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.