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COMMISSION REGULATION (EC) No 1266/2007

of 26 October 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)

(OJ L 283, 27.10.2007, p. 37)

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►M2	Commission Regulation (EC) No 384/2008 of 29 April 2008	L 116	3	30.4.2008
►M3	Commission Regulation (EC) No 394/2008 of 30 April 2008	L 117	22	1.5.2008
►M4	Commission Regulation (EC) No 708/2008 of 24 July 2008	L 197	18	25.7.2008
►M5	Commission Regulation (EC) No 1108/2008 of 7 November 2008	L 299	17	8.11.2008
►M6	Commission Regulation (EC) No 1304/2008 of 19 December 2008	L 344	28	20.12.2008
►M7	Commission Regulation (EC) No 123/2009 of 10 February 2009	L 40	3	11.2.2009
►M8	Commission Regulation (EC) No 789/2009 of 28 August 2009	L 227	3	29.8.2009

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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 Directive 82/894/EEC of 21 December 1982 on the notification of animal diseases within the Community ([1]), and in particular the second indent of Article 5(2),

Having regard to Council Directive 2000/75/EC of 20 November 2000 laying down specific provisions for the control and eradication of bluetongue ([2]), and in particular Article 6(1) and (3), Article 8(2)(d), Article 8(3), Article 9(1)(c), Articles 11 and 12 and the third paragraph of Article 19 thereof,

Whereas:

(1) Directive 2000/75/EC lays down control rules and measures to combat bluetongue in the Community, including the establishment of protection and surveillance zones and a ban on animals of the susceptible species leaving those zones. Exemptions from that ban may de decided by the Commission in accordance with the procedure provided for in that Directive.

(2) Commission Decision 2005/393/EC of 23 May 2005 on protection and surveillance zones in relation to bluetongue and conditions applying to movements from or through these zones ([3]) provides for the demarcation of the global geographic areas where protection and surveillance zones (the restricted zones) are to be established by the Member States.

(3) Following the adoption of Decision 2005/393/EEC, the bluetongue situation in the Community has considerably changed and new experience has been gained on disease control, in particular following the recent incursions of new serotypes of bluetongue virus, namely of serotype 8 in an area of the Community where outbreaks had never been reported before and which was not considered at risk of bluetongue, and of serotype 1 of that virus.

(4) On the basis of the experience gained, it is appropriate to improve harmonisation at Community level of the rules on the control, monitoring, surveillance, and restrictions on movements of susceptible animals, excluding wild animals, in relation to bluetongue as they are of fundamental importance for safe trade in susceptible farmed animals moving within and from restricted zones, with the aim of establishing a more sustainable strategy for the control of bluetongue. For the sake of harmonisation and clarity, it is therefore necessary to repeal Decision 2005/393/EC and to replace it by this Regulation.

(5) The new situation as regards bluetongue has also led the Commission to request scientific advice and support from the European Food Safety Authority (EFSA) which has delivered

([1]) OJ L 378, 31.12.1982. Directive as last amended by Commission Decision 2004/216/EC (OJ L 67, 5.3.2004, p. 27).
([2]) OJ L 327, 22.12.2000, p. 74. Directive as last amended by Directive 2006/104/EC (OJ L 363, 20.12.2006, p. 352).
([3]) OJ L 130, 24.5.2005, p. 22. Decision as last amended by Decision 2007/357/EC (OJ L 133, 25.5.2007, p. 44).

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two scientific reports and two scientific opinions on bluetongue in 2007.

(6) Pursuant to Directive 2000/75/EC, the demarcation of protection and surveillance zones must take account of geographical, administrative, ecological and epizootiological factors connected with bluetongue and of the control arrangements. In order to take account of those factors, it is necessary to lay down rules as regards the minimum harmonised requirements for monitoring and surveillance of bluetongue in the Community.

