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COMMISSION REGULATION (EC) No 708/2008

of 24 July 2008

amending Regulation (EC) No 1266/2007 as regards the conditions for exempting certain animals of susceptible species from the exit ban provided for in Council Directive 2000/75/EC

(Text with EEA relevance)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Council Directive 2000/75/EC of 20 November 2000 laying down specific provisions for the control and eradication of bluetongue (1), and in particular Article 9(1)(c), Articles 11 and 12 and the third paragraph of Article 19 thereof,

Whereas:

- Commission Regulation (EC) No 1266/2007 (2) lays (1)down rules for the control, monitoring, surveillance and restrictions on movements of animals, in relation to bluetongue, in and from the restricted zones. It also establishes the conditions for exemptions from the exit ban applicable to movements of susceptible animals, their semen, ova and embryos provided for in Directive 2000/75/EC.
- New scientific information recently gathered by several (2) Member States on bluetongue virus pathogenesis indicates that the trans-placental transmission of the bluetongue virus is likely to occur at least for serotype 8. Therefore, the precautionary measures taken to prevent the possible spread of that disease by pregnant animals or certain newborn animals, provided for in Regulation (EC) No 1266/2007, as amended by Commission Regulation (EC) No 384/2008 (3), should be maintained.
- Animals that were immune to the bluetongue infection (3) before artificial insemination or mating, due to vaccination with a modified life vaccine or an inactivated vaccine, are not considered to pose any significant risk as regards that disease provided that sufficient time has

elapsed between vaccination and insemination or mating. Regulation (EC) No 1266/2007, as amended by Regulation (EC) No 384/2008, only covers animals vaccinated by inactivated vaccines.

- As preliminary scientific information recently obtained (4) does not indicates that there is an additional risk associated with pregnant animals vaccinated with live modified vaccines at least 60 days prior to insemination or mating, it should be possible to exempt all immunised animals vaccinated with either inactivated or modified live vaccines from the exit ban provided that sufficient time has elapsed between vaccination and insemination or mating.
- (5) Animals that might not meet all the requirements necessary to move from a holding located in a restricted zone to another holding located outside the restricted zone in accordance with paragraph 1 of Article 8 of Regulation (EC) No 1266/2007 but that are exported to a third country do not pose an additional risk for the Community health status, since they are not destined for a holding in the Community. Consequently, the requirements for their movement to the exit point as defined in Commission Decision 93/444/EEC of 2 July 1993 on detailed rules governing intra-Community trade in certain live animals and products intended for exportation to third countries (4) should not exceed those applied to animals sent to slaughterhouses in accordance with paragraph 4 of Article 8 of Regulation (EC) No 1266/2007. Accordingly, no additional certification concerning the conditions laid down in Annex III to Regulation (EC) No 1266/2007 should be required where such animals are accompanied by a certificate in accordance with Decision 93/444/EEC. The reference to Decision 93/444/EEC in Annex III to Regulation (EC) No 1266/2007 should therefore be deleted.
- If in accordance with animal welfare rules a rest period is (6) foreseen due to the length of the transport for animals moved to a slaughterhouse or exit point, the derogations for movements of such animals should only apply if it is possible that the rest period takes place in a control post located in the same restricted zone of the holding of origin, as only in those cases there is no additional risk associated with such interruption of the direct transport in control posts.

 ^{(&}lt;sup>1)</sup> OJ L 327, 22.12.2000, p. 74. Directive as last amended by Commission Decision 2007/729/EC (OJ L 294, 13.11.2007, p. 26).
(²⁾ OJ L 283, 27.10.2007, p. 37. Regulation as last amended by Regulation (EC) No 394/2008 (OJ L 117, 1.5.2008, p. 22).
(³⁾ OL 116, 2009

^{(&}lt;sup>3</sup>) OJ L 116, 30.4.2008, p. 3.

⁽⁴⁾ OJ L 208, 19.8.1993, p. 34.

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- (7) Regulation (EC) No 1266/2007 should therefore be amended accordingly.
- (8) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on the Food Chain and Animal Health,

HAS ADOPTED THIS REGULATION:

Article 1

Regulation (EC) No 1266/2007 is amended as follows:

- 1. Article 8 is amended as follows:
 - (a) in paragraph 4, point (b) is replaced by the following:
 - '(b) the animals are transported
 - under veterinary supervision to the slaughterhouse of destination, where they are to be slaughtered within 24 hours of arrival, and
 - directly, unless a rest period foreseen by Regulation (EC) No 1/2005 (*) takes place in a control post situated in the same restricted zone.
 - (*) OJ L 3, 5.1.2005, p. 1.'
 - (b) the following paragraph 5a is inserted:

