

Council Directive 2004/68/EC of 26.4.2004 laying down animal health rules for the importation into and transit through the Community of certain live ungulate animals, amending Directives 90/426/EEC and 92/65/EEC and repealing Directive 72/462/EEC (Text with EEA relevance)

## Chapter II

### **Animal health requirements applicable to imports into the community of certain live ungulate animals**

#### *Article 3*

#### **Authorised third countries**

1 The importation of live ungulates into and transit through the Community shall only be authorised from third countries that appear on a list or lists to be drawn up or amended in accordance with the procedure referred to in Article 14(2).

Taking into account the health situation and the guarantees provided by the third country for the animals listed in Annex I, it may be decided in accordance with the procedure referred to in Article 14(2), that the authorisation provided for in the preceding subparagraph shall apply to the whole territory of an authorised third country or to only part of its territory.

For that purpose and on the basis of the relevant international standards, account shall be taken of how the authorised third country applies and implements those standards, in particular the principle of regionalisation within its own territory and in relation to its sanitary requirements for importation from other third countries and from the Community.

2 The authorisation for importation of live ungulates into or transiting through the Community as provided for in paragraph 1 and the specific animal health conditions provided for in Article 6(3) may be suspended or withdrawn in accordance with the procedure referred to in Article 14(2) where the animal health situation in the authorised third country justifies such suspension or withdrawal.

#### *Article 4*

#### **Preparation of the lists of authorised third countries**

When the lists of authorised third countries are drawn up or amended, particular account shall be taken of:

- (a) the health status of livestock, other domestic animals and wildlife in the third country, with particular regard to exotic animal diseases and any aspects of the general health and the environmental situation in the third country which may pose a risk to the health and the environmental status of the Community;
- (b) the legislation of the third country in relation to animal health and welfare;

- (c) the organisation of the competent veterinary authority and its inspection services, the powers of those services, the supervision to which they are subject, and the means at their disposal, including staff and laboratory capacity, to apply national legislation effectively;
- (d) the assurances which the competent veterinary authority of the third country can give regarding compliance or equivalence with the relevant animal health conditions applicable in the Community;
- (e) whether the third country is a member of the OIE and the regularity and rapidity of the information supplied by the third country relating to the existence of infectious or contagious animal diseases in its territory, in particular those diseases listed by the OIE;
- (f) the guarantees given by the third country directly to inform the Commission and the Member States:
  - (i) within 24 hours of the confirmation of the occurrence of any of the diseases listed in Annex II and of any change in the vaccination policy concerning such diseases;
  - (ii) within an appropriate period, of any proposed changes in the national health rules concerning live ungulate animals, in particular regarding importation;
  - (iii) at regular intervals, of the animal health status of its territory;
- (g) any experience of previous imports of live animals from the third country and the results of any import controls carried out;
- (h) the results of Community inspections and/or audits carried out in the third country, in particular the results of the assessment of the competent authorities or, where the Commission so requests, the report submitted by the competent authorities on the inspections which they have carried out;
- (i) the rules on the prevention and control of infectious or contagious animal diseases in force in the third country and their implementation, including rules on the importation from other third countries.

#### *Article 5*

#### **Publication of lists of authorised third countries by the Commission**

The Commission shall arrange for up-to-date versions of all lists drawn up or amended as provided for in Article 3(1) to be made available to the public. Those lists may be combined with other lists drawn up for animal and public health purposes and may also include models of health certificates.

#### *Article 6*

#### **Specific animal health conditions for imports and transit from authorised third countries of live ungulates into the Community**

1 Specific animal health conditions for the importation and transit of live ungulates from authorised third countries into the Community shall be laid down in accordance with the procedure referred to in Article 14(2).

They may take account of the following:

- a the animal species concerned;
- b the age and sex of the animals;
- c the intended destination or purpose of the animals;
- d the measures to be applied after importation of the animals into the Community;
- e any special provisions applicable in the framework of intra-Community trade.

2 The specific animal health conditions provided for in paragraph 1 shall be based on the rules laid down in Community legislation for the diseases to which the animals are susceptible.

3 However, where the equivalence of the official health guarantees provided for by the third country concerned can be formally recognised by the Community, the specific animal health conditions may be based on those guarantees.