(7) Surveillance and exchange of information are key elements of a risk-based approach to bluetongue control measures. For that purpose, it is appropriate, in addition to the definitions laid down in Article 2 of Directive 2000/75/EC, to provide in particular for a definition of a case of bluetongue, to enable a common understanding of the essential parameters related to an outbreak of bluetongue.

(8) In addition, the concept of restricted zones, used in Decision 2005/393/EC, has proven adequate, especially if the presence of the bluetongue virus is detected in the affected area in two consecutive seasons. For practical reasons and for the sake of clarity of Community legislation, it is appropriate to provide for a definition of restricted zones, consisting of both the protection and surveillance zones demarcated by the Member States pursuant to Article 8(1) of Directive 2000/75/EC.

(9) The determination of a bluetongue seasonally-free zone for which surveillance demonstrates no evidence of bluetongue transmission or of competent vectors is an essential tool for a sustainable management of outbreaks of bluetongue enabling safe movements. For that purpose, it is appropriate to provide for the harmonised criteria that should be used for the definition of the seasonally vector-free period.

(10) Outbreaks of bluetongue should be notified in accordance with Article 3 of Council Directive 82/894/EEC, using the codified forms and the codes set out in Commission Decision 2005/176/EC of 1 March 2005 laying down the codified form and the codes for the notification of animal diseases pursuant to Council Directive 82/894/EEC ([1]). In the light of the current epidemiological development of bluetongue, the scope of this notification requirement should be temporarily adapted by defining more precisely the obligation to notify primary outbreaks.

(11) According to the opinion of the Scientific Panel on Animal Health and Welfare of the EFSA on bluetongue origin and occurrence ([2]), adopted on 27 April 2007, it is essential that appropriate surveillance programmes are in place to detect the occurrence of bluetongue at the earliest possible stage. Such surveillance programmes should include a clinical, serological and entomological component that should operate seamlessly across all Member States.

(12) An integrated approach at Community level is required in order to be able to analyse the epidemiological information provided by the bluetongue monitoring and surveillance programmes, including both regional and global distribution of the bluetongue infection, as well as of the vectors.

([1]) OJ L 59, 5.3.2005, p. 40. Decision as amended by Decision 2006/924/EC (OJ L 354, 14.12.2006, p. 48).
([2]) The EFSA Journal (2007) 480, 1-20.

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(13) Council Decision 90/424/EEC of 26 June 1990 on expenditure in the veterinary field ([1]) provides for a Community financial contribution for the eradication, control and monitoring of bluetongue.

(14) Pursuant to Decision 90/424/EEC, Commission Decision 2007/367/EC of 25 May 2007 concerning a financial contribution by the Community to Italy for the implementation of a system for collection and analysis of epidemiological information on bluetongue ([2]) established the BlueTongue NETwork application (BT-Net system), which is a web-based system to collect, store, and analyse bluetongue surveillance data in the Member States. Full use of that system is of fundamental importance to establish the most appropriate measures for controlling the disease, verifying their efficacy and allowing safe movements of animals of susceptible species. To ensure more effective and efficient exchanges of information on the bluetongue monitoring and surveillance programmes in place between the Member States and the Commission, those exchanges should therefore be carried out through the BT-Net system.

(15) Unless it appears necessary to proceed to the demarcation of protection and surveillance zones at Community level pursuant to Article 8(2)(d) of Directive 2000/75/EC, that demarcation should be carried out by the Member States. However, for the sake of transparency, Member States should notify to the Commission their protective and surveillance zones and any changes thereof without delay. In particular, if a Member State intends not to maintain an epidemiological relevant geographical area in a restricted zone, it should provide to the Commission in advance with relevant information to substantiate the absence of bluetongue virus circulation in that area.

(16) Exemptions from the exit ban applicable to movements of susceptible animals, their semen, ova and embryos, from the restricted zone should be authorised on the basis of a risk analysis taking into account the data collected through the bluetongue surveillance programme, the exchange of data with other Member States and the Commission through the BT-Net system, the destination of the animals, and their compliance with certain health requirements guaranteeing the safety of the animals. Movements of animals for immediate slaughter should also be exempted from the exit ban under certain conditions. Taking into account the low level of risk of movements of animals for immediate slaughter and certain risk mitigation factors, it is appropriate to provide for specific conditions minimizing the risk of virus transmission by channelling the transport of animals from a holding located in a restricted zone towards slaughterhouses designated on the basis of a risk assessment.

