



COMMISSION OF THE EUROPEAN COMMUNITIES

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2008/0046 (CNS)

Proposal for a

**COUNCIL DIRECTIVE**

**simplifying procedures of listing and publishing information in the veterinary and zotechnical fields and amending Directives 64/432/EEC, 77/504/EEC, 88/407/EEC, 88/661/EEC, 89/361/EEC, 89/556/EEC, 90/427/EEC, 90/428/EEC, 90/429/EEC, 90/539/EEC, 91/68/EEC, 92/35/EEC, 92/65/EEC, 92/66/EEC, 92/119/EEC, 94/28/EC, 2000/75/EC, Decision 2000/258/EC and Directives 2001/89/EC, 2002/60/EC, and 2005/94/EC**

(presented by the Commission)

## **EXPLANATORY MEMORANDUM**

The general objective of the Commission's proposal is to harmonise and simplify the current procedures for updating and publishing information in the veterinary and zootechnical fields, such as lists of approved animal health establishments and breeding organisations in Member States and Third Countries and lists of certain national reference laboratories and other approved laboratories.

The Commission's proposal aims at amending 20 Directives and one Decision, ensuring a simplified approach, which will lead to benefits in terms of reduced workload and administrative burdens to the competent authorities in the Member States, the farming industry and trade operators and the Commission.

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- **Animal health establishments approved for intra-Community trade in live animals and their products and information to be provided in the zootechnical field**

Community legislation in the veterinary field lays down that assembly centres for bovine, porcine, caprine and ovine animals, dealers of those animals, poultry establishments, semen collection or storage centres and embryo collection or production teams and certain bodies, institutes and centres are to comply with certain conditions and must be officially approved by Member States for intra-Community trade of certain live animals and their products, and in particular animal genetic materials such as semen, ova and embryos.

Current Community legislation provides for different procedures with regard to registration, listing, update, transmission and publication of these animal health establishments. Differences in the procedure make the listing and the update however complicated and the practical use of these lists for the competent control services and the concerned operators very difficult.

Therefore the procedures should be harmonised and provide for more systematic, coherent and uniform rules with regard to the five key elements of the procedure, namely registration, listing, update, transmission and publication of the lists.

In addition, since it is for the Member States to control the conditions that must be fulfilled by the different animal health establishments in order to be listed, the responsibility for the drawing up of the lists should lay with the Member States, and not the Commission.

Member States should therefore draw-up and keep up-to-date lists of the animal health establishments concerned and make them available to the other Member States and to the public. In order to harmonise the model of those lists and the way to achieve a simple access to up-to-date lists for the Community, common criteria need to be introduced under the comitology procedure.

In the interests of clarity and consistency of Community rules, this new procedure should also apply in the zootechnical field, in particular to breeding associations approved for maintaining or establishing herd books, flock books or stud books in Member States and to information to be provided by Member States regarding equine competitions in accordance with Council Directive 90/428/EEC of 26 June 1990 on trade in equidae intended for competitions and laying down the conditions for participation therein.

- Animal health establishments approved in third countries for imports of animal products into the Community and authorities approved in third countries for the purpose of keeping a herd book, a flock book or a studbook

Similarly to the rules applied to intra Community trade, imports of semen, ova and embryos are regulated in such a way that the establishments of origin in third countries are to fulfil certain conditions in order to minimise animal health risks. Accordingly, imports into Community of such genetic materials should only be authorised from semen collection or storage centres and embryo collection or production teams officially approved for export to the Community by the competent authorities of the third country concerned in accordance with Community requirements and following Community veterinary inspections, where appropriate. Depending on the type of genetic materials and on the species concerned, the current procedures for listing animal health establishments and updating the relevant lists are different, ranging from decisions adopted under a comitology procedure in accordance with Council Decision 1999/468/EC of 28 June 1999 laying down the procedures for the exercise of implementing powers conferred on the Commission<sup>1</sup> to a simple consultation with Member States.

The co-existence of different procedures can lead to confusion and uncertainty amongst administrative officials in third countries, the farming industry and trade operators. Since it is for the third countries to check on the conditions that must be fulfilled by the different animal health establishments in order to be listed as approved for export to the Community in accordance with Community requirements, the current legal framework for the authorisation of those establishments should be harmonised and simplified, so that the responsibility for drawing up and updating the lists lies with the third countries and not the Commission. It is important to ensure that the level of animal health guarantees given by the third country concerned is not affected. The simplification measures are without prejudice to the right of the Commission to take safeguard measures if necessary.

The different existing procedures should therefore be replaced by a procedure under which the competent authorities of the third countries draw up, keep up-to-date the lists and communicate them to the Commission. The Commission should inform the Member States about these lists and makes them available to the public for information purposes. In the case of concerns with regard to the lists communicated by the third countries, adoption of safeguard measures is to be taken in accordance with Council Directive 97/78/EC.

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<sup>1</sup> OJ L 184, 17.7.1999, p. 23. Decision as last amended by Decision 2006/512/EC (OJ L 200, 22.7.2006, p. 11).

For reasons of clarity and consistency, that procedure should also apply to authorities in third countries approved for the purpose of keeping a herd book, a flock book or a studbook in accordance with Community zootechnical legislation.

- Laboratories

In the veterinary field, the Commission has the responsibility for setting up and updating the lists of approved national reference laboratories and other approved laboratories on the basis of information provided for by the Member States.

In accordance with existing Community legislation, amendments to those lists are made, following a request from a Member State and a decision adopted under a comitology procedure in accordance with Decision 1999/468/EC or by the Council on a proposal from the Commission.