'5a. Movements of animals not certified in accordance with paragraph 1 from a holding located in a restricted zone directly, to the exit point, as defined in Article 1(2)(a) of Decision 93/444/EEC, for export to a third country shall be exempted from the exit ban estab-

lished pursuant to Article 9(1)(c) and point 1 of Article 10 of Directive 2000/75/EC provided that:

- (a) no case of bluetongue has been recorded in the holding of origin for a period of at least 30 days prior to the date of dispatch;
- (b) the animals are transported to the exit point
 - under official supervision, and
 - directly, unless a rest period foreseen by Regulation (EC) No 1/2005 takes place in a control post situated in the same restricted zone.'
- (c) paragraph 6 is replaced by the following:

⁶. For the animals, their semen, ova and embryos referred to in paragraphs 1, 4 and 5a of this Article, the following additional wording shall be added to the corresponding health certificates laid down in Directives 64/432/EEC, 91/68/EEC and 92/65/EEC, or referred to in Decision 93/444/EEC:

"... (Animals semen, ova and embryos indicate as appropriate) in compliance with ... (Articles 8(1)(a) or 8(1)(b) or 8(4) or 8(5a), indicate as appropriate) of Regulation (EC) No 1266/2007".'

2. In Annex III, Section A is replaced by the text in the Annex to this Regulation.

Article 2

This Regulation shall enter into force on the seventh day following that of its publication in the Official Journal of the European Union.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels, 24 July 2008.

For the Commission Androulla VASSILIOU Member of the Commission EN

ANNEX

'A. Animals

The animals must have been protected against attacks by the vector *Culicoides* during transportation to the place of destination.

In addition, at least one of the conditions set out in points 1 to 7 must be complied with.

1. The animals were kept until dispatch during the seasonally vector-free period defined in accordance with Annex V, in a bluetongue seasonally-free zone for at least 60 days prior to the date of movement and were subjected to an agent identification test according to the Manual of Diagnostic Tests and Vaccines for Terrestrial Animals of the World Organisation for Animal Health (OIE) (OIE Terrestrial Manual), with negative results, carried out not earlier than seven days before the date of movement.

However, that agent identification test shall not be necessary for Member States or regions of a Member State where sufficient epidemiological data, obtained following the implementation of a monitoring programme for a period of not less than three years, substantiate the determination of the seasonally vector-free period defined in accordance with Annex V.

The Member States making use of that possibility shall inform the Commission and the other Member States in the framework of the Standing Committee on the Food Chain and Animal Health.

Where animals referred to in this point are intended for intra-Community trade, the following additional wording shall be added to the corresponding health certificates laid down in Directives 64/432/EEC, 91/68/EEC and 92/65/EEC:

"Animal(s) were kept until dispatch in a bluetongue seasonally-free zone during the seasonally vector-free period that started on ... (*insert date*) since birth or for at least 60 days and, if appropriate (*indicate as appropriate*), were then subjected to an agent identification test according to the OIE Terrestrial Manual on samples taken within seven days prior to dispatch, with negative results, in conformity with Annex III.A(1) to Regulation (EC) No 1266/2007."

2. The animals have been kept, until dispatch, protected against attacks by vectors for a period of at least 60 days prior to the date of dispatch.

Where animals referred to in this point are intended for intra-Community trade, the following additional wording shall be added to the corresponding health certificates laid down in Directives 64/432/EEC, 91/68/EEC and 92/65/EEC:

"Animal(s) in conformity with Annex III.A(2) to Regulation (EC) No 1266/2007."

3. The animals have been kept, until dispatch, in a bluetongue seasonally-free zone during the seasonally vector-free period, defined in accordance with Annex V, or have been protected against attacks by vectors for a period of at least 28 days and were subjected during that period to a serological test according to the OIE Terrestrial Manual to detect antibodies to the bluetongue virus group, with negative results, carried out at least 28 days following the date of the commencement of the period of protection against attacks by vectors or the seasonally vector-free period.

Where animals referred to in this point are intended for intra-Community trade, the following additional wording shall be added to the corresponding health certificates laid down in Directives 64/432/EEC, 91/68/EEC and 92/65/EEC:

"Animal(s) in conformity with Annex III.A(3) to Regulation (EC) No 1266/2007."

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4. The animals have been kept until dispatch in a bluetongue seasonally-free zone during the seasonally vector-free period, defined in accordance with Annex V, or have been protected against attacks by vectors for a period of at least 14 days and were subjected during that period to an agent identification test according to the OIE Terrestrial Manual, with negative results, carried out at least 14 days following the date of commencement of the period of protection against attacks by vectors or the seasonally vector-free period.

Where animals referred to in this point are intended for intra-Community trade, the following additional wording shall be added to the corresponding health certificates laid down in Directives 64/432/EEC, 91/68/EEC and 92/65/EEC:

"Animal(s) in conformity with Annex III.A(4) to Regulation (EC) No 1266/2007."