(17) Movements of animals within the same restricted zone where the same bluetongue virus serotype or serotypes are circulating, does not pose an additional risk to animal health and should therefore be allowed by the competent authority under certain conditions.

(18) According to the opinion of the Scientific Panel on Animal Health and Welfare of the EFSA on vectors and vaccines ([3]), adopted on 27 April 2007, movements of immunised animals due to vaccination or naturally immunised animals can be considered safe irrespective of the virus circulation at the place of origin or the vectors activity at the place of destination. It is therefore necessary to provide for the conditions that immunised animals must fulfil before moving from a restricted zone.

([1]) OJ L 224, 18.8.1990, p. 19. Decision as last amended by Regulation (EC) No 1791/2006 (OJ L 363, 20.12.2006, p. 1).
([2]) OJ L 139, 31.5.2007, p. 30.
([3]) The EFSA Journal (2007) 479, 1-29.

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(19) Council Directive 64/432/EEC of 26 June 1964 on animal health problems affecting intra-Community trade in bovine animals and swine ([1]), Council Directive 91/68/EEC of 28 January 1991 on animal health conditions governing intra-Community trade in ovine and caprine animals ([2]), 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 ([3]) and 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]) provide that health certificates are to accompany the movements of animals. Where exemptions from the exit ban applicable to movements of animals of susceptible species from the restricted zone are applied to animals intended for intra-Community trade or for export to a third country, those certificates should include a reference to this Regulation.

(20) In accordance with the opinion of the EFSA on vectors and vaccines, it is appropriate to lay down the conditions for the treatment with authorised insecticides at the place of loading of the vehicles transporting susceptible animals from a restricted zone to or through areas outside a restricted zone. When during the transit through a restricted zone, a rest period is foreseen in a control post the animals should be protected from any attacks by vectors. However, the treatment with authorised insecticides of animals, premises and their surroundings in infected holdings should only be carried out following a defined protocol on the basis of the positive outcome of a case-by-case risk assessment which takes into account geographical, epidemiological, ecological, environmental, entomological data and a cost/benefit assessment.

(21) The health certificates provided for in Directives 64/432/EEC, 91/68/EEC and 92/65/EEC and Decision 93/444/EEC covering animals intended for intra-Community trade or for export to a third country should include a reference to any insecticide treatment carried out pursuant to this Regulation.

(22) In view of the need to avoid unnecessary disruptions in trade it is urgent to establish a sustainable strategy for the control of the bluetongue virus enabling safe trade in animals of susceptible species moving within and from restricted zones.

(23) 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:

([1]) OJ 121, 29.7.1964, p. 1977/1964. Directive as last amended by Directive 2006/104/EC.

([2]) OJ L 46, 19.2.1991, p. 19. Directive as last amended by Directive 2006/104/EC.

([3]) 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).

([4]) OJ L 208, 19.8.1993, p. 34.

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CHAPTER 1

SUBJECT MATTER AND DEFINITIONS

Article 1

Subject matter

This Regulation lays down rules for the control, monitoring, surveillance and restrictions on movements of animals with the meaning of Article 2(c) of Directive 2000/75/EC, in relation to bluetongue, in and from the restricted zones.

Article 2

Definitions

For the purposes of this Regulation, the definitions in Article 2 of Directive 2000/75/EC shall apply.

In addition, the following definitions shall apply:

(a) 'case of bluetongue' means an animal that meets one of the following requirements:

(i) it presents clinical signs consistent with the presence of bluetongue;

(ii) it is a sentinel animal that had showed negative serological results in a previous test and has seroconverted from negative to positive for antibodies to at least one bluetongue serotype since that test;

(iii) it is an animal from which the bluetongue virus has been isolated and identified as such;

(iv) it is an animal which has tested positive to bluetongue serological tests or from which viral antigen or viral ribonucleic acid (RNA) specific to one or more of the bluetongue serotypes has been identified.

