

Council Directive 2008/73/EC of 15 July 2008 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, 90/426/EEC, 90/427/EEC, 90/428/EEC, 90/429/EEC, 90/539/EEC, 91/68/EEC, 91/496/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)

COUNCIL DIRECTIVE 2008/73/EC

of 15 July 2008

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, 90/426/EEC, 90/427/EEC, 90/428/EEC, 90/429/EEC, 90/539/EEC, 91/68/EEC, 91/496/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 the proposal from the Commission,

Having regard to the Opinion of the European Parliament,

Having regard to the Opinion of the European Economic and Social Committee,

Whereas:

- (1) Community legislation in the veterinary field provides that assembly centres for bovine, porcine, caprine and ovine animals, equine marshalling centres, 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) Community legislation provides for different procedures with regard to the registration, listing, updating, transmission and publication of those animal health 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 lie 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>(1)</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>(2)</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 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>(3)</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 stud books in accordance with Community zootechnical legislation.
- (12) Council Directive 91/496/EEC of 15 July 1991 laying down the principles governing the organisation of veterinary checks on animals entering the Community from third countries<sup>(4)</sup> provides that in the case where animals imported from third countries are placed in a quarantine centre within Community territory, this quarantine centre must be approved and the list of quarantine centres published in the *Official Journal of the European Union*. In the interests of clarity and consistency of Community rules, a simplified procedure should also apply to the updating of the list of quarantine centres in the Member States.
- (13) 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.
- (14) In accordance with 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.
- (15) 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.
- (16) 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.
- (17) 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 lie with the Member States and not the Commission. Similarly, the responsibility for drawing up lists of other approved laboratories should lie with the Member States.

- (18) 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 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.
- (19) 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.
- (20) 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>(5)</sup>, transitional measures should be provided for in this Directive.
- (21) Article 6(2)(a) of Council Directive 64/432/EEC of 26 June 1964 on animal health problems affecting intra-Community trade in bovine animals and swine<sup>(6)</sup> provides that bovine animals for breeding and production intended for intra-Community trade must come from an officially tuberculosis-free herd and, if more than six weeks old, have reacted negatively to an intradermal tuberculin test carried out during the 30 days prior to leaving the herd of origin. Due to traditional farming and trade practices, some Member States have encountered difficulties to comply with this pre-movement testing. It is therefore necessary to provide for the possibility of carrying out the intradermal tuberculin test at a place other than the holding of origin to be established under the comitology procedure.
- (22) Moreover, certain Annexes to Directive 64/432/EEC, which are of purely technical nature such as those relating to animal health tests, the list of compulsory notifiable diseases or the animal health certificates, should be amended by means of the comitology procedure to be able to rapidly take account of new scientific developments. However, the amendment of Annexes laying down detailed conditions with regard to the disease-free status, which may have an impact on intra-Community trade, should be reserved for the Council.
- (23) Technological and scientific developments have taken place since the beginning of the 1990s in the collection and the production of genetic materials. 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 in Annex A(I) to Directive 90/425/EEC<sup>(7)</sup> has not been updated to take account of this evolution and of the new OIE standards. It is therefore appropriate to amend the said Directive and to bring into its scope, provisions in respect of trade in and imports of genetic material derived from animals other than those of the ovine, caprine, equine and porcine species. Further, pending the establishment of detailed harmonised rules in this field, Member States should be allowed to apply national rules. Similarly, pending the establishment of detailed harmonised rules in respect of imports of animals covered by that Directive, Member States should be allowed to apply national rules.