- 5. The animals originate from a herd vaccinated according to a vaccination programme adopted by the competent authority and the animals have been vaccinated against the serotype(s) present or likely to be present in an epidemiologically relevant geographical area of origin, the animals are still within the immunity period of time guaranteed in the specifications of the vaccine approved in the vaccination programme and the animals meet at least one of the following requirements:
 - (a) they have been vaccinated more than 60 days before the date of movement;
 - (b) they have been vaccinated with an inactivated vaccine before at least the number of days necessary for the onset of the immunity protection set in the specifications of the vaccine approved in the vaccination programme and were subjected to an agent identification test according to the OIE Terrestrial Manual, with negative results, carried out at least 14 days after the onset of the immunity protection set in the specifications of the vaccine approved in the vaccination programme;
 - (c) they were previously vaccinated and they have been re-vaccinated with an inactivated vaccine within the immunity period of time guaranteed in the specifications of the vaccine approved in the vaccination programme;
 - (d) they were kept during the seasonally vector-free period, defined in accordance with Annex V, in a bluetongue seasonally-free zone, since birth or for a period of at least 60 days before the date of vaccination and have been vaccinated with an inactivated vaccine before at least the number of days necessary for the onset of the immunity protection set in the specifications of the vaccine approved in the vaccination programme.

Where animals referred to in this point are intended for intra-Community trade, the following additional wording shall be added to the corresponding health certificates laid down in Directives 64/432/EEC, 91/68/EEC and 92/65/EEC:

"Animal(s) vaccinated against bluetongue serotype/s ... (insert serotype/s) with ... (insert name of the vaccine) with a inactivated/modified live vaccine (indicate, as appropriate) in conformity with Annex III.A(5) to Regulation (EC) No 1266/2007."

- 6. The animals have never been vaccinated against bluetongue and were always kept in an epidemiologically relevant geographical area of origin where not more than one serotype was or is present or likely to be present and:
 - (a) they were subjected to two serological tests according to the OIE Terrestrial Manual to detect antibodies against the bluetongue virus serotype, with positive results; the first test must be carried out on samples taken between 60 and 360 days before the date of movement and the second test being carried out on samples taken not earlier than seven days before the date of the movement; or

(b) they were subjected to a serological test according to the OIE Terrestrial Manual to detect antibodies against the bluetongue virus serotype, with positive results; the test must be carried out at least 30 days before the date of the movement and the animals were subjected to an agent identification test according to the OIE Terrestrial Manual, with negative results, carried out not earlier than seven days before the date of the movement.

Where animals referred to in this point are intended for intra-Community trade, the following additional wording shall be added to the corresponding health certificates laid down in Directives 64/432/EEC, 91/68/EEC and 92/65/EEC:

"Animal(s) subjected to a serological test according to the OIE Terrestrial Manual to detect antibodies against the bluetongue virus serotype ... (*indicate serotype*) in conformity with Annex III.A(6) to Regulation (EC) No 1266/2007."

- 7. The animals have never been vaccinated against the bluetongue virus and were subjected with positive results to two adequate serological tests according to the OIE Terrestrial Manual able to detect specific antibodies against all the bluetongue virus serotypes present or likely to be present, in the epidemiologically relevant geographical area of origin, and:
 - (a) the first test must have been carried out on samples that were taken between 60 and 360 days before the date of movement and the second test must have been carried out on samples that were taken not earlier than seven days before the date of movement; or
 - (b) the specific serotype serological test must have been carried out at least 30 days before the date of the movement and the animals were subjected to an agent identification test according to the OIE Terrestrial Manual, with negative results, carried out not earlier than seven days before the date of movement.

Where animals referred to in this point are intended for intra-Community trade, the following additional wording shall be added to the corresponding health certificates laid down in Directives 64/432/EEC, 91/68/EEC and 92/65/EEC:

"Animal(s) subjected to a specific serological test according to the OIE Terrestrial Manual to detect antibodies against all the bluetongue virus serotypes ... (*indicate serotypes*) present or likely to be present in conformity with Annex III.A(7) to Regulation (EC) No 1266/2007."

For pregnant animals, at least one of the conditions set out in points 5, 6 and 7 must be complied with before insemination or mating, or the condition set out in point 3 must be complied with, the test being carried out not earlier than seven days before the date of movement.

Where animals are intended for intra-Community trade, one of the following additional wordings shall be added, as appropriate, to the corresponding health certificates laid down in Directives 64/432/EEC, 91/68/EEC and 92/65/EEC:

"Animal(s) is (are) not pregnant", or

"Animal(s) may be pregnant and complies (comply) with the condition(s) ... (set out in points 5, 6 and 7 before insemination or mating, or set out in point 3; indicate as appropriate)".'