However, amendments to such lists are often of purely formal nature, such as changes in the contact details of the laboratories in question.

The current practice has been to make only periodic updates of the lists of those laboratories to reduce the number of Commission decisions to be taken. However, this practice does not guarantee a rapid update of those lists. This could compromise the legal status of national reference laboratories and other approved laboratories. Since the Member States designate the national reference laboratories and provide all the necessary details and updates, the responsibility for the drawing up of the lists should lay with the Member States and not the Commission. The same should apply to other approved laboratories in the Member States.

Member States shall therefore draw-up and keep up-to-date the lists of national reference laboratories and other approved laboratories concerned and make them available to the other Member States and the public. In order to harmonise the model of those lists and the way to achieve a simple access to up-to-date lists for the Community, common criteria need to be introduced under the comitology procedure.

However, where the lists concern approved laboratories situated in third countries, the Commission should continue to be responsible for drawing up and publishing the lists of such laboratories.

The purpose of this proposal is:

- to harmonise and simplify the current procedures for updating and publishing lists of certain approved animal health establishments and breeding organisations in Member States and information to be provided by Member States regarding equine competition;
- to harmonise and simplify the current procedures for updating and publishing lists of certain approved animal health establishments and authorities approved for the purpose of keeping a herd book, a flock book or a studbook in third countries;
- to simplify the current procedures for updating and publishing lists of certain national reference laboratories and other approved laboratories.

Directives 64/432/EEC, 77/504/EEC, 88/407/EEC, 88/661/EEC, 89/361/EEC, 89/556/EEC, 90/427/EEC, 90/428/EEC, 90/429/EEC, 90/539/EEC, 91/68/EEC, 92/35/EEC, 92/65/EEC, 92/66/EEC, 92/119/EEC, 94/28/EC, 2000/75/EC, 2001/89/EC, 2002/60/EC, 2005/94/EC and Decision 2000/258/EC should be amended accordingly.

Proposal for a

**COUNCIL DIRECTIVE**

**simplifying procedures of listing and publishing information in the veterinary and zootechnical fields and amending Directives 64/432/EEC, 77/504/EEC, 88/407/EEC, 88/661/EEC, 89/361/EEC, 89/556/EEC, 90/427/EEC, 90/428/EEC, 90/429/EEC, 90/539/EEC, 91/68/EEC, 92/35/EEC, 92/65/EEC, 92/66/EEC, 92/119/EEC, 94/28/EC, 2000/75/EC, Decision 2000/258/EC and Directives 2001/89/EC, 2002/60/EC, and 2005/94/EC**

**(Text with EEA relevance)**

THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty establishing the European Community, and in particular Article 37 thereof,

Having regard to Council Directive 92/65/EEC of 13 July 1992 laying down animal health requirements governing trade in and imports into the Community of animals, semen, ova and embryos not subject to animal health requirements laid down in specific Community rules referred to Annex A(I) to Directive 90/425/EEC<sup>2</sup>, and in particular Article 10(6) thereof,

Having regard to the proposal from the Commission<sup>3</sup>,

Having regard to the opinion of the European Parliament<sup>4</sup>,

Having regard to the opinion of the European Economic and Social Committee<sup>5</sup>

Whereas:

- (1) Community legislation in the veterinary field provides that assembly centres for bovine, porcine, caprine and ovine animals, dealers of those animals, poultry establishments, semen collection or storage centres and embryo collection or production teams and certain bodies, institutes and centres ('animal health establishments') are to comply with certain conditions and must be officially approved by Member States for intra-Community trade in certain live animals and their products, and in particular animal genetic materials, such as semen, ova and embryos.
- (2) Current Community legislation provides for different procedures with regard to the registration, listing, updating, transmission and publication of those animal health

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<sup>2</sup> OJ L 268, 14.9.1992, p. 54. Directive as last amended by Commission Decision 2007/265/EC (OJ L 114, 1.5.2007, p. 17).

<sup>3</sup> OJ C [...], [...], p. [...].

<sup>4</sup> OJ C [...], [...], p. [...].

<sup>5</sup> OJ C [...], [...], p. [...].

establishments. However, differences in the procedures make the listing and the updating complicated and the practical use of those lists for the competent control services and the concerned operators very difficult.

- (3) Therefore those procedures should be harmonised and provide for more systematic, coherent and uniform rules with regard to the five key elements of such procedures, namely registration, listing, updating, transmission and publication of the lists.
- (4) In addition, since it is for the Member States to control the conditions that must be fulfilled by the different animal health establishments in order to be listed, the responsibility for the drawing up of the lists should lay with the Member States and not the Commission.
- (5) Member States should therefore draw up and keep up-to-date lists of the animal health establishments concerned and make them available to the other Member States and to the public. In order to harmonise the model forms of those lists and the way to achieve simple access to up-to-date lists for the Community, common criteria need to be established under a comitology procedure.
- (6) In the interests of clarity and consistency of Community rules, this new procedure should also apply in the zootechnical field, in particular to breeding associations approved for maintaining or establishing herd books in Member States and to information to be provided by Member States regarding equine competitions in accordance with Council Directive 90/428/EEC of 26 June 1990 on trade in equidae intended for competitions and laying down the conditions for participation therein<sup>6</sup>.
- (7) Similarly to the rules applied to intra-Community trade, imports of semen, ova and embryos are regulated in such a way that the animal health establishments of origin in third countries are to fulfil certain conditions in order to minimise animal health risks. Accordingly, imports into the Community of such genetic materials should only be authorised from semen collection or storage centres and embryo collection or production teams officially approved for export to the Community by the competent authorities of the third country concerned in accordance with Community requirements and following Community veterinary inspections, where appropriate.
- (8) Depending on the type of genetic materials and on the species concerned, the current procedures for listing animal health establishments and updating the relevant lists are different, ranging from decisions adopted under a comitology procedure in accordance with Council Decision 1999/468/EC of 28 June 1999 laying down the procedures for the exercise of implementing powers conferred on the Commission<sup>7</sup> to a simple consultation with Member States.
- (9) The co-existence of different procedures can lead to confusion and uncertainty amongst administrative officials in third countries, the farming industry and trade operators. Since it is for the third countries to check on the conditions that must be fulfilled by the different animal health establishments in order to be listed as approved for export to the Community in accordance with Community requirements, the current

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<sup>6</sup> OJ L 224, 18.8.1990, p. 60.

