# **EUROPEAN PARLIAMENT**

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20 March 2003

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## **REPORT**

on the proposal for a Council directive amending Directive 88/407/EEC laying down the animal health requirements applicable to intra-Community trade in and imports of semen of domestic animals of the bovine species (COM(2002) 527 - C5-0478/2002 - 2002/0229(CNS))

Committee on Agriculture and Rural Development

Rapporteur: Heinz Kindermann

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#### Symbols for procedures

- \* Consultation procedure *majority of the votes cast*
- \*\*I Cooperation procedure (first reading)
  majority of the votes cast
- \*\*II Cooperation procedure (second reading)

  majority of the votes cast, to approve the common position

  majority of Parliament's component Members, to reject or amend
  the common position
- \*\*\* Assent procedure
  majority of Parliament's component Members except in cases
  covered by Articles 105, 107, 161 and 300 of the EC Treaty and
  Article 7 of the EU Treaty
- \*\*\*I Codecision procedure (first reading)

  majority of the votes cast
- \*\*\*II Codecision procedure (second reading)

  majority of the votes cast, to approve the common position

  majority of Parliament's component Members, to reject or amend

  the common position
- \*\*\*III Codecision procedure (third reading)

  majority of the votes cast, to approve the joint text

(The type of procedure depends on the legal basis proposed by the Commission)

#### Amendments to a legislative text

In amendments by Parliament, amended text is highlighted in *bold italics*. Highlighting in *normal italics* is an indication for the relevant departments showing parts of the legislative text for which a correction is proposed, to assist preparation of the final text (for instance, obvious errors or omissions in a given language version). These suggested corrections are subject to the agreement of the departments concerned.

## **CONTENTS**

	Page
PROCEDURAL PAGE	4
DRAFT EUROPEAN PARLIAMENT LEGISLATIVE RESOLUTION	5
EXPLANATORY STATEMENT	12

#### PROCEDURAL PAGE

By letter of 29 October 2002 the Council consulted Parliament, pursuant to Article 37 of the EC Treaty, on the proposal for a Council directive amending Directive 88/407/EEC laying down the animal health requirements applicable to intra-Community trade in and imports of semen of domestic animals of the bovine species (COM(2002) 527 – 2002/0229(CNS)).

At the sitting of 10 October 2002 the President of Parliament announced that he had referred the proposal to the Committee on Agriculture and Rural Development as the committee responsible and the Committee on the Environment, Public Health and Consumer Policy for its opinion (C5-0478/2002).

The Committee on Agriculture and Rural Development appointed Heinz Kindermann rapporteur at its meeting of 5 November 2002.

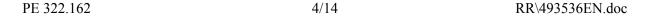
The committee considered the Commission proposal and draft report at its meetings of 2 December 2002, 17 February 2003 and 19 March 2003.

At the last meeting it adopted the draft legislative resolution unanimously.

The following were present for the vote: Joseph Daul (chairman), Friedrich-Wilhelm Graefe zu Baringdorf and Albert Jan Maat (vice-chairmen), Heinz Kindermann (rapporteur), Gordon J. Adam, Danielle Auroi, Carlos Bautista Ojeda, Arlindo Cunha, Christel Fiebiger, Francesco Fiori, Christos Folias, Jean-Claude Fruteau, Georges Garot, Lutz Goepel, María Esther Herranz García (for Encarnación Redondo Jiménez), Salvador Jové Peres, Dimitrios Koulourianos, Wolfgang Kreissl-Dörfler (for António Campos), Astrid Lulling (for Agnes Schierhuber), Véronique Mathieu, Hans-Peter Mayer (for Michl Ebner), Xaver Mayer, Karl Erik Olsson, Christa Prets (for María Izquierdo Rojo) and Dominique F.C. Souchet.

The Committee on the Environment, Public Health and Consumer Policy decided on 27 November 2002 not to deliver an opinion.

The report was tabled on 20 March 2003.



#### DRAFT EUROPEAN PARLIAMENT LEGISLATIVE RESOLUTION

on the proposal for a Council directive amending Directive 88/407/EEC laying down the animal health requirements applicable to intra-Community trade in and imports of semen of domestic animals of the bovine species  $(COM(2002)\ 527-C5-0478/2002-2002/0229(CNS))$ 

#### (Consultation procedure)

The European Parliament,

- having regard to the Commission proposal to the Council (COM(2002) 527)<sup>1</sup>,
- having regard to Article 37 of the EC Treaty, pursuant to which the Council consulted Parliament (C5-0478/2002),
- having regard to Rule 67 of its Rules of Procedure,
- having regard to the report of the Committee on Agriculture and Rural Development (A5-0076/2003),
- 1. Approves the Commission proposal as amended;
- 2. Calls on the Commission to alter its proposal accordingly, pursuant to Article 250(2) of the EC Treaty;
- 3. Calls on the Council to notify Parliament if it intends to depart from the text approved by Parliament:
- 4. Asks the Council to consult Parliament again if it intends to amend the Commission proposal substantially;
- 5. Instructs its President to forward its position to the Council and Commission.