In addition, a set of epidemiological data must indicate that the clinical signs or results of laboratory tests suggesting bluetongue infection are the consequence of virus circulation in the holding in which the animal is kept and not the result of the introduction of vaccinated or seropositive animals from restricted zones;

(b) 'outbreak of bluetongue' means an outbreak of that disease as defined in Article 2(c) of Directive 82/894/EEC;

(c) 'primary outbreak of bluetongue' means an outbreak as defined in Article 2(d) of Directive 82/894/EEC, taking into account that, for the purposes of the application of the first indent of Article 3(1) of that Directive, a case of bluetongue is a primary outbreak in the following cases:

(i) if it is not epidemiologically linked with a previous outbreak; or

(ii) it implies the demarcation of a restricted zone or a change in an existing restricted zone as referred to in Article 6;

(d) 'restricted zone' means a zone consisting of both protection and surveillance zones established pursuant to Article 8(1) of Directive 2000/75/EC;

(e) 'bluetongue seasonally-free zone' means an epidemiological relevant geographical area of a Member State for which, for a part of the year, surveillance demonstrates no evidence of bluetongue virus transmission or of adult *Culicoides* likely to be competent bluetongue vectors;

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(f) ‘transit’ means the movement of animals:

(i) from or through a restricted zone;

(ii) from a restricted zone through a non-restricted zone back to the same restricted zone; or

(iii) from a restricted zone through a non-restricted zone to another restricted zone.

CHAPTER 2

MONITORING AND SURVEILLANCE AND EXCHANGE OF INFORMATION

Article 3

Notification of bluetongue

Member States shall notify primary outbreaks and outbreaks of bluetongue through the Animal Disease Notification System, using the codified forms and the codes set out in Decision 2005/176/EC.

Article 4

Bluetongue monitoring and surveillance programmes

Member States shall implement the following programmes in accordance with the minimum requirements set out in Annex I:

(a) bluetongue monitoring programmes in restricted zones (the bluetongue monitoring programmes);

(b) bluetongue surveillance programmes outside restricted zones (bluetongue surveillance programmes).

Article 5

Epidemiological information

1. Member States shall transmit to the BlueTongue NETwork application (BT-Net system), established by Decision 2007/367/EC, information on bluetongue gathered in the course of the implementation of the bluetongue monitoring and/or surveillance programmes, and in particular:

(a) a monthly report, transmitted not later than one month after the end of the reporting month, which shall contain at least:

(i) the data on the sentinel animals from the bluetongue monitoring programmes in place in the restricted zones;

(ii) the entomological data from the bluetongue monitoring programmes in place in the restricted zones;

(b) an intermediate report covering the first six months of the year, and transmitted each year by 31 July at the latest, which shall contain at least:

(i) the data from the bluetongue surveillance programmes in place outside the restricted zones;

(ii) the vaccination data from the restricted zones;

(c) an annual report, transmitted by 30 April of the following year at the latest, which shall contain the information referred to in points (b)(i) and (ii) for the previous year.

2. The information to be transmitted to the BT-Net system is set out in Annex II.

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CHAPTER 3

RESTRICTIONS ON MOVEMENTS OF ANIMALS AND OF THEIR SEMEN, OVA AND EMBRYOS

Article 6

Restricted zones

1. Member States shall notify to the Commission their restricted zones, and any change in the situation of those zones within 24 hours.

2. Before taking any decision to remove an epidemiologically relevant geographical area from a restricted zone, Member States shall provide the Commission with substantiated information demonstrating the absence of bluetongue virus circulation in that area during a period of two years following the implementation of the bluetongue monitoring programme.

3. The Commission shall inform the Member States in the framework of the Standing Committee on the Food Chain and Animal Health of the list of restricted zones.