<sup>7</sup> OJ L 184, 17.7.1999, p. 23. Decision as last amended by Decision 2006/512/EC (OJ L 200, 22.7.2006, p. 11).

legal framework for the authorisation of those establishments should be harmonised and simplified, so that the responsibility for drawing up and updating the lists lies with the third countries and not the Commission. It is important to ensure that the level of animal health guarantees given by the third country concerned is not affected. The simplification measures are without prejudice to the right of the Commission to take safeguard measures if necessary.

- (10) The different existing procedures should therefore be replaced by a procedure under which imports into the Community should only be permitted from third countries in which competent authorities draw up and keep up-to-date the lists and communicate them to the Commission. The Commission should inform the Member States about those lists and make them available to the public for information purposes. In the case of concerns with regard to the lists communicated by the third countries, safeguard measures are to be adopted in accordance with Council Directive 97/78/EC of 18 December 1997 laying down the principles governing the organisation of veterinary checks on products entering the Community from third countries<sup>8</sup>.
- (11) For reasons of clarity and consistency of Community legislation, that procedure should also apply to authorities in third countries approved for the purpose of keeping herd books, flock books or studbooks in accordance with Community zootechnical legislation.
- (12) In the veterinary field, the Commission is responsible for setting up and updating the lists of approved national reference laboratories and other approved laboratories on the basis of information provided by the Member States.
- (13) In accordance with existing Community legislation, amendments to those lists are made, following a request from a Member State and a decision adopted under a comitology procedure in accordance with Decision 1999/468/EC, or by the Council on a proposal from the Commission.
- (14) However, amendments to such lists are often of a purely formal nature, such as changes in the contact details of the national reference laboratories or the other approved laboratories in question.
- (15) The current practice has been to make only periodic updates of the lists of those laboratories to reduce the number of Commission decisions to be taken. However, that practice does not guarantee a rapid update of those lists. This could compromise the legal status of national reference laboratories and other approved laboratories.
- (16) Since the Member States designate the national reference laboratories and provide all the necessary details and updates, the responsibility for the drawing up of the lists of such laboratories should lay with the Member States and not the Commission. Similarly, the responsibility for drawing up lists of other approved laboratories should lay with the Member States.
- (17) Member States should therefore draw up and keep up-to-date the lists of the national reference laboratories and other approved laboratories concerned and make them

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<sup>8</sup> OJ L 24, 30.1.1998, p. 9. Directive as last amended by Directive 2006/104/EC (OJ L 363, 20.12.2006, p. 352).



available to the other Member States and the public. In order to harmonise the model of those lists and the way to achieve simple access to up-to-date lists for the Community, common criteria should be established under the comitology procedure.

- (18) However, where the lists concern approved laboratories situated in third countries, the Commission should continue to be responsible for drawing up and publishing the lists of such laboratories.
- (19) In order to avoid any disruption concerning applications for approval of laboratories submitted by Member States pursuant to Council Decision 2000/258/EC of 20 March 2000 designating a specific institute responsible for establishing the criteria necessary for standardising the serological tests to monitor the effectiveness of rabies vaccines<sup>9</sup>, transitional measures should be provided for in this Directive.
- (20) Council Directives 64/432/EEC<sup>10</sup>, 77/504/EEC<sup>11</sup>, 88/407/EEC<sup>12</sup>, 88/661/EEC<sup>13</sup>, 89/361/EEC<sup>14</sup>, 89/556/EEC<sup>15</sup>, 90/427/EEC<sup>16</sup>, 90/428/EEC<sup>17</sup>, 90/429/EEC<sup>18</sup>, 90/539/EEC<sup>19</sup>, 91/68/EEC<sup>20</sup>, 92/35/EEC<sup>21</sup>, 92/65/EEC, 92/66/EEC<sup>22</sup>, 92/119/EEC<sup>23</sup> and 94/28/EC<sup>24</sup>, 2000/75/EC<sup>25</sup>, Council Decision 2000/258/EC, Council Directives 2001/89/EC<sup>26</sup>, 2002/60/EC<sup>27</sup>, and 2005/94/EC<sup>28</sup> should therefore be amended accordingly,

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<sup>9</sup> OJ L 79, 30.3.2000, p. 40. Decision as last amended by Commission Decision 2003/60/EC (OJ L 23, 28.1.2003, p. 30).

<sup>10</sup> OJ L 121, 29.7.1964, p. 1977/64. Directive as last amended by Directive 2006/104/EC.

<sup>11</sup> OJ L 206, 12.8.1977, p. 8. Directive as last amended by Regulation (EC) No 807/2003 (OJ L 122, 16.5.2003, p. 36).

<sup>12</sup> OJ L 194, 22.7.1988, p. 10. Directive as last amended by Commission Decision 2006/16/EC (OJ L 11, 7.1.2006, p. 21).