- (24) The Council, in accordance with point 34 of the Interinstitutional Agreement on better law-making<sup>(8)</sup>, should encourage the Member States to draw up, for themselves and in the interest of the Community their own tables, which will, as far as possible, illustrate the correlation between the Directive and the transposition measures and to make them public.
- (25) Council Directives 64/432/EEC, 77/504/EEC<sup>(9)</sup>, 88/407/EEC<sup>(10)</sup>, 88/661/EEC<sup>(11)</sup>, 89/361/EEC<sup>(12)</sup>, 89/556/EEC<sup>(13)</sup>, 90/426/EEC<sup>(14)</sup>, 90/427/EEC<sup>(15)</sup>, 90/428/EEC, 90/429/EEC<sup>(16)</sup>, 90/539/EEC<sup>(17)</sup>, 91/68/EEC<sup>(18)</sup>, 91/496/EEC, 92/35/EEC<sup>(19)</sup>, 92/65/EEC, 92/66/EEC<sup>(20)</sup>, 92/119/EEC<sup>(21)</sup>, 94/28/EC<sup>(22)</sup>, 2000/75/EC<sup>(23)</sup>, Decision 2000/258/EC, Council Directives 2001/89/EC<sup>(24)</sup>, 2002/60/EC<sup>(25)</sup>, and 2005/94/EC<sup>(26)</sup> should therefore be amended accordingly,

HAS ADOPTED THIS DIRECTIVE:

*Article 1*

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

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

1. in Article 6, the first subparagraph of paragraph 2(a) shall be replaced by:

come from an officially tuberculosis-free bovine herd, and in the case of animals more than six weeks old, have reacted negatively to an intradermal tuberculin test carried out in accordance with the provisions of point 2.2 of Annex B either during the 30 days prior to leaving the herd of origin or in a place and under conditions to be defined in accordance with the procedure referred to in Article 17.;
2. the following Article 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).;
3. 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.;
4. in Article 13, the following paragraphs 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).;
5. Article 16 shall be replaced by the following:

*Article 16*

Annexes A and D (Chapter I) shall be amended by the Council, acting by a qualified majority on a Commission proposal, in particular with regard to their adaptation to technological and scientific developments.
- Annexes B, C, D (Chapter II), E and F shall be amended by the Commission in accordance with the procedure referred to in Article 17.;
6. 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;
7. Annex C shall be amended as follows:
  - (a) in point 4.1, the introductory sentence shall be replaced by the following:

National reference laboratories designated in accordance with Article 6a shall be responsible for.;
  - (b) point 4.2 shall be deleted;
8. 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 shall be inserted in Directive 77/504/EEC:

#### Article 4a

1 Member States shall draw up and keep up to date a list of bodies as referred to in Article 1(b), first indent, 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 storages 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**

Directive 88/661/EEC is hereby amended as follows:

1. the following Article shall be inserted:

*Article 4a*

Member States shall draw up and keep up to date a list of bodies as referred to in Article 1(c), first indent, 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).;

2. the following Article shall be inserted:

*Article 7a*

Member States shall draw up and keep up to date a list of bodies as referred to in Article 1(d), first indent, 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 bodies as referred to in Article 2(b), first indent, 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 shall be 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 90/426/EEC**

In Article 7 of Directive 90/426/EEC, paragraph 1 shall be replaced by the following:

1. The equidae must be transported, as soon as possible, from the holding of origin either directly or via an approved market or marshalling centre as defined as “assembly centre” in Article 2(2)(o) of Directive 64/432/EEC to the place of destination in vehicles or containers which have been regularly cleansed and disinfected with a disinfectant at intervals to be fixed by the Member State of dispatch. The vehicles must be designed in such a way that equidae droppings, litter or fodder cannot escape from the vehicle during transportation. Transportation must be effected in such a way that the health and well-being of the equidae can be protected effectively..

#### *Article 8*

### **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 bodies maintaining or establishing studbooks as referred to in Article 2(c), first indent, 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 9*

### **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 organisation of:
- (a) competitions reserved for equidae registered in a specific stud book 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 authorised to reserve, through the bodies officially approved or recognised 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 10*

#### **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 11*

#### **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 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 reagents used by the laboratories approved for the purpose of carrying out the diagnostic tests provided for in this Directive;
  - (c) they shall organise periodic comparative tests..