Text proposed by the Commission

Amendments by Parliament

# Amendment 1 RECITAL 4

- 4. The same requirements for storage should apply to all establishments whether or not they are associated with a production
- 4. The same requirements for storage should apply to all establishments whether or not they are associated with a production unit. *However, the Member States must be*

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5/14 PE 322 162

<sup>&</sup>lt;sup>1</sup> OJ C 20 (E), 28.1.2003, pp. 246-254.

unit.

given the opportunity to decide whether or not to approve the establishment of semen storage centres on their territory in addition to semen collection centres.

Nevertheless, any refusal of approval must not interfere with the free movement of goods within the European Union.

#### Justification

On various grounds, some Member States have expressed reservations about approving semen storage centres. Accordingly, each Member State should have the right to decide for itself whether or not to approve the establishment of semen storage centres on its territory in addition to semen collection centres. National decisions which impede attainment of the objective of free movement of goods in the Union are unacceptable.

## Amendment 2 ARTICLE 1, PARAGRAPH 1(b) Article 2(b) (Directive 88/407/EEC)

"Semen collection centre" means an officially approved and supervised establishment situated in the territory of a Member State or third country, in which semen is produced and stored for use in artificial insemination;

"Semen storage centre" means an officially approved and supervised establishment situated in the territory of a Member State or third country in which semen is stored for use in artificial insemination.'

"Semen collection centre" means an officially approved and *officially* supervised establishment situated in the territory of a Member State or third country, in which semen is produced and stored for use in artificial insemination;

"Semen storage centre" means an officially approved and *officially* supervised establishment situated in the territory of a Member State or third country in which semen is stored for use in artificial insemination.'

#### Justification

It should be spelt out with absolute clarity that not only the approval but also the supervision of the centres is subject to official scrutiny.

# Amendment 3 ARTICLE 1, PARAGRAPH 4

In Articles 5, 9 (2) and 9 (3), the words

In Articles 5(2), 9 (2) and 9 (3), the words

PE 322.162 6/14 RR\493536EN.doc

"semen collection centre(s)" are replaced by the words "semen collection or storage centre(s)". "semen collection centre(s)" are replaced by the words "semen collection or storage centre(s)".

#### Justification

This article must be amended in order to bring it into line with the change proposed in the following amendment.

Amendment 4
ARTICLE 1, PARAGRAPH 4a (new)
Article 5, paragraph 1 (Directive 88/407/EEC)

4a. Article 5(1) to read:

The Member State in which the semen collection centre is located shall ensure that approval pursuant to Article 3(a) is given only in the event of compliance with the provisions set out in Annex A and of the semen collection centre's being in a position to comply with the other provisions of this Directive.

A Member State may decide to grant approval for the establishment of semen storage centres on its territory. It shall ensure that approval pursuant to Article 3(a) is given only in the event of compliance with the provisions set out in Annex A and of the semen storage centre's being in a position to comply with the other provisions of this Directive.

The Member State shall also ensure that the official veterinarian monitors these provisions and rescinds approval in the event of subsequent non-compliance with one or more of the provisions.

#### Justification

Responsibility for deciding whether or not the establishment of semen storage centres is to be

approved on the territory of a Member State should lie with the Member State concerned. See Justification to Amendment 1.

# Amendment 5 ARTICLE 1, PARAGRAPH 5, SUBPARAGRAPH 3 Article 9, paragraph 1 (Directive 88/407/EEC)

The Member States shall have *ten* working days, from receipt of the proposed modifications, to send any written comments to the Commission.

The Member States shall have *twenty* working days, from receipt of the proposed modifications, to send any written comments to the Commission.

#### Justification

Given normal administrative practice, a period of 10 days in which the Member States may forward any comments on amendments to the list of semen storage centres approved in third countries is inadequate and should be extended to 20 days.

# Amendment 6 ARTICLE 3

This Directive shall enter into force on the ... following that of its publication in the *Official Journal of the European Communities*. Intra-community trade in and imports of semen certified according to the provisions and the model of certificate formerly in force *shall be accepted for a period of six months after the date of publication of this Directive*.

