

COUNCIL DIRECTIVE 93/60/EEC

of 30 June 1993

amending Directive 88/407/EEC laying down the animal health requirements applicable to intra-Community trade in and imports of deep-frozen semen of domestic animals of the bovine species and extending it to cover fresh bovine semen

THE COUNCIL OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Economic Community, and in particular Article 43 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 Directive 88/407/EEC ⁽⁴⁾ lays down the animal health requirements applicable to intra-Community trade in, and imports of, deep-frozen semen of domestic animals of the bovine species;

Whereas Article 4 of the said Directive defined provisional measures for trade in semen from bulls which are seropositive for infectious bovine rhinotracheitis (IBR); whereas these requirements should be reviewed, on the basis of a report from the Commission; whereas this report indicates that it is necessary to phase out bulls which were seropositive or of unknown status prior to vaccination in the centre by 1998 and to maintain the possibility of vaccinating in a centre in the future; whereas it is necessary to amend the aforementioned Article 4 in this respect;

Whereas routine foot-and-mouth disease vaccination has been discontinued in the Community as from August 1991; whereas, therefore, it is necessary to amend the provisions of Directive 88/407/EEC to take account of this change in policy; whereas this change also permits trade in fresh bovine semen to take place under harmonized rules;

Whereas it is opportune to make further amendments to the said Directive to clarify certain issues and to take account of technical progress, particularly in respect of

treatment of bulls against leptospirosis, and to align the rules with respect to brucellosis, tuberculosis and leucosis on those laid down in Directive 64/432/EEC ⁽⁵⁾;

Whereas it is appropriate to provide for amendments to the Annexes under a procedure establishing close cooperation between Member States and the Commission within the Standing Veterinary Committee,

HAS ADOPTED THIS DIRECTIVE:

Article 1

Directive 88/407/EEC is hereby amended as follows:

1. In the title and in Article 1, the words 'deep-frozen' shall be deleted.
2. Article 4 (1) shall be replaced by the following:

'1. Without prejudice to paragraph 2, Member States shall authorize the admission of semen from bulls giving a negative reaction to the serum neutralization test or the Elisa test for infectious bovine rhinotracheitis/infectious pustular vulvo-vaginitis or showing a positive result after vaccination in accordance with this Directive.

Member States may, until 31 December 1998, authorize the admission of semen of bulls giving a positive reaction to the serum neutralization test or the Elisa test for infectious bovine rhinotracheitis/infectious pustular vulvo-vaginitis and not having been vaccinated in accordance with this Directive.

In that case, each consignment must pass an examination by inoculation into a live animal and/or virus isolation test.

This requirement shall not apply in respect of the semen of animals which, prior to their first routine vaccination at the insemination centre, reacted negatively to the tests referred to in the first

⁽¹⁾ OJ No C 324, 10. 12. 1992, p. 13.

⁽²⁾ OJ No L 72, 15. 3. 1993, p. 153.

⁽³⁾ OJ No C 108, 19. 4. 1993, p. 12.

⁽⁴⁾ OJ No L 194, 22. 7. 1988, p. 10. Directive as last amended by Directive 90/425/EEC (OJ No L 224, 18. 8. 1990, pl. 29).

⁽⁵⁾ Council Directive 64/432/EEC of 26 June 1964 on animal health problems affecting intra-Community trade in bovine animals and swine (OJ No L 121, 29. 7. 1964, p. 1977/64.). Directive as last amended by Directive 92/102/EEC (OJ No L 355, 5. 12. 1992, p. 32).

subparagraph. However, the semen of animals given emergency vaccinations following an outbreak of IBR must pass a virus isolation test.

These examinations may, by bilateral agreement, be carried out either in the country of collection or in the country of destination.

In that case, at least 10 % of each collection of semen (with a minimum of five straws) must be treated.

Protocols for tests to be used in accordance with this Article shall be laid down in accordance with the procedure in Article 18⁷.

3. Article 4 (3) shall be replaced by the following:

'3. Member States may not oppose the admission of semen from bulls vaccinated against foot-and-mouth disease. However, where the semen was obtained from a bull which had been vaccinated against foot-and-mouth disease during the 12 month period prior to collection, 5 % of the semen from each collection (with a minimum of five straws) intended for sending to another Member States shall be subjected, in a laboratory in the Member State of destination or in a laboratory designated by it, to a virus isolation test for foot-and-mouth disease, with negative results⁸.