#### *Article 12*

#### **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 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 13*

#### **Amendments to Directive 91/496/EEC**

In Article 10 of Directive 91/496/EEC, paragraph 4 shall be replaced by the following:

4.
  - a The procedure laid down in Article 22 must be followed for the approval and subsequent updating of the list of quarantine centres referred to in the first indent of paragraph 1. The Commission shall publish the list of these quarantine centres and any subsequent updates in the *Official Journal of the European Union*.
  - b Quarantine centres referred to in the second indent of paragraph 1 and the first indent of paragraph 2 that fulfil the conditions laid down in Annex B shall be approved by the Member States, each centre being given an approval number. Each Member State shall

draw up and keep up to date a list of approved quarantine centres and their approval numbers and make it available to the other Member States and to the public. Quarantine centres shall be subject to the inspection provided for in Article 19.

Detailed rules for the uniform application of this subparagraph may be adopted in accordance with the procedure referred to in Article 22..

#### *Article 14*

### **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 15*

### **Amendments to Directive 92/65/EEC**

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

1. Article 11 shall be replaced by the following:

#### *Article 11*

- 1 The Member States shall ensure that, without prejudice to the decisions to be taken in implementation of Articles 21 and 23, only semen, ova and embryos meeting the conditions laid down in paragraphs 2, 3, 4 and 5 are the subject of trade.

- 2 Semen of the ovine, caprine and equine species must, without prejudice to any criteria to be complied with for the entry of equids in stud books for certain specific breeds:

- have been collected, processed and stored with a view to artificial insemination in a centre approved from the health point of view in accordance with Annex D(I), or, in the case of ovine and caprine animals by way of derogation from the above, in a holding satisfying the requirements of Directive 91/68/EEC,
- have been collected from animals meeting the conditions laid down in Annex D(II),

- have been collected, processed, preserved, stored and transported in accordance with Annex D(III),
  - have been accompanied during transport to another Member State by a health certificate corresponding to a specimen to be determined in accordance with the procedure referred to in Article 26.
- 3
- Ova and embryos of the ovine, caprine, equine and porcine species must:
- have been removed from donor females meeting the conditions laid down in Annex D(IV) by a collection team or have been produced by a production team approved by the competent authority of the Member State and satisfying the conditions to be established in Annex D(I) in accordance with the procedure referred to in Article 26,
  - have been collected, processed and preserved in an appropriate laboratory, stored and transported in accordance with Annex D(III),
  - be accompanied during transport to another Member State by a health certificate corresponding to a specimen to be determined in accordance with the procedure referred to in Article 26.

Semen used for the insemination of donor females must comply with the provisions of paragraph 2 in the case of sheep, goats and equids and with the provisions of Directive 90/429/EEC for swine.

Any additional guarantees may be determined in accordance with the procedure referred to in Article 26.

- 4
- The approved centres referred to in the first indent of paragraph 2 and the approved 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 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.

- 5
- The animal health requirements and the specimen health certificates applicable to semen, ova and embryos of species not mentioned in paragraphs 2 and 3 shall be established in accordance with the procedure referred to in Article 26.

Pending the establishment of animal health requirements and specimen health certificates for trade in such semen, ova and embryos, national rules shall continue to apply.;

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.;

3. in Article 17, paragraph 2 and 3 shall be replaced by the following:
2. Only animals, semen, ova and embryos referred to in Article 1 which satisfy the following requirements may be imported into the Community:
- a they must come from a third country on a list to be drawn up in accordance with paragraph 3(a);
  - b they must be accompanied by the health certificate corresponding to a specimen to be drawn up in accordance with the procedure referred to in Article 26, signed by the competent authority of the exporting country and certifying that,
    - (i) the animals
      - meet the additional conditions or offer the equivalent guarantees referred to in paragraph 4, and
      - come from approved centres, bodies, institutes offering guarantees at least equivalent to those in Annex C;
    - (ii) semen, ova and embryos come from approved collection and storage centres or collection and production teams offering guarantees at least equivalent to those to be established in Annex D(I) in accordance with the procedure referred to in Article 26.