<sup>13</sup> OJ L 382, 31.12.1988, p. 36. Directive as last amended by Regulation (EC) No 806/2003 (OJ L 122, 16.5.2003, p. 1).

<sup>14</sup> OJ L 153, 6.6.1989, p. 30.

<sup>15</sup> OJ L 302, 19.10.1989, p. 1. Directive as last amended by Commission Decision 2006/60/EC (OJ L 31, 3.2.2006, p. 24).

<sup>16</sup> OJ L 224, 18.8.1990, p. 55.

<sup>17</sup> OJ L 224, 18.8.1990, p. 60.

<sup>18</sup> OJ L 224, 18.8.1990, p. 62. Directive as last amended by Regulation (EC) No 806/2003.

<sup>19</sup> OJ L 303, 31.10.1990, p. 6. Directive as last amended by Directive 2006/104/EC.

<sup>20</sup> OJ L 46, 19.2.1991, p. 19. Directive as last amended by Directive 2006/104/EC.

<sup>21</sup> OJ L 157, 10.6.1992, p. 19. Directive as last amended by Directive 2006/104/EC.

<sup>22</sup> OJ L 260, 5.9.1992, p. 1. Directive as last amended by Directive 2006/104/EC.

<sup>23</sup> OJ L 62, 15.3.1993, p. 69. Directive as last amended by Commission Directive 2007/10/EC (OJ L 63, 1.3.2007, p. 24).

<sup>24</sup> OJ L 178, 12.7.1994, p. 66.

<sup>25</sup> OJ L 327, 22.12.2000, p. 74. Directive as last amended by Directive 2006/104/EC.

<sup>26</sup> OJ L 316, 1.12.2001, p. 5. Directive as last amended by Directive 2006/104/EC.

<sup>27</sup> OJ L 192, 20.7.2002, p. 27. Directive as last amended by Directive 2006/104/EC.

<sup>28</sup> OJ L 10, 14.1.2005, p. 16.

HAS ADOPTED THIS DIRECTIVE:

*Article 1*  
*Amendments to Directive 64/432/EEC*

Directive 64/432/EEC is hereby amended as follows:

- (1) The following Article 6a shall be inserted:

*"Article 6a*

Member States shall designate State Institutes, National Reference Laboratories or Official Institutes responsible for coordinating the standards and methods of diagnosis referred to in Annexes A to D. They shall maintain up-to-date lists thereof and make them available to the other Member States and to the public.

The tasks and responsibilities of those State Institutes, National Reference Laboratories and Official Institutes are set out in Annexes B and C and Chapter II of Annex D.

Detailed rules for the uniform application of this Article may be adopted in accordance with the procedure referred to in Article 17(2)."

- (2) In Article 11, paragraph 3 shall be replaced by the following:

"3. The competent authority shall issue an approval number to each approved assembly centre. Approvals of assembly centres may be limited to a particular species or to animals for breeding and production or to animals for slaughter.

The competent authority shall draw up and keep up-to-date a list of approved assembly centres and their approval numbers and make it available to the other Member States and to the public."

- (3) In Article 13, the following paragraphs 5 and 6 shall be added:

"5. Member States shall draw up and keep up-to-date a list of approved dealers and registered premises used by dealers in connection with their business and their approval numbers and make that list available to the other Member States and to the public.

6. Detailed rules for the uniform application of paragraph 5 may be adopted in accordance with the procedure referred to in Article 17(2)."

- (4) Annex B shall be amended as follows:

- (a) point 4.1 shall be replaced by the following:

"4.1. Tasks and responsibilities

The State Institutes, National Reference Laboratories or Official Institutes designated in accordance with Article 6a shall be responsible for the official testing of tuberculins or reagents referred to in paragraphs 2 and 3 respectively in their respective Member States to ensure that each of these tuberculins or reagents is adequate in relation to the standards referred to in point 2.1 and paragraph 3 respectively."

- (b) point 4.2 shall be deleted.
- (5) In Annex C, point 4.2 shall be deleted.
- (6) In Annex D, Chapter II.A, points 2 and 3 shall be replaced by the following:
  - "2. The State Institutes, National Reference Laboratories or Official Institutes designated in accordance with Article 6a for coordinating standards and methods of diagnosis of the tests for enzootic bovine leucosis must be made responsible for calibrating the standard working antigen of the laboratory against the official EC standard serum (EI serum) provided by the National Veterinary Institute, Technical University of Denmark.
  - 3. The standard antigens used in the laboratory must be submitted at least once a year to the State Institutes, National Reference Laboratories or Official Institutes designated in accordance with Article 6a, for testing against the official EC standard serum. Apart from such standardisation, the antigen in use may be calibrated in accordance with the method described in B."

*Article 2*  
*Amendments to Directive 77/504/EEC*

The following Article 4a shall be inserted:

*"Article 4a*

- 1. Member States shall draw up and keep up-to-date a list of breeders' organisations and associations which are officially recognised for the purpose of maintaining or establishing herd-books and make it available to the other Member States and to the public.
- 2. Detailed rules for the uniform application of this Article may be adopted in accordance with the procedure referred to in Article 8(2)."

*Article 3*  
*Amendments to Directive 88/407/EEC*

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

- (1) In Article 5, paragraph 2 shall be replaced by the following:

- "2. All semen collection or storage centres shall be registered, each centre being given a veterinary registration number. Each Member State shall draw up and keep up-to-date a list of semen collection or storage centres and their veterinary registration numbers and make it available to the other Member States and to the public.
3. Detailed rules for the uniform application of this Article may be adopted in accordance with the procedure referred to in Article 18(2)."