4. Article 12 shall be replaced by the following:

Article 12

The rules laid down in Council Directive 90/675/EEC of 10 December 1990 laying down the principles governing the organization of veterinary checks on products entering the Community from third countries(*) shall apply in particular to the organization and follow-up of checks to be carried out by the Member States and the safeguard measures to be applied.

(*) OJ No L 373, 31. 12. 1990, p. 1. Directive as last amended by Regulation (EEC) No 1601/92 (OJ No L 173, 27. 6. 1992, p. 13.)

5. Articles 13 and 14 shall be deleted.

6. In Annex A, Chapter II, the following shall be added to point (f) (i):

'Deep-frozen embryos may also be stored in approved centres provide that:

- such storage is authorized by the competent authority,
- the embryos meet the requirements of Council Directive 89/556/EEC of 25 September 1989 on

animal health conditions governing intra-Community trade in and importation from third countries of embryos of domestic animals of the bovine species (*),

- the embryos are stored in separate storage flasks in the premises for storing approved semen.

(*) OJ No L 302, 19. 10. 1989, p. 1. Directive as amended by Directive 90/425/EEC (OJ No L 224, 18. 8. 1990, pl. 29.)

7. In Annex A, Chapter II, (f) (vii) shall be replaced by the following:

- '(vii) each individual dose of semen is clearly marked in such a way that the date of collection of the semen, the breed and identification of the donor animal, the name of the centre and the serological status of the donor animal in respect of infectious bovine rhinotracheitis and infectious pustular vulvo-vaginitis, possibly in code, can be readily established; the characteristics and form of this marking will be established in accordance with the procedure laid down in Article 19.'

8. In Annex B, Chapter I, paragraph 1 (b) shall be replaced by the following:

- '(b) prior to their stay in the isolation accommodation described in (a), have belonged to a herd which is officially tuberculosis free and officially brucellosis free in accordance with Directive 64/432/EEC. The animals may not previously have been kept in one or more herds of a lower status.'

9. In Annex B, Chapter I, the first subparagraph of paragraph 1 (c) shall be replaced by the following:

- 'have come from a herd free of enzootic bovine leucosis as defined in Directive 64/432/EEC, or have been produced by dams which have been subjected, with negative results, to an Agar Gel immunodiffusion test, carried out in accordance with Annex G of Directive 64/432/EEC, after removal of the animals from their "dam" In the case of animals derived by embryo transfer, 'dam' means the recipient of the embryo.'

10. In Annex B, Chapter I, paragraph 1 (d) (ii) shall be replaced by the following:

- '(ii) a serum agglutination test carried out in accordance with the procedure described in Annex C to Directive 64/432/EEC and showing a brucella count lower than 30 IU of agglutination per millilitre, or a complement

fixation test showing a brucella count lower than 20 EEC units per millilitre (20 ICFT units).'

11. In Annex B, Chapter I, paragraph 1 (e) (i) shall be replaced by the following:
 - (i) a serum agglutination test complying with the procedure described in Annex C to Directive 64/432/EEC and showing a brucella count lower than 30 IU of agglutination per millilitre, or a complement fixation test showing a brucella count lower than 20 EEC units per millilitre (20 ICFT units).'
12. In Annex B, Chapter I, in the last sentence of paragraph 1 (e), the words 'and have treatment against leptospirosis comprising two injections of streptomycin at an interval of 14 days (25 mg per kilogram of live body weight)' shall be deleted.
13. The following paragraph shall be added to Annex B, Chapter I:

'6. However, until 1 July 1995 the Member States may admit to approved semen collection centres animals of the bovine species originating in herds which are free of brucellosis. In that case, the animals must, during the aforementioned period, be subjected to a complement fixation test showing a brucella count lower than 20 EEC units per millilitre (20 ICFT units) as provided for in (d) (ii) and (e) (i).'
14. In Annex B, Chapter II, paragraph 1 (ii) shall be replaced by the following:
 - (ii) a serum agglutination test for brucellosis, carried out in accordance with the procedure described in Annex C to Directive 64/432/EEC, giving a count lower than 30 IU of agglutination per millilitre, or a complement fixation test showing a brucella count lower than 20 EEC units per millilitre (20 ICFT units).'
15. In Annex B, Chapter II, paragraph 1 (iii) shall be replaced by the following:
 - (iii) a screening test for enzootic bovine leucosis, carried out in accordance with the procedure described in Annex G to Directive 64/432/EEC, with a negative result;'
16. In Annex B, Chapter II, paragraph 1 (iv) the words 'until 31 December 1992' shall be deleted.
17. In Annex B, Chapter II, paragraph 3 the third subparagraph shall be replaced by the following subparagraphs:

