

COMMISSION OF THE EUROPEAN COMMUNITIES

COM(92) 462 final

Brussels, 12 November 1992

Report from the Commission
on
the animal health rules to be applied to bovine semen for
intra-Community trade and imports from the third countries in
accordance with Article 4 of Directive 88/407/EEC

and

proposal
for a
Council Directive

amending Council Directive 88/407/EEC of 14 June 1988
laying down the animal health
requirements applicable to intraCommunity trade in and imports
of deep-frozen semen of domestic animals of the bovine
species and extending it to cover fresh bovine semen

(presented by the Commission)

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EXPLANATORY MEMORANDUM

Council Directive 88/407/EEC 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. At the time of adoption, the situation in Member States with respect to the status of infectious bovine rhinotracheitis/infectious pustular vulvovaginitis (IBR/IPV) in semen collection centres varied considerably. Article 4 therefore required the Commission to report on the situation, with appropriate proposals.

The general IBR/IPV situation in Member States has not changed significantly since the Directive was adopted. There is still a need to allow collection of semen from bulls which are positive to a blood test for this disease, because of the long term nature of breeding programmes (typically 10 years). It is therefore proposed to continue the use of bulls which were positive before vaccination until the 10-year cycle comes to an end (1998), and to allow vaccination to continue until such time as Member States make progress in eradication in the national herd.

Additionally, proposals are made to

- clarify the situation with respect to the brucellosis, enzootic bovine leucosis (EBL) and tuberculosis status of the bull on entry to a collection centre,
- discontinue virus isolation testing for foot and mouth disease (FMD) for bulls vaccinated more than 12 months prior to collection, and to reduce the number of semen straws to be tested from 10 to 5%,
- discontinue the treatment of bulls with streptomycin against leptospirosis,
- remove the requirement for a bull to be on a collection centre for 30 days before collection for trade purposes,
- extend the Directive to cover fresh semen and
- allow future amendments to the annexes by the Commission under the Regulatory procedure.

- 1 bis -

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Introduction

Council Directive 88/407/EEC laying down the animal health rules applicable to intra-community trade in and imports from third countries of deep-frozen semen of domestic animals of the bovine species was adopted by Council on 14 June 1988⁽¹⁾. It was subsequently amended in particular by Council Directive 90/120/EEC⁽²⁾ on 5 March 1990, with respect to rules relating to semen derived from bulls which were serologically positive for IBR, either before entry or following vaccination on the centre. Special rules were introduced in Article 4 to allow Member States to continue trade in semen from such bulls, for a transitional period until 31 December 1992. These rules were required to be reviewed by 1 January 1992.

The purpose of this report is to make such reviews, and also to identify other problems found during the implementation of the Directives, in support of proposals for suitable amendments.

IBR

IBR is a disease of cattle caused by a Herpes virus. It can manifest itself in either a respiratory form or a urogenital form. It is the respiratory form which is most commonly recognised in the Community. The disease may appear in the acute or sub acute form, but no serological differences have been identified between the strains. In the urogenital form, it causes balanoposthitis in the male and vulvovaginitis in the female. It may be the cause of infertility, particularly in the female. Vaccines may be used to control its effects. However, vaccines probably do not prevent infection by field virus.

(1) OJ No L 194 of 22.07.1988, p. 10

(2) OJ No L 71 of 17.03.1990, p. 37

The presence of virus in the semen is a potential means of spread. This is complicated by the problem of latency. This means that, after a clinical or subclinical infection, the virus may remain latent for the life of the animal. It may also be reactivated and shed at irregular intervals, particularly if the animal is stressed or has corticosteroids administered to it. Infected bulls must therefore be regarded as potential lifelong shedders of virus.