#### *Article 7*

#### **Guarantees from the authorised third country regarding imports of live ungulates into the Community**

Imports of live ungulates into the Community shall be allowed only if the authorised third country provides the following guarantees:

- (a) the animals must come from a disease-free territory, in accordance with the basic general criteria listed in Annex II and into which the entry of animals vaccinated against the diseases listed in that Annex must be prohibited;
- (b) the animals must comply with the specific animal health conditions provided for in Article 6;
- (c) before the day of loading for shipment to the Community, the animals must have remained in the territory of the authorised third country for a period of time to be set out in the specific animal health conditions referred to in Article 6;
- (d) before shipment to the Community, the animals must have undergone a check by an official veterinarian to ensure that they are healthy and that the transport conditions provided for in Directive 91/628/EEC are complied with, in particular as regards watering and feeding;
- (e) the animals must be accompanied by a veterinary certificate which complies with Article 11 and with a specimen veterinary certificate established in accordance with the procedure referred to in Article 14(2). Provision may be made for the use of electronic documents under the same procedure;
- (f) upon arrival in the Community, the animals must be checked at an agreed border inspection post in accordance with Article 4 of Directive 91/496/EEC.

#### *Article 8*

#### **Derogation from guarantees to be provided by authorised third countries**

By way of derogation from Articles 6 and 7, specific provisions, including model veterinary certificates, may be laid down in accordance with the procedure referred to in Article 14(2) for the importation or transit of live ungulates from third countries authorised under Article 3(1) if those animals:

- (a) are intended exclusively for grazing or draught purposes, on a temporary basis, in the vicinity of the Community frontiers;
- (b) are related to sporting events, circuses, shows and exhibitions but not related to commercial transactions of the animals themselves;
- (c) are intended for a zoo, an amusement park, an experimental laboratory, or as defined in Article 2(c) of Directive 92/65/EEC, approved body, approved institute or approved centre;
- (d) exclusively transit the territory of the Community through approved Community border inspection posts under customs and official veterinary approval and supervision, with no stop in the Community other than those necessary for animal welfare purposes;
- (e) accompany their owners as pet animals or;
- (f) are presented at an approved Community border inspection post after they have left the Community:
  - within a period of 30 days for one of the purposes referred to in points (a), (b) and (e) or,
  - transiting a third country or;
- (g) which belong to endangered species.

#### *Article 9*

##### **Derogation from Article 7(a) as regards imports or transit from authorised third countries where diseases listed in Annex II are present and/or vaccinations are carried out**

By way of derogation from Article 7(a), and in accordance with the procedure referred to in Article 14(2), conditions may be established for the importation or transit of live ungulates into the Community from an authorised third country where certain diseases listed in Annex II are present and/or vaccinations against those diseases are carried out. Such derogations shall be established country by country.

#### *Article 10*

##### **Derogation from Article 7(a) as regards imports or transit from authorised third countries where imports or transit have been suspended or prohibited**

By way of derogation from Article 7(a), and in accordance with the procedure referred to in Article 14(2), a specific period may be determined after which the importation or transit of live ungulates from an authorised third country may be resumed after the suspension or prohibition of importation or transit due to any change in the health situation, together with any additional conditions to be fulfilled after such resumption.

When deciding to resume the importation or transit of such animals, account shall be taken of:

- international standards,

- whether an outbreak or a number of epizootiologically interrelated outbreaks of one of the diseases listed in Annex II occurs within a geographically limited area in an authorised third country or region,
- whether the outbreak or outbreaks are successfully eradicated within a limited period of time.

### *Article 11*

#### **Veterinary Certificates**

- 1 A veterinary certificate complying with the requirements set out in Annex III shall be presented with each consignment of animals upon their import or transit into the Community.
- 2 The veterinary certificate shall certify that the requirements of this Directive and other Community legislation on animal health, or where applicable in accordance with Article 6(3), provisions that are equivalent to those requirements, have been complied with.
- 3 The veterinary certificate may include certification statements required under other Community legislation on public health, animal health and animal welfare.
- 4 The use of the veterinary certificate provided for in paragraph 1 may be suspended or withdrawn in accordance with the procedure referred to in Article 14(2) where the animal health situation in the authorised third country justifies such suspension or withdrawal.

### *Article 12*

#### **Inspections and audits in third countries**

- 1 Inspections and/or audits may be carried out in third countries by experts from the Commission in order to verify conformity with or equivalence to Community animal health rules.  
The experts from the Commission may be accompanied by experts from the Member States authorised by the Commission to carry out such inspections and/or audits.
- 2 The inspections and/or audits provided for in paragraph 1 shall be carried out on behalf of the Community, and the Commission shall meet the costs incurred.
- 3 The procedure for carrying out the inspections and/or audits in third countries as provided for in paragraph 1 may be established or amended in accordance with the procedure referred to in Article 14(2).
- 4 If a serious animal health risk is identified during an inspection and/or audit as provided for in paragraph 1, even if it is not directly related to the objectives of the inspection/audit, the Commission shall immediately, take the measures necessary to safeguard animal health, as laid down in Article 18 of Directive 91/496/EEC, including the suspension or withdrawal of the authorisation provided for in Article 3(1).

