II

(Acts whose publication is not obligatory)

COUNCIL

COUNCIL DIRECTIVE

of 24 January 1979

amending Directive 64/432/EEC as regards brucellosis

(79/109/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,

Having regard to the opinion of the European Parliament (1),

Having regard to the opinion of the Economic and Social Committee (2),

Whereas Council Directive 64/432/EEC of 26 June 1964 on animal health problems affecting intra-Community trade in bovine animals and swine (3), as last amended by Directive 77/98/EEC (4), lays down common standards on anti-brucellosis measures applicable to animals intended for intra-Community trade ;

Whereas equivalent measures for the diagnosis and control of bovine brucellosis are, by way of derogation, still applicable in the new Member States ; whereas in order to ensure the continuation of free trade in bovine animals and swine within the Community, it is necessary to adapt the technical provisions of Directive 64/432/EEC which relate to brucellosis in order to take account of this situation ;

Whereas, in view of new scientific knowledge and technical developments in the diagnosis and control of bovine brucellosis, an adjustment of existing Community measures in this field is necessary,

HAS ADOPTED THIS DIRECTIVE :

Article 1

In Article 2 of Directive 64/432/EEC, the following point shall be added :

'(o) "Region" means that part of a Member State's territory which is at least 2 000 km² in area and which is subject to inspection by the competent authorities and includes at least one of the following administrative areas :

— Belgium : province/provincie,

— Germany : Regierungsbezirk,

— Denmark : Amt or island,

— France : département,

— Italy : provincia,

— Luxembourg : —,

— Netherlands : provincie,

— United Kingdom :

  — England, Wales and Northern Ireland : county,

  — Scotland : district or island area,

— Ireland : county.'

(1) OJ No C 266, 7. 11. 1977, p. 45.
(2) OJ No C 18, 23. 1. 1978, p. 35.
(3) OJ No 121, 29. 7. 1964, p. 1977/64.
(4) OJ No L 26, 31. 1. 1977, p. 81.

Article 2

In Article 3 of Directive 64/432/EEC, the following paragraphs shall be added :

'13. By way of derogation from Annex A (II) (A) (1) (c) (ii) it may be decided, under 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 99·8 % of the bovine herds have been declared officially brucellosis-free within the meaning of Article 2 (e) for at least 10 years, and where no case of abortion due to a brucella infection has been recorded for at least three years, 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 in which the brucellosis has reappeared — shall submit to the Standing Veterinary Committee a proposal for a decision to rescind the derogation decision taken in respect of that Member State or of that part thereof composed of several adjacent regions.

It may also be decided, under the procedure laid down in Article 12, that the provisions of Annex A (II) (A) (1) (c) (iii) may be applied to a part of a Member State comprising several adjacent regions.'

Article 3

Annex A (II) (A) (1) (c) (i) of Directive 64/432/EEC shall be replaced by the following :

'(i) have shown a brucella count lower than 30 international units of agglutination per millilitre when given two official sero-agglutination tests at intervals of at least three months and at most 12 months, carried out in accordance with Annex C ; however :

— the first sero-agglutination test may be replaced by three ring-tests carried out at three-monthly intervals provided that the second sero-agglutination test is carried out at least six weeks after the third ring-test ;

— the first sero-agglutination test referred to in the first indent may be replaced by a buffered brucella antigen test carried out in accordance with Annex C (D) ;'.

Article 4

In Annex A (II) (A) (1) (d) (i) of Directive 64/432/EEC, in the introductory sentence, the words 'or a part of a Member State comprising several adjacent regions' shall be inserted after the words 'in Member States'.

Article 5

In Annex A (II) (A) (1) (c) of Directive 64/432/EEC, the following subparagraphs shall replace the existing subparagraph (ii) :

'(ii) are checked annually to establish that brucellosis is not present by three ring-tests carried out at intervals of at least three months or two ring-tests at an interval of at least three months and one serological test (sero-agglutination test or buffered brucella antigen test or plasma-agglutination test or plasma ring-test) carried out not less than six weeks after the second ring-test. If ring-tests are not carried out, two serological tests (sero-agglutination test or buffered brucella antigen test or plasma-agglutination test or plasma ring-test) shall be carried out each year at intervals of at least three months and not more than six months ;

Where, in a Member State or region thereof in which all bovine herds are subject to official operations to combat brucellosis, not more than 1 % of bovine herds is infected, it shall be sufficient to carry out each year two ring-tests at an interval of at least three months, or one serological test (sero-agglutination test or buffered brucella antigen test or plasma-agglutination test or plasma ring-test) ;

(iii) derogations may be permitted from the requirements laid down in (ii) regarding annual checks that brucellosis is not present in any Member State where at least 99·8 % of bovine herds have been recognized as officially brucellosis-free for at least four years ; in this case, the interval between checks may be extended to two years and the checks must be carried out using one of the serological tests referred to in (ii) ;'.