4. Member States shall draw up and keep updated a list of the restricted zones in their territory and make it available to the other Member States and to the public.

5. The Commission shall publish, for information purposes only, on its website the updated list of restricted zones.

That list shall include information on the bluetongue virus serotypes circulating in each restricted zone, which permits, for the purposes of Articles 7 and 8, the identification of the restricted zones demarcated in different Member States where the same bluetongue virus serotypes are circulating.

Article 7

Conditions for movements within the same restricted zone

1. Movements of animals within the same restricted zone where the same bluetongue virus serotype or serotypes are circulating shall be allowed by the competent authority provided that the animals to be moved do not show any clinical signs of bluetongue on the day of transport.

2. However, movements of animals from a protection zone to a surveillance zone may only be allowed if:

(a) the animals comply with the conditions set out in Annex III; or

(b) the animals comply with any other appropriate animal health guarantees based on a positive outcome of a risk assessment of measures against the spread of the bluetongue virus and protection against attacks by vectors, required by the competent authority of the place of origin and approved by the competent authority of the place of destination, prior to the movement of such animals;

(c) the animals are destined for immediate slaughter.

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2a. Member States may, on the basis of the outcome of a risk assessment which must take into account sufficient epidemiological data obtained following the implementation of monitoring in accordance with point 1.1.2.1 or point 1.1.2.2 of Annex I, demarcate a part of a protection zone as a ‘restricted zone with vaccination and without

▼M8

circulation of bluetongue virus of a specific serotype or serotypes' (lower-risk area), subject to the following conditions:

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(i) vaccination is applied in that part of the protection zone for a specific bluetongue virus serotype or serotypes;

(ii) there is no bluetongue virus circulating in that part of the protection zone for that specific bluetongue serotype or serotypes.

A Member State which intends to demarcate a part of a protection zone as a 'lower-risk area' shall notify its intention to the Commission. That notification shall be accompanied by all the necessary information and data to justify the demarcation in view of the epidemiological situation of the zone concerned, in particular with regard to the bluetongue monitoring programme in place. It shall also inform the other Member States without delay.

Movements of animals within the same restricted zone from an area where the same bluetongue virus serotype or serotypes are circulating to a part of the same restricted zone demarcated as a 'lower-risk area' may only be permitted if:

(a) the animals comply with the conditions set out in Annex III; or

(b) the animals comply with any other appropriate animal health guarantees based on a positive outcome of a risk assessment of measures against the spread of the bluetongue virus and protection against attacks by vectors, required by the competent authority of the place of origin and approved by the competent authority of the place of destination, prior to the movement of such animals; or

(c) the animals are destined for immediate slaughter.

3. The Member State of origin shall immediately inform the Commission and the other Member States of the animal health guarantees referred to in paragraph 2(b) or 2a(b).

4. For the animals referred to in paragraphs 1, 2 and 2a 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 in compliance with … (Article 7(1), or 7(2)(a), or 7(2)(b), or 7 (2)(c), or 7(2a)(a) or 7(2a)(b), or 7(2a)(c), indicate as appropriate) of Regulation (EC) No 1266/2007'.

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Article 8

Conditions for exemption from the exit ban provided for in Directive 2000/75/EC

1. Movements of animals, their semen, ova and embryos, from a holding or semen collection or storage centre located in a restricted zone to another holding or semen collection or storage centre shall be exempted from the exit ban established pursuant to Article 9(1)(c) and point 1 of Article 10 of Directive 2000/75/EC provided that the animals, their semen, ova and embryos comply with:

(a) the conditions set out in Annex III to this Regulation; or

(b) comply with any other appropriate animal health guarantees based on a positive outcome of a risk assessment of measures against the spread of the bluetongue virus and protection against attacks by vectors, required by the competent authority of the place of origin and approved by the competent authority of the place of destination, prior to the movement of such animals.

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2. The Member State of origin shall immediately inform the Commission and the other Member States of the animal health guarantees referred to in paragraph 1(b).