(2) Article 9 shall be replaced by the following:

*"Article 9*

1. Member States shall only authorise imports of semen dispatched from a semen collection or storage centre situated in one of the third countries appearing on the list referred to in Article 8 and for which the competent authority of the third country concerned is able to give the guarantees that the following conditions are met:
  - (a) it meets the conditions:
    - (i) for approval of semen collection centres or storage centres set out in Chapter I of Annex A;
    - (ii) relating to the supervision of such centres set out in Chapter II thereof;
  - (b) it has been officially approved by the competent authority of the third country for exports to the Community;
  - (c) it is placed under the supervision of a centre veterinarian;
  - (d) it is subject to inspections by an official veterinarian of the third country at least twice a year.
2. The list of semen collection or storage centres that the competent authority of the third country appearing on the list referred to in Article 8 has approved in accordance with the conditions set out in paragraph 1 of this Article and from which semen may be dispatched to the Community shall be communicated to the Commission.

The approval of a semen collection or storage centre must be immediately suspended or withdrawn by the competent authority of the third country where it no longer complies with the conditions set out in paragraph 1 and the Commission must be immediately informed thereof.

The Commission shall provide the Member States with any new and updated lists that it receives from the competent authority of the third country in accordance with this paragraph and shall make them available to the public for information purposes.

3. Detailed rules for the uniform application of this Article may be adopted in accordance with the procedure referred to in Article 18(2)."

(3) Article 12 shall be replaced by the following:

*"Article 12*

The rules laid down in Directive 97/78/EC shall apply, in particular to the organisation of, and follow-up to, the checks to be carried out by the Member States and the safeguard measures to be applied in accordance with the procedure referred to in Article 22 of that Directive."

*Article 4*  
*Amendments to Directive 88/661/EEC*

The following Article 4a shall be inserted:

*"Article 4a*

Member States shall draw up and keep up-to-date a list of breeders' associations and/or breeding organizations as referred to in Article 1(c) and make it available to the other Member States and to the public.

Detailed rules for the uniform application of this Article may be adopted in accordance with the procedure referred to in Article 11(2)."

*Article 5*  
*Amendments to Directive 89/361/EEC*

Article 5 of Directive 89/361/EEC shall be replaced by the following:

*"Article 5*

Member States shall draw up and keep up-to-date a list of breeders' organisations and associations which are officially approved for the purpose of maintaining or establishing flock books and which meet the criteria determined in accordance with the first indent of Article 4 and make it available to the other Member States and to the public.

Detailed rules for the uniform application of this Article may be adopted in accordance with the procedure referred to in Article 8."

*Article 6*  
*Amendments to Directive 89/556/EEC*

Directive 89/556/EEC is hereby amended as follows:

(1) In Article 5(2), the first subparagraph, shall be replaced by the following:

- "2. The competent authority of each Member State concerned shall register embryo collection teams and give a veterinary registration number to each team.

Each Member State shall draw up and keep up-to-date a list of embryo collection teams and their veterinary registration numbers and make it available to the other Member States and to the public."

- (2) Article 8 shall be replaced by the following:

*"Article 8*

1. Member States shall only authorise imports of embryos dispatched from an embryo collection or production team situated in one of the third countries appearing on the list referred to in Article 7 and for which the competent authority of the third country concerned is able to give the guarantees that the following conditions are met:
  - (a) it meets the conditions:
    - (i) for the approval of embryo collection and embryo production teams set out in Chapter I of Annex A;
    - (ii) relating to the collection, processing, storage and transport of embryos by such teams set out in Chapter II of that Annex;
  - (b) it has been officially approved by the competent authority of the third country for exports to the Community;
  - (c) it is subject to inspections by an official veterinarian of the third country at least twice a year.
2. The list of embryo collection or production teams that the competent authority of the third country appearing on the list referred to in Article 7 has approved in accordance with the conditions set out in paragraph 1 of this Article and from which embryos may be dispatched to the Community shall be communicated to the Commission.

The approval of an embryo collection or production team must be immediately suspended or withdrawn by the competent authority of the third country where it no longer complies with the conditions set out in paragraph 1 and the Commission must be immediately informed thereof.

The Commission shall provide the Member States with any new and updated lists that it receives from the competent authority of the third country concerned in accordance with this paragraph and shall make them available to the public for information purposes.
3. Detailed rules for the uniform application of this Article may be adopted in accordance with the procedure referred to in Article 18(2)."

(3) Article 11 is replaced by the following:

*"Article 11*

The rules laid down in Directive 97/78/EC shall apply, in particular to the organisation of, and follow-up to, the checks to be carried out by the Member States and the safeguard measures to be applied in accordance with the procedure referred to in Article 22 of that Directive."

*Article 7*  
*Amendments to Directive 90/427/EEC*

Article 5 of Directive 90/427/EEC shall be replaced by the following:

*"Article 5*

Member States shall draw up and keep up-to-date the list of organisations and associations maintaining or establishing studbooks, which are approved or recognised on the basis of the criteria determined in accordance with Article 4(2)(a) and make it available to the other Member States and to the public.

Detailed rules for the uniform application of this Article may be adopted in accordance with the procedure referred to in Article 10."

*Article 8*  
*Amendments to Directive 90/428/EEC*

In Article 4 of Directive 90/428/EEC, paragraph 2 shall be replaced by the following:

"2. However,

- the obligations referred to in Article 3 shall not affect the organization of:
  - (a) competitions reserved for equidae registered in a specific studbook for the purpose of permitting the improvement of the breed;
  - (b) regional competitions with a view to selecting equidae;
  - (c) historic or traditional events.