### Article 13

#### **Empowering provisions**

1 The following may be established in accordance with the procedure referred to in Article 14(2):

- a detailed rules for the application of this Directive;
- b rules regarding the origin of animals;
- c the criteria for classifying authorised third countries or regions thereof with regard to animal diseases;
- d provisions for the use of electronic documents relating to model veterinary certificates as provided for in Article 7(e);
- e models of veterinary certificates as provided for in Article 11(1).

2 The Annexes to this Directive may be amended in accordance with the procedure referred to in Article 14(2) in order to take account, in particular of:

- a scientific opinions and scientific knowledge particularly concerning new risk assessments;
- b technical developments and/or amendments to international standards;
- c the setting of safety targets for animal health.

### Article 14

#### **Committee procedure**

1 The Commission shall be assisted by the Standing Committee on the Food Chain and Animal Health instituted by Article 58 of Regulation (EC) No 178/2002.

2 Where reference is made to this paragraph, Articles 5 and 7 of Decision 1999/468/EC shall apply.

The period laid down in Article 5(6) of Decision 1999/468/EC shall be set at 15 days.

3 The Committee shall adopt its rules of procedure.

### Article 15

#### **Amendment to Directive 90/426/EEC**

Directive 90/426/EEC is hereby amended as follows:

1) Article 12 shall be replaced by the following:

#### *Article 12*

1 The importation of equidae into the Community shall only be authorised from third countries that appear on a list or lists to be drawn up or amended in accordance with the procedure referred to in Article 24(2).

Taking into account the health situation and the guarantees provided by the third country for equidae, it may be decided in accordance with the procedure referred to in

Article 24(2) that the authorisation provided for in the preceding subparagraph shall apply to the whole territory of the third country or to only part of its territory.

For that purpose and on the basis of the relevant international standards, account shall be taken of how the third country applies and implements those standards, in particular the principle of regionalisation, within its own territory and in relation to its sanitary requirements for importation from other third countries and from the Community.

- 2) when the lists provided for in paragraph 1 are drawn up or amended, particular account shall be taken of:
- a the health status of the equidae, other domestic animals and wildlife in the third country, with particular regard to exotic animal diseases and any aspects of the general health and the environmental situation in the third country which may pose a risk to the health and environmental status of the Community;
  - b the legislation of the third country in relation to animal health and welfare;
  - c the organisation of the competent veterinary authority and its inspection services, the powers of those services, the supervision to which they are subject, and the means at their disposal, including staff and laboratory capacity, to apply national legislation effectively;
  - d the assurances which the competent veterinary authority of the third country can give regarding compliance or equivalence with the relevant animal health conditions applicable in the Community;
  - e whether the third country is a member of the "Office International des Epizooties" (OIE) and the regularity and rapidity of the information supplied by the third country relating to the existence of infectious or contagious diseases of equidae in its territory, in particular those diseases listed by the OIE and in Annex A of this Directive;
  - f the guarantees given by the third country to directly inform the Commission and the Member States:
    - (i) within 24 hours, of the confirmation of the occurrence of infectious diseases of equidae listed in Annex A and of any change in the vaccination policy concerning such diseases;
    - (ii) within an appropriate period, of any proposed changes in the national sanitary rules concerning equidae, in particular regarding the importation of equidae;
    - (iii) at regular intervals, of the animal health status of its territory concerning equida;
  - g any experience of previous imports of live equidae from the third country and the results of any import controls carried out;
  - h the results of Community inspections and/or audits carried out in the third country, in particular the results of the assessment of the competent authorities or, where the Commission so requests, the report submitted by the competent authorities on the inspections which they have carried out;
  - i the rules on the prevention and control of infectious or contagious animal diseases in force in the third country and their implementation, including rules on importation of equidae from other third countries.

- 3 The Commission shall arrange for up-to-date versions of all lists drawn up or amended as provided for in paragraph 1 to be made available to the public.

Those lists may be combined with other lists drawn up for animal and public health purposes and may also include models of health certificates.

4 Special import conditions for each third country or group of third countries, having regard to the animal health situation concerning equidae in the third country or countries concerned shall be established in accordance with the procedure referred to in Article 24(2).

5 Detailed rules for the application of this Article and criteria for including third countries or parts of third countries in the lists provided for in paragraph 1 may be adopted in accordance with the procedure referred to in Article 24(2).

2) the following point shall be added to Article 19:

(iv) may designate a Community reference laboratory for one or more of the diseases of equidae listed in Annex A and shall stipulate the functions, tasks and procedures regarding collaboration with laboratories responsible for diagnosing infectious diseases of equidae in the Member States..