This Directive shall enter into force on the ... following that of its publication in the Official Journal of the European Communities. Until [date: 18 months after the entry into force of this Directive], Member States must continue to authorise intra-community trade in and imports of semen certified according to the provisions of Directive 88/407/EEC formerly in force and the model of certificate formerly in force

After [date: 18 months after the entry into force of this Directive], only semen collected, processed and stored before that date may be certified in accordance with the provisions of Directive 88/407/EEC formerly in force.

Or. de

#### Justification

A transitional period for intra-Community trade in and imports of semen collected and certified in accordance with the Directive formerly in force should be rejected. On the contrary, trade in semen lawfully collected in accordance with the requirements of the currently applicable Directive should continue to be authorised without any time limit, even after the new Directive has entered into force. Destruction of such semen is not necessary on animal health grounds and does not make economic sense. With regard to certification, after the date indicated (18 months after the entry into force of this Directive), only semen collected, processed and stored before that date should be certifiable in accordance with the provisions of Directive 88/407/EEC formerly in force.

## Amendment 7 ANNEX A, CHAPTER I, HEADING

CONDITIONS FOR THE APPROVAL
OF CENTRES

CONDITIONS FOR THE *OFFICIAL*APPROVAL OF CENTRES

Justification

It should be made clear that what is involved here is official approval.

# Amendment 8 ANNEX A, CHAPTER II, HEADING

CONDITIONS RELATING TO THE SUPERVISION OF CENTRES

CONDITIONS RELATING TO THE OFFICIAL SUPERVISION OF CENTRES

Justification

It should be made clear that what is involved here is official supervision.

Amendment 9 ANNEX A, CHAPTER II Annex A, Chapter II, paragraph 1(f)(i), first indent

- such semen is produced from bovine animals which fulfil the conditions laid
- such semen is produced from bovine animals which fulfil the conditions laid

RR\493536EN.doc 9/14 PE 322.162

down in Chapter I. 1 (d) (i), (ii), (iii) and (v) of Annex B,

#### Justification

When any decision is taken concerning approval for the exceptional processing of semen not collected in an approved semen collection centre, an approved semen collection centre must ensure that the semen is produced from bovine animals which also meet the requirements relating to the whole virus serological IBR/IPV test. Otherwise, the status sought of BHV1-free cattle and cattle herds, especially of breeding bulls, cannot be guaranteed. Accordingly, subparagraph (iv) also needs to be incorporated as a condition. By the same token, for simplicity's sake, reference may be made to all the requirements set out in subparagraph (d).

## Amendment 10 ANNEX A, CHAPTER II Annex A, Chapter II, paragraph 2(a)

- (a) be so supervised that a record is kept of all movement of semen (in and out the centre) and of the status of the donor bulls whose semen is stored there, and which must comply with the requirements of Directive 88/407/EEC;
- (a) be so supervised that a record is kept of all movement of semen (in and out the centre) and of the status of the donor bulls whose semen is stored there, and which must comply with the requirements of Directive 88/407/EEC; however, movement of semen may be authorised in one direction only; there must be no possibility of the semen being returned to the storage centre;

#### Justification

With a view to preventing infection, movement of semen must be in one direction only (one-way principle), i.e. from the producer to the storage centre and from the storage centre to the stockfarmer. It must not be possible for semen to be returned to the storage centre.

## Amendment 11 ANNEX A, CHAPTER II

Annex A, Chapter II, paragraph 2, point (e), (i) (new) (Directive 88/407/EEC)

- (e) be so supervised that:
  - (i) only semen collected at collection centres approved in accordance with Directive 88/407/EEC is stored in approved storage centres,
- (e) be so supervised that:
  - (i) only semen collected at collection centres approved in accordance with Directive 88/407/EEC is stored in approved storage centres,

PE 322.162 10/14 RR\493536EN.doc

without coming into contact with any other semen.

without coming into contact with any other semen.

Furthermore, only semen coming from an approved collection or storage centre and transported in such a way that it has not come into contact with any other batch of semen may enter an approved storage centre.

Or. fr

#### Justification

The conditions governing the movement of the semen of bovine animals between approved centres must be spelt out. A collection centre actually constitutes a complete epidemiological unit. An epidemiological unit which includes live animals, laboratories and storage and prestorage facilities has a distinct and precise health status. Approval of a collection centre takes into account its health status, which must comply with specific requirements. That being the case, the same rules must be applied to all equipment or biological products, such as bovine semen, which leave a storage centre as are applied to live animals: accordingly, such products may be traded only between storage centres which have an identical status, i.e. both must be approved. That would, therefore, make it impossible for semen to be traded between an agricultural holding and a storage centre. Furthermore, in order to prevent any possible contamination from semen coming from a farm or another unapproved collection centre with a different health status, semen traded between two approved storage centres must not come into contact with another batch.