Member States intending to avail themselves of these possibilities shall make this intention and the justifications thereof available to the other Member States and to the public beforehand.

- for each competition or type of competition Member States shall be authorized to reserve, through the bodies officially approved or recognized for that purpose, a certain percentage of the prize money or profits referred to in paragraph 1(c) for the safeguard, development and improvement of breeding.

The percentage may not exceed 20 % from 1993.

The criteria for the distribution of these funds in the Member State concerned shall be made available to the other Member States and to the public."

*Article 9*  
*Amendments to Directive 90/429/EEC*

Directive 90/429/EEC is hereby amended as follows:

- (1) In Article 5, paragraph 2 shall be replaced by the following:

"2. All semen collection centres shall be registered, each centre being given a veterinary registration number.

Each Member State shall draw up and keep up-to-date a list of semen collection centres and their veterinary registration numbers and make it available to the other Member States and to the public."

- (2) Article 8 shall be replaced by the following:

*"Article 8*

1. Member States shall only authorise imports of semen dispatched from a semen collection centre situated in one of the third countries appearing on the list referred to in Article 7 and for which the competent authority of the third country concerned is able to give the guarantees that the following conditions are met:
  - (a) it meets the conditions:
    - (i) for the approval of semen collection centres set out in Chapter I of Annex A;
    - (ii) relating to the supervision of such centres set out in Chapter II thereof;
  - (b) it has been officially approved by the competent authority of the third country for exports to the Community;
  - (c) it is placed under the supervision of a centre veterinarian;
  - (d) it is subject to inspections by an official veterinarian of the third country concerned at least twice a year.



2. The list of semen collection centres that the competent authority of the third country appearing on the list referred to in Article 7 has approved in accordance with the conditions set out in paragraph 1 of this Article and from which semen may be dispatched to the Community shall be communicated to the Commission.

The approval of a semen collection centre must be immediately suspended or withdrawn by the competent authority of the third country where it no longer complies with the conditions set out in paragraph 1 and the Commission must be immediately informed thereof.

The Commission shall provide the Member States with any new and updated lists that it receives from the competent authority of the third country concerned in accordance with this paragraph and shall make them available to the public for information purposes.

3. Detailed rules for the uniform application of this Article may be adopted in accordance with the procedure referred to in Article 18(2)."

(3) In Article 15, paragraph 2 shall be replaced by the following:

- "2. The rules laid down in Directive 97/78/EC shall apply, in particular to the organisation of, and follow-up to, the checks to be carried out by the Member States and the safeguard measures to be applied in accordance with the procedure referred to in Article 22 of that Directive."

*Article 10*  
*Amendments to Directive 90/539/EEC*

Directive 90/539/EEC is hereby amended as follows

- (1) Article 4 shall be replaced by the following:

*"Article 4*

Each Member State shall designate a national reference laboratory to be responsible for coordinating the diagnostic methods provided for in this Directive and their use by the approved laboratories located in its territory.

Each Member State shall make the details of its national reference laboratory, and any subsequent changes, available to the other Member States and to the public.

Detailed rules for the uniform application of this Article may be adopted in accordance with the procedure referred to in Article 32(2)."

- (2) The following Article 6a shall be inserted:

*"Article 6a*

Each Member State shall draw up and keep up-to-date a list of establishments approved in accordance with point 1(a) of Article 6 and their distinguishing numbers, and shall make it available to the other Member States and to the public.

Detailed rules for the uniform application of this article may be adopted in accordance with the procedure referred to in Article 32."

- (3) Annex I shall be amended as follows:

- (i) point 1 shall be deleted.  
(ii) point 2 shall be replaced by the following:

"2. The national reference laboratories for avian diseases designated in accordance with Article 4 shall be responsible in each Member State for coordinating the diagnostic methods provided for in this Directive. To this end:

- (a) they may supply approved laboratories with the reagents needed for diagnostic testing;  
(b) they shall monitor the quality of all the reagents used by the approved laboratories;  
(c) they shall organize periodic comparative tests."

*Article 11*

*Amendments to Directive 91/68/EEC*

Directive 91/68/EEC is hereby amended as follows:

- (1) In Article 8a, paragraph (3) shall be replaced by the following:

"(3) The competent authority shall issue an approval number to each approved assembly centre. Approvals may be limited to one or more species covered by this Directive or to animals for breeding or fattening, or to animals for slaughter.

The competent authority shall draw up and keep up-to-date a list of approved assembly centres and their unique approval numbers and make it available to the other Member States and to the public."

(2) In Article 8b, the following paragraph 5 shall be added:

"(5) Member States shall draw up and keep up-to-date a list of approved dealers and registered premises used by dealers in connection with their business and their approval numbers and shall make it available to the other Member States and to the public.

Detailed rules for the uniform application of this paragraph may be adopted in accordance with the procedure referred to in Article 15(2)."

*Article 12*  
*Amendments to Directive 92/35/EEC*

Directive 92/35/EEC is hereby amended as follows

(1) Article 14 shall be replaced by the following:

*"Article 14*

1. Member States shall designate a national laboratory to carry out the laboratory examinations provided for in this Directive, and shall make the details of that laboratory, and any subsequent changes, available to the other Member States and to the public.

Detailed rules for the uniform application of this paragraph may be adopted in accordance with the procedure referred to in Article 19.

2. The functions and duties of the national laboratories designated in accordance with paragraph 1 are set out in Annex I.

3. The national laboratories designated in accordance with paragraph 1 shall liaise with the Community reference laboratory referred to in Article 15."