Pending the establishment of lists of third countries, approved establishments listed in point (b), animal health requirements and specimen health certificates as referred to in paragraphs (a) and (b), national rules shall continue to apply provided they are not more favourable than those laid down in Chapter II.

- 3 The following shall be established:
- a in accordance with the procedure referred to in Article 26, 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 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 teams referred to in the first subparagraph and their veterinary registration numbers shall be communicated to the Commission.

The approval of centres or teams 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;



- c in accordance with the procedure referred to in Article 26, 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 16*

#### **Amendments to Directive 92/66/EEC**

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

- 1. Article 14 shall be 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 17*

#### **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 18*

#### **Amendments to Directive 94/28/EC**

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

1. Article 3 shall be amended as follows:
  - (a) paragraph 1 shall be replaced by the following:
    1. A list of bodies 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 a body 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.;
  - (b) in paragraph 2, point (a) shall be deleted;
  - (c) paragraph 3 shall be deleted;
2. 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 19*

#### **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 20*

#### **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.          the following Article shall be inserted:

#### *Article 5a*

Applications for approval of laboratories submitted by the Member States prior to 1 January 2010, in accordance with Article 3 and Annex II, shall continue to be governed by this Decision, in its version before 3 September 2008.;

3.          Annexes I and II shall be replaced by the text in the Annex to this Directive.

#### *Article 21*

#### **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 22*

#### **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 23*

#### **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 24*

**Transposition**

1 Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with this Directive by 1 January 2010 at the latest. They shall forthwith communicate to the Commission the text of those provisions.

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 25*

**Entry into force**

This Directive shall enter into force on the 20th day following its publication in the *Official Journal of the European Union*.

*Article 26*

**Addressees**

This Directive is addressed to the Member States.

Done at Brussels, 15 July 2008.

*For the Council*

*The President*

M. BARNIER

## ANNEX

## ANNEX AFSSA, Nancy

I

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.

- (1) OJ L 224, 18.8.1990, p. 60.
- (2) 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).
- (3) 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).
- (4) OJ L 268, 24.9.1991, p. 56. Directive as last amended by Directive 2006/104/EC.
- (5) 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).
- (6) OJ L 121, 29.7.1964, p. 1977/64. Directive as last amended by Commission Decision 2007/729/EC (OJ L 294, 13.11.2007, p. 26).
- (7) 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).
- (8) OJ C 321, 31.12.2003, p. 1. Corrected by OJ C 4, 8.1.2004, p. 7.
- (9) 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).
- (10) OJ L 194, 22.7.1988, p. 10. Directive as last amended by Commission Decision 2008/120/EC (OJ L 42, 16.2.2008, p. 63).
- (11) 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).
- (12) OJ L 153, 6.6.1989, p. 30.
- (13) 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).
- (14) OJ L 224, 18.8.1990, p. 42. Directive as last amended by Directive 2006/104/EC.
- (15) OJ L 224, 18.8.1990, p. 55.
- (16) OJ L 224, 18.8.1990, p. 62. Directive as last amended by Regulation (EC) No 806/2003.
- (17) OJ L 303, 31.10.1990, p. 6. Directive as last amended by Commission Decision 2007/729/EC (OJ L 294, 13.11.2007, p. 26).
- (18) OJ L 46, 19.2.1991, p. 19. Directive as last amended by Directive 2006/104/EC.
- (19) OJ L 157, 10.6.1992, p. 19. Directive as last amended by Commission Decision 2007/729/EC.
- (20) OJ L 260, 5.9.1992, p. 1. Directive as last amended by Directive 2006/104/EC.
- (21) 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).
- (22) OJ L 178, 12.7.1994, p. 66.
- (23) OJ L 327, 22.12.2000, p. 74. Directive as last amended by Commission Decision 2007/729/EC.
- (24) OJ L 316, 1.12.2001, p. 5. Directive as last amended by Commission Decision 2007/729/EC.
- (25) OJ L 192, 20.7.2002, p. 27. Directive as last amended by Commission Decision 2007/729/EC.
- (26) OJ L 10, 14.1.2006, p. 16.