 29, 03.02.1979, p. 27
(3) OJ No L 158, 26.06.1979, p. 17
(4) OJ No 121, 29.7.1964, p. 1977/64
(5) OJ No

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) it may be decided, under the procedure laid down in Article 12, that in a Member State or region thereof where at least 99.8% of the bovine herds have been declared officially tuberculosis free within the meaning of Article 2(d) for at least 10 years, and where for at least 6 years bovine tuberculosis has not been recorded on an annual basis in more that 1 herd per 10 000 herds in that Member State or region, it being understood that all bovine animals reacting to a tuberculin test and all bovine animals slaughtered within that Member State or region must have been submitted to a post mortem examination by an official veterinarian and if necessary a bacteriological examination, the inspections for determining whether this status is to be preserved may be carried out in a manner and in regions to be decided under the same procedure.

If one of the conditions provided for in the first subparagraph ceases to be fulfilled, the Commission - after assessing the circumstances of the recrudescence of tuberculosis - shall adopt, under the same procedure, a decision to rescind the derogation decision taken in respect of that Member State or region of a Member State."

2. (a) In Article 7(1)(C) in the second sentence, the words "if over 30 days of age" shall be inserted between the words "animals" and "must".

(b) In Article 7(1)(C), in the second paragraph the date "31 December 1979" shall be replaced by "31 December 1982".

3. The following paragraph shall be added to Annex A(I):

If in an officially tuberculosis free bovine herd an animal is deemed to have reacted positively to a routine maintenance tuberculin test or in which a clinical case of tuberculosis has been diagnosed at routine post-mortem examination and subsequently confirmed by laboratory examination in an animal coming from an officially tuberculosis free herd then the status "officially tuberculosis-free" must be suspended until such time as all of 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 at least two months after complete elimination of the infection in the herd and the second one at least 42 days later.

4. (a) In Annex A,(II),(A)(1)(c) in the introductory sentence the words "and castrated males over 30 months of age" shall be inserted after the words "over 12 months old".

(b) In Annex A,(II)(A)(2)(c), in the first sentence the words "castrated males need not be subjected to testing", shall be inserted after the word "however".

In Annex A(II)(A)(2)(d) the following sentence shall be added at the end of the first paragraph "Castrated males need not be subjected to premovement testing".

(c) In Annex A(II)(A)(3)(c) in the first sentence the words "and castrated males over 30 months of age" shall be inserted after the words "over 12 months old".

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

Done at Brussels,

For the Council

The President

ANNEX

"ANNEX B (5)

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 in tuberculous cattle and in guinea-pigs.

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, 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°C 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 must be made 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 Veterinaere Serumlaboratorium, Copenhagen V;
    (h) Ireland : Institute of the supplying country;
    (i) United Kingdom : The Central Veterinary Laboratory, Weybridge, Surrey, England.

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

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

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

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

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

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

19. The potency of tuberculins must be estimated 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 in the lyophilized state in ampoules containing 1.8 mg of PPD, i.e. 0.00002 mg PPD contains one community tuberculin unit of activity.

23. The EEC standard for PPD of Avian Tuberculin has a potency of 50,000 International Units (IU) per mg. of the dried material of the purified protein derivative and is dispensed in the lyophilized state in ampoules containing 10 mg of PPD plus 26.3 mg of salts, i.e. 0.0000726 mg of the standard contains one international unit of activity.

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 the tuberculin inoculation. 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 B.C.G. vaccine.

(bb) For the assay of avian tuberculins, guinea-pigs shall be sensitized by injection of 2 mg of heat-killed avian type tubercle bacilli suspended in 0.5 ml of sterile liquid paraffin or by the injection of live avian type tubercle 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 0.2 ml of dilutions of the standard tuberculin in isotonic buffered saline solution containing Tween 80, 0.0005 per cent, 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 randomised Latin square design (four sites on each side of an eight-point assay is used). The diameters of the reactions at each site should be measured and recorded after 24 to 28 hours.

For each sample of tuberculin under test, an estimate of relative potency against the appropriate standard and its fiducial limits shall be made by statistical methods, using the diameters of the reactions and the logarithms of the doses as metameters. The bovine tuberculin under test is of acceptable potency if its estimated potency guarantees per bovine dose 2000 C.T.U.'s (± 25%) in cattle. The potency of each tuberculin under test shall be expressed as appropriate in Community tuberculin units or International Units per m.l.

(b) Potency testing on bovine animals

Periodic potency testing of bovine tuberculins must be carried out on naturally or artificially infected tuberculous cattle. These potency tests, in 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 estimated by statsticial 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 manufacturers 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 proportions of any added substance
- the species or the bacillus from which the tuberculin has been made.

27. Community laboratories will be established for the periodic 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.

The Council acting on a proposal from the Commission shall designate the community laboratories before January 1, 1984.

Under the procedure laid down in Article 12, the Standing Veterinary Committee will nominate the tuberculins to be tested and the examinations to be carried out and may amend the list of laboratories where these examinations are to be effected.

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 2000 C.T.U.'s of bovine tuberculin
(2) not less than 2000 I.U.'s 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 particularly 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 a 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 pea-like swelling at each site of injection. The skin-fold thickness of each injection site shall be remeasured 72 hrs after injection and recorded.

(b) Interpretation of reactions :

The interpretation of reactions shall be based on clinical observatic and the recorded increase(s) in skin-fold thickness at the sites of injection 72 hrs 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 then this reaction may be considered as being inconclusive.

(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)

(aa) Animals inconclusive to the single intradermal test shall be subjected to another test after an interval 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

(ba) For the establishment and maintenance of officially tuberculosis free herds the interpretation of the test shall be as follows :

Positive : A positive bovine reaction and more than 4 mm greater than the avian reaction or the presence of clinical signs.

Inconclusive : A positive bovine reaction and from 1 to 4 mm greater than the avian reaction and the absence of clinical signs

Negative : A negative bovine reaction

or

a positive bovine reaction but equal to or less than a positive 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 an interval of 42 days. Animals which are not negative to this second test shall be deemed to be positive to the test.

(bb) 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.

(c) The qualification of official tuberculosis herd freedom must 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.