Few countries have attempted to eradicate the disease in their national herd. Denmark has a national programme, and Ireland has had rules in the past designed to prevent the introduction of virulent forms which, it was claimed were absent from the island. In the AI industry, as a general rule, attempts are made to ensure freedom of the bulls from IBR, in view of its importance as a disease of breeding. This is done either by exclusion of any seropositive animal from the centres, or by a policy of vaccination after initial testing (with negative results). Some countries maintain separate IBR positive and negative studs. In positive centres, semen from a clinically affected animal would not be used. Furthermore, there are still some centres which contain bulls which were not tested prior to entry, and which were vaccinated, before the Directive was adopted. Their true status is, therefore, unknown. Trade in semen from the latter category of bulls is permitted until 31/12/92, subject to a negative virus isolation test being carried out on the semen before export. Trade in semen from bulls which were seronegative before vaccination is also permitted, without virus isolation. In both cases, Member States in which all centres are seronegative may refuse semen from centres which do not have that status.

A major problem with semen is its long storage time after collection. Because of this, and the length of cattle breeding programmes (typically 5 years to prove a dairy bull and at least 5 years full use after testing), there will be a great deal of semen in stores by the end of the transitional period. A limited survey has been carried out in some Member States. This survey shows that an abrupt cessation of trade in semen from positive bulls at the end of 1992 will be very costly and will rob the industry of valuable genetic material. (Table 1).

Similarly, there are bulls of great genetic value in centres in some third countries. It is important to have access to this genetic material for a further limited period. Many breeding programmes started at the time of adoption of the Directive, i.e. 1988, and the bulls in these programmes will be used at least until 1998.

It is clear that Council Directive 88/407/EEC gave impetus to the objective of finally eradicating this disease from AI centres. While this should continue to be the long-term aim, the practicality of maintaining a bull centre free from IBR without vaccination in a country where the cattle in the national population are infected must be questioned. The airborne route of infection is not normally considered to be a major source of infection, especially over long distances. However, this route cannot be excluded. Therefore, it is essential to consider the possible action to be taken if a centre becomes infected.

There are three options:

- slaughter of all stock,
- vaccination of all stock,
- testing with removal of infected animals and vaccination of the remainder.

The first option is unacceptable, in view of the financial and genetic value of the bulls. The second option would leave infected bulls on the centre; this would present a hazard to incoming animals, and is not consistent with the long-term aim. The third option is best, therefore.

The draft proposal attached to this report proposes to maintain the trade in semen from bulls of unknown status until the end of 1998, and to allow vaccination of seronegative bulls on the centres where desired by the Member State concerned. The virus isolation test would continue to be required for all semen from seropositive bulls which had not been found to be seronegative prior to vaccination on the centre. Seropositive bulls may not enter a centre at all. The protocols for the serological and virological tests and the number of straws to be tested will be established by the Commission.

Foot and Mouth Disease (FMD)

Article 4 of the Directive also makes provisions for virus isolation or animal inoculation tests on semen from bulls vaccinated against FMD, when going to a non-vaccinating country. Council Directive 90/423/EEC⁽³⁾ banned the use of FMD vaccine as and from 1/1/92, and, in practice, all Member States had stopped by August 1991. This requirement should therefore be reviewed. The opinion of the Scientific Veterinary Committee is that semen produced from bulls vaccinated more than 12 months before semen collection presents only a negligible risk, assuming that the centre was free from FMD at the time of collection. Therefore it is proposed that the testing should apply to trade in semen between all Member States, but only on semen collected within 12 months of vaccination. Additionally, the Scientific Veterinary Committee has recommended that the number of straws to be tested can be reduced to 5% from 10%.

Furthermore, under a non-vaccination policy, there is no further need to keep fresh semen out of the scope of the Directive. Virus isolation tests would limit the practicality of trade in fresh semen, but are not needed for all collections (see preceding paragraph). This applies equally to IBR.

Quarantine of bulls and semen

Annex C requires

- i) that the bulls are kept on the approved centre for 30 days prior to collection, and
- ii) that the semen is stored 30 days prior to dispatch.

This double quarantine is considered to be unnecessary, and one element could be deleted. The quarantine on semen itself gives the best guarantee that the health status at the time of collection was satisfactory. Furthermore, the bulls are subjected to intensive testing before entry into the centre.