#### **EXPLANATORY STATEMENT**

#### 1. Introduction

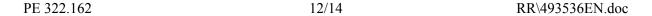
Harmonised legal provisions for intra-Community trade in and imports of deep-frozen semen of domestic animals of the bovine species were laid down in 1988 in Directive 88/407/EEC. That Directive lays down that the Member State in which the semen was collected must ensure that it was collected and processed in approved and officially supervised semen collection centres, that it was collected from animals whose health status excluded the risk of any spread of animal diseases, that it was collected, processed, stored and transported in conditions which guarantee its perfect condition from the animal health point of view and, finally, that the semen was accompanied during transport to the country of destination by an animal health certificate confirming compliance with the provisions referred to above.

That Directive is now to be changed in several respects by the proposal put before us for consideration.

#### The Commission's amendments

The major changes proposed to the current Directive concern four aspects:

- (a) it should, in future, be possible for semen to be stored in locations other than the semen collection centres where it was collected. Accordingly, a definition of 'semen storage centres' is introduced in Article 2(b), and such centres are put on an equal footing with semen collection centres;
- (b) the animal health requirements relating to the movement of animals into semen collection centres are to be changed so as to bring them into line with the new directives of the World Animal Health Organisation (OIE), with particular regard to infectious bovine rhinotracheitis / infectious pustular vulvo-vaginitis (IBR / IPV) and bovine viral diarrhoea / mucosal disease (BVD / MD). Annex B would be changed accordingly;
- (c) the procedure for the approval of semen collection centres in third countries is to be simplified. To that end, Article 9(1) would be amended;
- (d) the Commission is to be empowered to use the comitology procedure to amend the four annexes to the directive: the conditions for the technical approval and those relating to the supervision of semen collection centres and semen storage centres, the conditions applying to the movement of donor bulls into semen collection centres, the conditions which semen must satisfy for the purposes of intra-Community trade, and the format of the health certificate. To that end, Articles 17 and 18 would be amended and Article 19 deleted



### 3. Assessment of the Commission proposal and amendments

The existing Directive needs to be adjusted to take account of scientific progress and of the new directives of the OIE. Accordingly, the amendments proposed to that end have the total support of your rapporteur, although he has made one minor adjustment (see Amendment 9).

However, he has many reservations with regard to both the approval of what are to be called 'semen storage centres' and the simplification of approval procedures for semen collection centres in third countries. Such reservations were expressed in the initial debate in the Committee on Agriculture and Rural Development. We shall look at those reservations in greater detail later on.

With regard to semen storage centres, the principal fear is that, in the light of campaigns to eradicate animal diseases, approval thereof might lead to an increase in risk potential with regard to traceability and supervision. In addition, it is feared that approval of such centres would be tantamount to liberalising trade in semen and, hence, would pose a threat to breeding programme structures in the Member States.

The proposal basically concerns cross-border trade in semen, i.e. from one Member State to another. It would not result in interference in national rules governing trade in semen or breeding programmes. Nevertheless, your rapporteur would propose that the decision as to whether or not semen storage centres should be approved on the territory on a Member State should be left to the Member State concerned. Should it decide to approve such centres, it would have to guarantee permanent official supervision of the semen storage centres and the traceability of the semen. The latter aspect is of crucial importance, should any outbreak of animal diseases occur. All movements of semen into and out of centres must, therefore, be recorded in an officially supervised register.

Detailed provisions governing official approval and official supervision of semen storage centres are introduced into Annex A to the Directive, whereby semen storage centres would be subject to the same strict rules governing hygiene, supervision and traceability as those already applying to semen collection centres. In addition, precautions must be taken to ensure that trade in semen without traceability is possible in one direction only (one-way principle), i.e. from the producer to the centre and from the centre to the stockfarmer. To that end, your rapporteur proposes an appropriate addition in Amendment 10.

Guarantees must also be given that all stages of production and storage of and trade in semen are subject to official supervision, i.e. that responsibility for supervision must lie with the Member States and/or third countries involved. That must be spelt out at several points in the proposal for a directive.

The new procedure for the inclusion of semen collection centres and semen storage centres in third countries in the list of establishments entitled to export to the Community is generally to be welcomed on grounds of administrative simplification. Pursuant to that procedure, changes to the list will be made solely under the comitology procedure if at least one Member State expressed doubts about the proposed changes to the list. However, the period laid down for the Member States to forward their observations to the Commission needs to be extended, so that Member State administrations also have sufficient time in which to review the proposed

changes in detail. Accordingly, your rapporteur proposes 20 working days instead of the 10 working days proposed by the Commission.