(2) In Annex I, Section A shall be deleted.

*Article 13*  
*Amendments to Directive 92/65/EEC*

Directive 92/65/EEC is hereby amended as follows:

(1) In Article 11, the following paragraph 5 shall be added:

"5. The approved centres referred to in the first indent of paragraph 2 and the approved collection teams referred to in the first indent of paragraph 3 shall be registered by the competent authority of the Member State concerned, each centre and team being given a veterinary registration number.

Each Member State shall draw up and keep up-to-date a list of those approved centres and approved collection teams and their veterinary registration numbers and shall make it available to the other Member States and to the public.

Detailed rules for the uniform application of this paragraph may be adopted in accordance with the procedure referred to in Article 26(2)."

(2) In Article 13(2), point (d) shall be replaced by the following:

"(d) All approved bodies, institutes and centres shall be registered and issued with an approval number by the competent authority.

Each Member State shall draw up and keep up-to-date a list of approved bodies, institutes and centres and their approval numbers and shall make it available to the other Member States and to the public.

Detailed rules for the uniform application of this point may be adopted in accordance with the procedure referred to in Article 26(2)."

(3) In Article 17, paragraph 3 shall be replaced by the following:

"3. The following shall be established:

- (a) in accordance with the procedure referred to in Article 26(2), a list of third countries or parts of third countries able to provide Member States and the Commission with guarantees equivalent to those provided for in Chapter II in relation to animals, semen, ova and embryos;
- (b) in accordance with this point, a list of approved centres or collection teams as referred to in the first indent of paragraph 2 of Article 11 and the first indent of paragraph 3 of that article situated in one of the third countries appearing on the list referred to in point (a) of this paragraph and for which the competent authority is able to give the guarantees provided for in Article 11(2) and (3).

The list of approved centres and collection teams referred to in the first subparagraph and their veterinary registration numbers shall be communicated to the Commission.

The approval of a collection centre or team must be immediately suspended or withdrawn by the competent authority of the third country where it no longer complies with the conditions referred to in Article 11(2) and (3) and the Commission must be immediately informed thereof.

The Commission shall provide the Member States with any new and updated lists that it receives from the competent authority of the third country in accordance with the second and third subparagraphs and shall make them available to the public for information purposes.

Detailed rules for the uniform application of this point may be adopted in accordance with the procedure referred to in Article 26(2).

- (c) in accordance with the procedure referred to in Article 26(2), the specific animal health requirements, in particular for the protection of the Community from certain exotic diseases, or guarantees equivalent to those provided for in this Directive.

The specific requirements and equivalent guarantees established for third countries may not be more favourable than those provided for in Chapter II."

- (4) In Article 20, the first paragraph shall be replaced by the following:

"The rules laid down in Directive 97/78/EC shall apply in particular to the organisation of, and follow-up to, the checks to be carried out by the Member States and the safeguard measures to be applied in accordance with the procedure referred to in Article 22 of that Directive."

*Article 14*  
*Amendments to Directive 92/66/EEC*

Directive 92/66/EEC is hereby amended as follows:

- (1) Article 14 is amended as follows:

- (a) Paragraph 2 shall be replaced by the following:

"2. The national laboratories referred to in paragraph 1 shall be responsible for coordinating standards and methods of diagnosis, use of reagents and testing of vaccines."

- (b) In paragraph 3, the introductory phrase shall be replaced by the following:

"3. The national laboratories referred to in paragraph 1 shall be responsible for coordinating the standards and diagnostic methods laid down in each Newcastle-disease diagnostic laboratory within the Member State. To this end:"

- (c) Paragraph 4 shall be replaced by the following:

"4. The national laboratories referred to in paragraph 1 shall liaise with the Community reference laboratory referred to in Article 15.

5. Member States shall maintain up-to-date lists of the national laboratories or institutes referred to in paragraph 1 and make them available to the other Member States and to the public.

Detailed rules for the uniform application of this paragraph may be adopted in accordance with the procedure referred to in Article 25(2)."

- (2) Annex IV shall be deleted.

*Article 15*  
*Amendments to Directive 92/119/EEC*

Directive 92/119/EEC is hereby amended as follows:

- (1) In Article 17, paragraph 5 shall be replaced by the following:
- "5. Member States shall maintain up-to-date lists of the national laboratories referred to in paragraph 1 and make them available to the other Member States and to the public."
- (2) In Annex II, point 5 shall be deleted.

*Article 16*  
*Amendments to Directive 94/28/EC*

Directive 94/28/EC is hereby amended as follows:

- (1) In Article 3, paragraph 1 shall be replaced by the following:
- "1. A list of authorities in respect of the species and/or races concerned that the competent authority of the third country has approved for the purpose of this Directive shall be communicated to the Commission.
- The approval of an authority must be immediately suspended or withdrawn by the competent authority of the third country where it no longer complies with the conditions referred to in Article 3(2)(b) and the Commission must be immediately informed thereof.
- The Commission shall provide the Member States with any new and updated lists that it receives from the competent authority of the third country concerned in accordance with the second subparagraph and shall make them available to the public for information purposes."
- (2) Article 3 shall be amended as follows:
- (a) In paragraph 2, point (a) shall be deleted;
- (b) Paragraph 3 shall be deleted.

- (3) In Article 10, the following paragraph shall be added:

"Where any serious infringement to the provisions in Article 3(2)(b) so warrants, in particular in the light of findings in relation to on-the-spot checks referred to in the first paragraph of this Article, measures may be adopted to suspend the import of animals, semen, ova and embryos referred to in Article 1(1) in accordance with the procedure referred to in Article 12."