⁽³⁾ OJ No. L 224 of 18.08.1990, p. 13

It is therefore proposed that the requirement for the bull to be in the centre for 30 days prior to collection can be revoked. To allow trade in fresh semen, it is also necessary to remove the quarantine for this category; this can be justified on the basis of the very low volume of trade in fresh compared with frozen semen.

Other problems

Other difficulties have been highlighted by Member States. Appropriate amendments have therefore been proposed.

- a) The double requirement to treat bulls and semen with antibiotics against Leptospirosis can be replaced by single treatment of the semen with suitable antibiotics.
- b) Currently, a bull must either come from a herd which is free from enzootic bovine leucosis or its dam must be tested within 30 days of movement of the bull to the centre. This is illogical, as it is the status of the dam at the time of weaning which is most relevant. Therefore it is proposed that this test on the dam should be done after removal of the bull from its dam. Where the bull is born as a result of embryo transfer, the recipient female is regarded as the dam.
- c) The current requirement in respect of brucellosis status is that the bull must come from an officially free herd and must not have been in any other herd of lower status. The latter requirement is automatic, given the rules for movement into officially free herds, and has led to confusion of interpretation. It is therefore proposed that reference is made directly to the definition of an officially free herd in Directive 64/432/EEC⁽⁴⁾.

(4) OJ No L 121 of 29.09.1964, p. 2012/64

TABLE 1

IBR - Positive and negative bulls on centre in
Belgium and the Netherlands

Predicted situation on 1 January 1993

Year of birth	IBR Pos	IBR Neg	Total
<u>THE NETHERLANDS</u>			
1981	1	0	1
1982	3	0	3
1983	2	0	2
1984	7	1	8
1985	5	5	10
1986	5	6	11
1987	10	22	32
1988	61	340	401
1989	95	440	535
1990	-	450	450
1991	-	450	450
TOTAL	179	1714	1903
<u>BELGIUM</u>			
1987	10	1	11
1988	89	27	116
1989	104	28	132
1990	96	37	133
1991	-	128	128
TOTAL	299	221	510

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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 Council Directive 88/407/EEC⁽⁴⁾, as last amended by Directive 90/425/EEC⁽⁵⁾ 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 Directive 88/407/EEC 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 on the centre by 1998; and to maintain the possibility to vaccinate on a centre in the future; whereas it is necessary to amend Article 4 in this respect;

(1) OJ No C

(2) OJ No C

(3) OJ No C

(4) OJ No L 194, 22.07.1988, p. 10

(5) OJ No L 224, 18.08.1990, p. 29

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 the Directive to take account of this change in policy; whereas this change in policy also permits trade in fresh bovine semen to take place under harmonised rules;

Whereas it is opportune to make further amendments to the Directive to clarify certain issues and to take account of changes in technical knowledge, particularly in respect of treatment of bulls against leptospirosis, and to align the rules with respect to brucellosis, tuberculosis and leucosis with those laid down in Council Directive 64/432/EEC⁽⁶⁾;

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, the words "deep frozen" are deleted.
2. In Article 1, the words "deep frozen" are deleted.
3. In Article 3, the existing text is prefixed by the number 1, and the following paragraph 2 is added:

"2. Member States which implement an alternative control system providing guarantees equivalent to those laid down in this Directive as regards movements within their territory of bovine semen, in particular with regard to the certificate, may grant one another derogations from the provisions of paragraph 1(d) and Article 6, on a reciprocal basis.
They shall notify the Commission thereof."

(6) OJ No L 121, 29.09.1964, p. 2012/64

4. Article 4 paragraph 1 is 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 rhino-tracheitis/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 rhino-tracheitis/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 a virus isolation test.

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

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

Protocols for tests to be used in accordance with this Article, and the number of straws to be tested for each collection, shall be laid down in accordance with the procedure in Article 18."