#### *Article 16*

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

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

1) the first subparagraph of Article 1 shall be replaced by the following:

This Directive lays down the animal health requirements governing trade in and imports into the Community of animals, semen, ova and embryos not subject to the animal health requirements laid down in the specific Community acts referred to in Annex F..

2) Article 6 shall be amended as follows:

(a) in A(l), point (e) shall be replaced by;

(e) must be accompanied by a certificate corresponding to the specimen given in Annex E part 1, bearing the following declaration:

##### Declaration

I, the undersigned (official veterinarian), certify that the ruminant(s)<sup>(1)</sup>/suida(e)<sup>(1)</sup> other than that<sup>(1)</sup>/those<sup>(1)</sup> covered by Directive 64/432/EEC:

(i) belong/belongs<sup>(1)</sup> to the;

(species)

(ii) at the time of examination, do<sup>(1)</sup>/does<sup>(1)</sup> not show any clinical sign of any disease to which it<sup>(1)</sup>/they<sup>(1)</sup> is<sup>(1)</sup>/are<sup>(1)</sup> susceptible;

(iii) come(s) from an officially tuberculosis free<sup>(1)</sup>/officially brucellosis free<sup>(1)</sup> or brucellosis free herd<sup>(1)</sup>/holding<sup>(1)</sup> not subject to swine fever restrictions or from a holding



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*Status: This is the original version (as it was originally adopted).*

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where it<sup>(1)</sup>/they<sup>(1)</sup> was<sup>(1)</sup>/were<sup>(1)</sup> subjected with negative results to the test(s) laid down in Article 6(2)(b) of Directive 92/65/EEC.;

(b) In A(1), point (f) shall be deleted;

(c) in A(2), point (b) shall be replaced by:

where they do not come from a herd meeting the conditions laid down in (a), they must come from a holding in which no case of brucellosis or tuberculosis has been recorded in the 42 days preceding loading of the animals and in which the ruminants have in the 30 days prior to dispatch undergone with negative results a test for brucellosis and tuberculosis.;

(d) in A(3), points (e), (f) and (g) shall be deleted;

(e) the following point shall be added to (A):

4) The testing requirements referred to in this Article and their criteria may be established in accordance with the procedure laid down in Article 26. These decisions shall take into consideration the case of ruminants reared in the arctic regions of the Community.

Pending the decisions provided for in the preceding subparagraph, national rules shall continue to apply.;

3) Article 17 shall be amended as follows:

(a) in paragraph 3, points (a) and (b) shall be replaced by the following:

(a) 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 and,

(b) without prejudice to Commission Decision 94/63/EC of 31 January 1994 drawing up a list of third countries from which Member States authorise imports of semen, ova and embryos of the ovine and caprine species and ova and embryos of the porcine species<sup>(2)</sup>, a list of the collection centres for which these third countries are able to give the guarantees provided for in Article 11."

The Commission shall inform the Member States of any proposed amendments to the lists of centres and the Member States shall have ten working days, from the date of receipt of the proposed amendments, to send written comments to the Commission.

Where no written comments are received from the Member States within that period of ten working days, the proposed amendments shall be considered to have been accepted by the Member States and imports shall be authorised in accordance with the amended lists when the Commission notifies the competent authorities of the Member States and the third country concerned that the amendments are published on the web site of the Commission.

Where written comments are received from at least one Member State within the period of ten working days, the Commission shall inform

the Member States and the Standing Committee on the Food Chain and Animal Health at its next meeting for a decision to be adopted in accordance with the procedure referred to in the second subparagraph of Article 26.;

4) in Article 23, the words "from Article 6 (A)(l)(e) and" shall be deleted;

5) Article 26 shall be replaced by the following:

*Article 26*

1 The Commission shall be assisted by the Standing Committee on the Food Chain and Animal Health instituted by Article 58 of Regulation (EC) No 178/2002 of the European Parliament and of the Council.<sup>(3)</sup>

2 Where reference is made to this paragraph, Articles 5 and 7 of Decision 1999/468/EC shall apply.

The period laid down in Article 5(6) of Decision 1999/468/EC<sup>(4)</sup> shall be set at three months.

3 The Committee shall adopt its Rules of Procedure.;

6) The text in Annex IV to this Directive shall be added as Annex F.

- (1) Delete where inapplicable.;
- (2) [OJ L 28, 2.2.1994, p. 47](#). Decision as last amended by Decision 2004/211/EC";
- (3) [OJ L 31, 1.2.2002, p. 1](#).
- (4) [OJ L 184, 17.7.1999, p. 23.](#)";