'These provisions shall not apply to sero-positive bulls which, prior to their first vaccination in accordance with this Directive at the insemination centre, gave a negative reaction to the serum neutralization test or the ELISA test for infectious bovine rhinotracheitis or infectious pustular vulvo-vaginitis.

Sero-positive bulls referred to in the second subparagraph of Article 4 (1) must be isolated since their semen may be the subject of intra-Community trade in accordance with the provisions for trade in semen from such bulls.'
18. In Annex C, paragraph 1 (b) shall be replaced by the following:
 - (b) (i) have not been vaccinated against foot-and-mouth disease during the 12 months prior to collection, or
 - (ii) have been vaccinated against foot-and-mouth disease during the 12 months prior to collection, in which case 5 % (with a minimum of five straws) of each collection shall be submitted to virus isolation test for foot-and-mouth disease with negative results;'
19. In Annex C, paragraph 1 (d) shall be replaced by the following:
 - (d) have been kept at an approved semen collection centre for a continuous period of at least 30 days immediately prior to the collection of the semen in the case of collections of fresh semen;'
20. In Annex C, paragraph 1 (f) and (g) shall be replaced by the following:
 - (f) are kept in semen collection centres which have been free from foot-and-mouth disease for at least three months prior to collection of the semen and 30 days after collection or, in the case of fresh semen, until the date of dispatch and are situated in the centre of an area of 10 kilometres radius in which for at least 30 days there has been no case of foot-and-mouth disease;
 - (g) have been kept in semen collection centres which, during the period commencing 30 days prior to collection and ending 30 days after collection of the semen or, in the case of fresh semen, until the date of dispatch, have been free from those bovine diseases which are compulsorily notifiable in accordance with Annex E to Directive 64/432/EEC;'
21. In Annex C, paragraph 3 (i) shall be replaced by the following:
 - (i) be stored in approved conditions for a minimum period of 30 days prior to dispatch. This requirement shall not apply to fresh semen;'
22. In Annex D (IV), paragraph 4 (iii), the word 'consignment' shall be replaced by the word 'collection'.

23. In Annex D (IV), paragraph 5 shall be replaced by:

'5. the semen described above was collected from bulls:

(i) which have not been vaccinated against foot-and-mouth disease within 12 months prior to collection ⁽¹⁾; or

(ii) which have been vaccinated against foot-and-mouth disease with 12 months prior to collection, in which case the semen comes from a collection in which 5 % of each collection intended for trade (with a minimum of 5 straws) has been subjected, with negative results, to a virus isolation test for foot-and-mouth disease in laboratory ⁽²⁾;

24. In Annex D, IV the following shall be added:

'6. the semen was stored in approved conditions for a minimum period of 30 days prior to dispatch ⁽³⁾.'

25. In Annex D, in footnote 2, the words 'the second subparagraph of Article 4 (1)' shall be replaced by 'Article 4'.

26. In Annex D, the following shall be added as footnote 3:

'⁽³⁾ May be deleted for fresh semen.'

Article 2

The Commission shall submit to the Council, before 1 January 1998, a report on this Directive, taking account

of experience gained and technical and scientific developments, particularly in the fight against, and eradication of, diseases, together with any appropriate proposals. The Council shall act by a qualified majority on those proposals by 30 June 1998.

Article 3

1. Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with this Directive 1 July 1994. They shall forthwith inform the Commission thereof.

When Member States adopt those provisions, 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 adopted by the Member States.

2. Member States shall inform the Commission of the text of the essential provisions of national law which they adopt in the area governed by this Directive.

Article 4

This Directive is addressed to the Member States.

Done at Luxembourg, 30 June 1993.

For the Council

The President

S. BERGSTEIN