5. Article 4 paragraph 3 is replaced by the following:

"3. Member States may not oppose the admission of semen produced 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 each collection (with a minimum of five straws) intended for sending to another Member State shall be subjected to a virus isolation test for foot and mouth disease, with negative results."

6. Article 12 is 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⁽⁷⁾ 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."

7. Articles 13 and 14 are deleted.

8. Article 17 is replaced by the following :

"Article 17

Amendments to the annexes to this Directive, in particular to adapt them to advances in technology, shall be decided in accordance with the procedure laid down in Article 18."

9. In Article 18 at the end of the 4th paragraph, the words "save where the Council has decided against the said measure by a simple majority" are deleted.
10. In Article 19 at the end of the 4th paragraph, the words "save where the Council has decided against the said measures by a simple majority" are deleted.
11. In Annex A, chapter II, the following subparagraph is added at the end :

"The competent authority may authorize the storage in the approved semen storage premises of embryos which meet the requirements of Directive 89/556/EEC of 25 September 1989 on animal health conditions governing intra-Community trade in and imports from third countries of embryos of domestic animals of the bovine species⁽⁸⁾."

(7) OJ No L 373 of 31.12.1990, p. 1

(8) OJ No L 302 of 19.10.1989, p. 1

12. In Annex B, Chapter I, paragraph 1, (b) is replaced by :

"(b) prior to their stay in isolation accommodation described in (a), have belonged to a herd which is officially tuberculosis free and officially brucellosis free, as defined in Annex A.II of Directive 64/432/EEC."

13. In Annex B, Chapter I the first sub paragraph of paragraph 1(c) is replaced by:

"have come from an enzootic bovine leucosis free herd as defined in Directive 64/432/EEC, or have been produced by dams which have been subjected 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."

14. In Annex B, Chapter I, paragraph 1(e), in the last sentence the words "and have treatment against leptospirosis comprising two injections of streptomycin at an interval of 14 days (25mg per kilogram of live body weight)." are deleted.

15. In Annex B, Chapter II, paragraph 1, (iii) is replaced by:

"(iii) a serological test for enzootic bovine leucosis, carried out in accordance with Annex C to Directive 64/432/EEC, with a negative result."

16. In Annex B, Chapter II, paragraph 1(iv) the words "until 31 December 1992" are deleted.

17. In Annex B, Chapter II, paragraph 3 the words "until 31 December 1992" and, at the end, the words "under Article 4(1) second, third and fifth subparagraphs" are deleted.

18. In Annex C paragraph 1, (b) is replaced by the following:

"b) (i) were not vaccinated against foot and mouth disease during the 12 months prior to collection

or

(ii) were vaccinated against foot and mouth disease during the 12 months prior to collection, in which case 5% (with a minimum of five straws) of the collection shall be submitted to a virus isolation/animal inoculation test for foot and mouth disease with negative results,"

19. In Annex C, sub-paragraph 1(d) is deleted and the remaining sub-paragraphs are accordingly renumbered.

20. In Annex C paragraph 3, (i) is replaced by the following:

"be stored in approved conditions for a minimum period of 30 days prior to dispatch. This requirement shall not apply to fresh semen."

21. In Annex D IV, paragraph 4 (iii), the word "consignment" is replaced by the word "collection".

22. In Annex D IV, paragraph 5 is 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 within 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)."

23. In Annex D IV the following is added:

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

24. In Annex D, in footnote (2), the words "the second subparagraph of Article 4(1)" are replaced by "Article 4".

25. In Annex D, the following footnote (3) is added :

"(3) may be deleted for fresh semen."

Article 2

1. Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with this Directive by 1 April 1993. They shall inform the Commission thereof.
2. When Member States adopt the measures referred to in paragraph 1, 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 laid down by the Member States.

Article 3

This Directive is addressed to the Member States.

Done at

For the Council

DOCUMENTS

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Catalogue number : CB-CO-92-486-EN-C

ISBN 92-77-49019-5