*Article 17*  
*Amendments to Directive 2000/75/EC*

Directive 2000/75/EC is hereby amended as follows:

- (1) Article 15 shall be replaced by the following:

*"Article 15*

1. Member States shall designate a national laboratory responsible for carrying out the laboratory tests provided for by this Directive, and shall make the details of that laboratory, and any subsequent changes, available to the other Member States and to the public.

Detailed rules for the uniform application of this paragraph may be adopted in accordance with the procedure referred to in Article 20(2).

2. The tasks of the national laboratories designated in accordance with paragraph 1 are listed in Annex I.
3. The national laboratories designated in accordance with paragraph 1 of this Article shall liaise with the Community reference laboratory referred to in Article 16."

- (2) In Annex I, Section A shall be deleted.

*Article 18*  
*Amendments to Decision 2000/258/EC*

Decision 2000/258/EC is hereby amended as follows:

- (1) Article 3 shall be replaced by the following:

*"Article 3*

1. On the basis of a favourable result of the appraisal of an applicant laboratory in a Member State, documented by AFSSA, Nancy, the competent authority of the Member State may authorise the applicant laboratory to carry out the serological tests to monitor the effectiveness of rabies vaccines.

Member States shall draw up and keep up-to-date a list of those laboratories that they have authorised and shall make it available to the other Member States and to the public.

2. On the basis of a favourable result of the appraisal of an applicant laboratory in a third country documented by AFSSA, Nancy, and following an application for approval from the competent authority of the third country of origin of the applicant laboratory, such laboratory shall be authorised in accordance with the procedure referred to in Article 5(2) to carry out serological tests to monitor the effectiveness of rabies vaccines.
  3. Detailed rules for the uniform application of this Article may be adopted in accordance with the procedure referred to in Article 5(2)."
- (2) Annexes I and II shall be replaced by the text in the Annex to this Directive.

*Article 19*  
*Amendments to Directive 2001/89/EC*

Directive 2001/89/EC is hereby amended as follows:

- (1) In Article 17(1), point (b) shall be replaced by the following:

"(b) a national laboratory is responsible for coordinating standards and methods of diagnosis in each Member State in accordance with the provisions of Annex III.

Member States shall make the details of their national laboratory, and any subsequent changes, available to the other Member States and to the public in a manner that may be specified in accordance with the procedure referred to in Article 26(2)."
- (2) Annex III shall be amended as follows:
  - (a) the title shall be replaced by the following:

"Duties of national laboratories for classical swine fever"
  - (b) point 1 shall be deleted.

*Article 20*  
*Amendments to Directive 2002/60/EC*

Directive 2002/60/EC is hereby amended as follows:

- (1) In Article 18(1), point (b) shall be replaced by the following:

"(b) a national laboratory is responsible for coordinating standards and diagnostic methods in each Member State in accordance with Annex IV.



Member States shall make the details of their national laboratory, and any subsequent changes, available to the other Member States and to the public in a manner that may be specified in accordance with the procedure referred to in Article 23(2)."

(2) Annex IV shall be amended as follows:

(a) the title shall be replaced by the following:

"Duties of national laboratories for African swine fever"

(b) Point 1 shall be deleted.

*Article 21*  
*Amendments to Directive 2005/94/EC*

In Article 51 of Directive 2005/94/EC, paragraph 2 shall be replaced by the following:

"2. Member States shall designate a national reference laboratory and shall make the details thereof, and any subsequent changes, available to the other Member State and to the public in a manner that may be specified in accordance with the procedure referred to in Article 64(2)."

*Article 22*  
*Transposition*

1. Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with this Directive by 1 July 2009 at the latest. They shall forthwith communicate to the Commission the text of those provisions and a correlation table between those provisions and this Directive.

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. Member States shall determine how such reference is to be made.

2. Member States shall communicate to the Commission the text of the main provisions of national law which they adopt in the field covered by the Directive.

*Article 23*  
*Transitional provisions*

Applications for approval of laboratories submitted by the Member States prior to 1 July 2009, in accordance with Article 3 of Decision 2000/258/EC and Annex II thereto, shall be governed by that Decision, as worded before the amendments made by this Directive.

*Article 24*  
*Entry into force*

This Directive shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union*.

*Article 25*  
*Addressees*

This Directive is addressed to the Member States.

Done at Brussels,

*For the Council*  
*The President*

ANNEX

"ANNEX I

AFSSA, Nancy  
Laboratoire d'études sur la rage et la pathologie des animaux sauvages  
Technopôle Agricole et Vétérinaire  
BP 40 009  
54220 Malzéville Cedex  
France

## ANNEX II

The specific institute responsible for establishing the criteria necessary for standardising the serological test to monitor the action of rabies vaccines shall:

- coordinate the establishment, improvement and standardisation of methods of serological titration on carnivores vaccinated against rabies;
- appraise those laboratories in Member States which have submitted an application to perform the serological titrations referred to in the first indent; the result of this appraisal must be sent to the applicant laboratory and to the competent authorities of the Member State where the result is favourable for the purposes of approval;
- appraise those laboratories in third countries which have submitted an application to perform the serological titrations referred to in the first indent; the result of this appraisal must be sent to the applicant laboratory and to the Commission where the result is favourable for the purpose of approval;
- provide any useful information on analysis methods and comparative trials to those laboratories and organise training sessions and further training courses for their staff;
- organise inter-laboratory aptitude tests (proficiency tests);
- provide scientific and technical assistance to the Commission and the competent authorities concerned on the matters referred to in this Annex, in particular in cases of disagreement on results of serological titrations."