Article 6

Annex A (II) (A) (2) (b) of Directive 64/432/EEC shall be replaced by the following :

'(b) all or some of the female bovine animals have been vaccinated :

— when six months old at most, with live Buck 19 vaccine or other vaccines approved under the procedure laid down in Article 12,

— when 15 months old at most, with killed 45/20 adjuvant vaccine officially inspected and recognized ;'.

Article 7

Annex A (II) (A) (2) (c) of Directive 64/432/EEC shall be replaced by the following :

'(c) all the bovine animals satisfy the conditions laid down in 1 (b) and (c) ; however, the bovine animals under 30 months old which have been vaccinated with live Buck 19 vaccine may show a brucella count equal to or higher than 30 i.u. of agglutination per millilitre but lower than 80 i.u. of agglutination per millilitre provided that, when the complement fixation reaction is tested, they show :

— a count lower than 30 EEC units in the case of females vaccinated less than 12 months previously,

— a count lower than 20 EEC units in all other cases.

The sero-agglutination tests referred to in 1 (c) (i), first indent, may be replaced by buffered brucella antigen tests carried out in accordance with Annex C (D) ;'.

Article 8

In Annex A (II) (A) (2) (d), second paragraph, first line of Directive 64/432/EEC, the words 'with live Buck 19 vaccine' shall be inserted between the words 'vaccinated' and 'and'.

Article 9

In Annex C of Directive 64/432/EEC the following sections shall be added :

'D. **The buffered brucella antigen test**

The buffered brucella antigen test may be carried out using one of the following methods :

A. *Manual test*

1. The standard serum shall be the second international standard anti-brucella abortus serum which is supplied by the Central Veterinary Laboratory, Weybridge, Surrey, England.

2. The antigen shall be prepared without reference to the cell concentration, but its sensitivity must be standardized in relation to the second international standard anti-brucella abortus serum in such a way that the antigen produces a positive reaction with serum dilution of 1 : 47·5 and a negative reaction with a dilution of 1 : 55.

3. The antigen shall be suspended in buffered brucella antigen diluent at a pH of 3·65 ± 0·5 and may have been stained by the use of Rose Bengal dye.

4. Weybridge Strain No 99 or USDA 1119 or any other strain of equivalent sensitivity must be used for preparing the antigen.

5. The culture media used for keeping the strain in the laboratory and for producing the antigen must be such that they do not encourage bacterial dissociation (S — R) ; potato agar medium or continuous culture methods should be used.

6. The antigen shall be tested against eight freeze-dried known positive and negative sera.

7. The official supervision and control of standard serum and antigen shall be carried out by the official bodies listed in Annex C (A) (9).

8. The antigen shall be delivered ready for use.

9. The buffered brucella antigen test shall be carried out in the following manner :

(a) one drop (0·03 ml) of antigen should be placed alongside one drop (0·03 ml) of the serum on a white plate ;

(b) they should be mixed with an applicator stick, first in a straight line and then in a circle of about 10 to 12 mm diameter ;

(c) the plate should then be rocked back and forth for four minutes (about 30 times per minute) ;

(d) readings should be taken in a good light ; if there is no evidence of agglutination, the test shall be regarded as negative ; any degree of agglutination shall be regarded as positive, unless there has been excessive drying round the edges.

B. *Automated method*

The automated method must be at least as sensitive and accurate as the manual method.

E. **Plasma ring-test**

A. *Extraction of the plasma*

The tube containing blood, coagulation of which having been inhibited by the addition of EDTA, should be centrifuged for three at 3 000 r/min and subsequently kept at 37 °C for 12 to 24 hours.

B. *Evaluation*

0·2 ml of stabilized plasma should be placed in a tube with 1 ml of untreated milk. After mixing, one drop (0·05 ml) of ABR-antigen should be added and the whole again mixed. The antigen should be standardized in relation to a standard antigen supplied by the body referred to in (A) (9) (a).

Following an incubation period of 45 minutes at 37 °C, a reading should be taken within 15 minutes. The result shall be regarded as positive if the colour of the ring has become the same as, or darker than, that of the milk column.

F. **Plasma agglutination**

The plasma extracted in accordance with E (A) may be used immediately after centrifuging, no thermal stabilization being necessary.

0·05 ml of plasma should be mixed with 1 ml of antigen for 50 % sero-agglutination, which corresponds to a dilution of 1 : 20 for sero-agglutination. A reading should be taken after 18 to 24 hours incubation at 37 °C. % or more agglutination shall be regarded as positive.'

Article 10

The Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with this Directive by 1 April 1979 and shall forthwith inform the Commission thereof.

Article 11

This Directive is addressed to the Member States.

Done at Brussels, 24 January 1979.

For the Council

The President

J. FRANÇOIS-PONCET