COMMISSION REGULATION (EC) No 289/2008

of 31 March 2008

amending Regulation (EC) No 1266/2007 on implementing rules for Council Directive 2000/75/EC as regards the control, monitoring, surveillance and restrictions on movements of certain animals of susceptible species in relation to bluetongue

(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:

(1) Commission Regulation (EC) No 1266/2007 [2] lays 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.

(2) Where exemptions from the exit ban applicable to movements of animals of susceptible species, their semen, ova an embryos from the restricted zones are applied to such animals or products intended for intra-Community trade or for export to a third country, health certificates provided for in Council Directive 64/432/EEC [3], Council Directive 91/68/EEC [4], Council Directive 92/65/EEC [5] and referred to in Commission Decision 93/444/EEC [6] are to include a reference to Regulation (EC) No 1266/2007. On the basis of the experience gained, it is appropriate to provide for an additional wording to be added to all those health certificates in order to make more explicit the health conditions under which the animals, semen, ova and embryos are exempted from the exit ban.

(3) Council Directive 88/407/EEC of 14 June 1988 laying down the animal health requirements applicable to intra-Community trade in and imports of semen of domestic animals of the bovine species [7], Council Directive 89/556/EEC of 25 September 1989 on animal health conditions governing intra-Community trade in and importation from third countries of embryos of domestic animals of the bovine species [8], Commission Decision 95/388/EC of 19 September 1995 determining the specimen certificate for intra-Community trade in semen, ova and embryos of the ovine and caprine species [9] and Decision 93/444/EEC provide that health certificates are to accompany the movements of semen, ova and embryos of bovine, ovine and caprine species.

(4) On the basis of the experience gained, where exemptions from the exit ban applicable to movements of semen, ova and embryos of animals of the susceptible species from the restricted zones are applied, those health certificates should also include a reference to Regulation (EC) No 1266/2007. An additional wording should therefore be added to those health certificates in order to make more explicit the health conditions under which the semen, ova and embryos are exempted from the exit ban.

(5) *In vivo* derived embryos and ova of bovine animals do not pose any significant risk as regards bluetongue. Therefore exemptions from the exit ban should be applicable to them provided that the donor animals do not show any clinical signs of bluetongue on the day of collection of the embryos and ova.

(6) For clarity reasons, certain changes as regards the naturally immunised animals referred in points 6 and 7 of Annex III and the provisions reated to ova and embryos should be introduced in the text.

(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,

---

(1) 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.
(3) OJ 121, 29.7.1964, p. 1977/64. Directive as last amended by Decision 2007/729/EC.
(4) OJ L 46, 19.2.1991, p. 19. Directive as last amended by Directive 2006/104/EC (OJ L 363, 20.12.2006, p. 352).
(5) 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).
(6) OJ L 208, 19.8.1993, p. 34.
(7) 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).
(8) 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).
(9) OJ L 234, 3.10.1995, p. 30. Decision as last amended by Decision 2005/43/EC (OJ L 20, 22.1.2005, p. 34).

HAS ADOPTED THIS REGULATION:

Article 1

Annex III to Regulation (EC) No 1266/2007 is amended in accordance with the Annex to this Regulation.

Article 2

This Regulation shall enter into force on the seventh day following 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, 31 March 2008.

For the Commission
Androulla VASSILIOU
Member of the Commission

ANNEX

Annex III to Regulation (EC) No 1266/2007 is replaced by the following:

'ANNEX III

Conditions for exemption from the exit ban (referred to in Articles 7(2)(a) and 8(1)(a))

A. **Animals**

The animals must have been protected against attacks by 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 since birth or 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 or export to a third country, 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:

   "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 Terestrial 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."

   (*) http://www.oie.int/eng/normes/en_mcode.htm?e1d10

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 or export to a third country, 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:

   "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 or export to a third country, 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:

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

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 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 or export to a third country, 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:

"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 or export to a third country, 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:

"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 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 between 60 and 360 days before the date of 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 or export to a third country, 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:

"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 bluetongue and were subjected to an adequate specific serological test according to the OIE Terrestrial Manual able to detect the specific antibodies against all the bluetongue virus serotypes present or likely to be present, with positive results to all serotypes present or likely to be present in the epidemiologically relevant geographical area of origin, and

(a) the specific serotype serological test is carried out between 60 and 360 days before the date of movement; or

(b) the specific serotype serological test is 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 or export to a third country, 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:

"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."

B. **Semen of animals**

Semen must have been obtained from donor animals which comply with at least one of the following conditions:

(a) they have been kept outside a restricted zone for a period of at least 60 days before commencement of, and during, collection of the semen;

(b) they have been protected against attacks by vectors for a period of at least 60 days before commencement of, and during, collection of the semen;

(c) they were kept during the seasonally vector-free period in a bluetongue seasonally-free zone, defined in accordance with Annex V, for a period of at least 60 days before commencement of, and during, collection of the semen and 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 commencement of collection of the semen.

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

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

(d) they have been subjected to a serological test according to the OIE Terrestrial Manual to detect antibodies to the bluetongue virus group, with negative results, at least every 60 days during the collection period and between 21 and 60 days following the final collection;

(e) they have been subjected, with negative results, to an agent identification test according to the OIE Terrestrial Manual carried out on blood samples collected:

(i) at commencement and final collection; and

(ii) during the period of semen collection:

— at least every seven days, in the case of a virus isolation test,

— at least every 28 days, in the case of a polymerase chain reaction test.

Where the semen referred to in this Section is intended for intra-Community trade or export to a third country, the following additional wording shall be added to the corresponding health certificates laid down in Council Directive 88/407/EEC (*) and Commission Decision 95/388/EC (**), or referred to in Decision 93/444/EEC:

"Semen obtained from donor animals which comply with ..... (*point (a), (b), (c), (d) or (e), indicate as appropriate*) of Annex III.B to Regulation (EC) No 1266/2007".

(*) OJ L 194, 22.7.1988, p. 10.
(**) OJ L 234, 3.10.1995, p. 30.

C. **Ova and embryos of animals**

1. *In vivo* derived embryos and ova of bovine animals must have been obtained from donor animals which do not show any clinical signs of bluetongue on the day of collection.

2. Embryos and ova of animals other than bovine animals and *in vitro* produced bovine embryos must have been obtained from donor animals which comply with at least one of the following conditions:

(a) they have been kept outside a restricted zone for at least 60 days before commencement of, and during, collection of the embryos/ova;

(b) they have been protected against attacks by vectors for at least 60 days before commencement of, and during, collection of the embryos/ova;

(c) they have been subjected to a serological test according to the OIE Terrestrial Manual to detect antibodies to the bluetongue virus group, between 21 and 60 days following collection of the embryos/ova, with negative results;

(d) they have been subjected to an agent identification test according to the OIE Terrestrial Manual on a blood sample taken on the day of collection of the embryos/ova, with negative results.

3. Where the ova and embryos referred to in points 1 and 2 are intended for intra-Community trade or export to a third country, the following additional wording shall be added to the corresponding health certificates laid down in Council Directive 89/556/EEC (***) and Decision 95/388/EC, or referred to in Decision 93/444/EEC:

"Embryos/ova obtained from donor animals which comply with ..... *(point 1; point 2(a), point 2(b), point 2(c) or point 2(d), indicate as appropriate)* of Annex III.C to Regulation (EC) No 1266/2007".

Point 2(a) of Annex B to Directive 89/556/EEC shall not apply to ova and embryos collected from donor animals kept in holdings subject to veterinary prohibition or quarantine measures pertaining to bluetongue.

(***) OJ L 302, 19.10.1989, p. 1.'