3. A channelling procedure shall be set up, under the control of the competent authority of the place of destination, to ensure that the animals, their semen, ova and embryos moved in accordance with the conditions provided for in paragraph 1(b), are not subsequently moved to another Member State unless the animals comply with the conditions provided for in paragraph 1(a).

4. Movements of animals from a holding located in a restricted zone for immediate slaughter shall be exempted from the exit ban established 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;

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(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 ([1]) takes place in a control post situated in the same restricted zone;

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(c) the competent authority at the place of dispatch notifies the intended movement of the animals to the competent authority of the place of destination at least 48 hours prior to the loading of the animals.

5. Notwithstanding paragraph 4(b), the competent authority of the place of destination may require, on the basis of a risk assessment, the competent authority of the place of origin to set up a channelling procedure for the transport of the animals referred to therein towards designated slaughterhouses.

Any such designated slaughterhouses shall be identified on the basis of a risk assessment that shall take into account the criteria set out in Annex IV.

Information on the designated slaughterhouses shall be made available to the other Member States and to the public. That information shall also be made available through the BT-Net system.

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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 established 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.

6. For the animals, their semen, ova and embryos referred to in paragraphs 1, 4 and 5a of this Article, the following additional

([1]) OJ L 3, 5.1.2005, p. 1.

▼M4

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'.

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Article 9

Further conditions for the transit of animals

1. The transit of animals shall be allowed by the competent authority provided that:

(a) animals from a restricted zone being moved through areas outside a restricted zone and the means in which they are transported are treated with authorised insecticides and/or repellents after adequate cleansing and disinfection at the place of loading and in any case prior to leaving the restricted zone;

(b) animals being moved from an area outside a restricted zone through a restricted zone and the means in which they are transported are treated with authorised insecticides and/or repellents after adequate cleansing and disinfection at the place of loading and in any case prior to entry into the restricted zone;

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(c) when a rest period of more than one day is foreseen at a control post during the movement through a restricted zone, the animals are protected against attacks by vectors in a vector proof establishment.

2. Paragraph 1 of this Article shall not apply if the transit takes place:

(a) exclusively from or through epidemiologically relevant geographical areas of the restricted zone during the bluetongue seasonally vector-free period defined in accordance with Annex V, or

(b) from or through parts of the restricted zone demarcated as a 'lower-risk area' in accordance with Article 7(2a).

3. Where the animals comply with at least one of the conditions set out in points 5, 6 and 7 of Section A of Annex III, the treatment of animals provided for in paragraph 1(a) and (b) and the protection of animals provided for in paragraph 1(c) shall not apply.

4. For the animals referred to in paragraph 1 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:

'Insecticide/repellent treatment with … *(insert name of the product)* on … *(insert date)* in conformity with Regulation (EC) No 1266/2007 (*)

(*) OJ L 283, 27.10.2007, p. 37'

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Article 9a

Transitional provisions

1. Until ►M6 31 December 2009 ◄, by way of derogation from Article 8(1)(a) and based on the outcome of a risk assessment taking into account the entomological and epidemiological conditions of the introduction of animals, Member States of destination may require that the movement of animals, which are covered by the exemption provided for in Article 8(1) and which comply with at least one of the conditions

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set out in points 1 to 4 of Section A of Annex III but which do not comply with points 5, 6 and 7 of that Section, comply with the following additional conditions:

(a) those animals must be less than 90 days old;

(b) they must have been kept since birth in vector protected confinement;

(c) the tests referred in points 1, 3 and 4 of Section A of Annex III must have been carried out on samples taken not earlier than seven days before the date of the movement.

2. A Member State which intends to apply the additional conditions laid down in paragraph 1 shall notify the Commission in advance.

It shall provide the Commission with all the necessary information and data required to justify the application of those additional conditions in view of its entomological and epidemiological situation, in particular with regard to the vector species and virus serotype involved, climate conditions, and the type of husbandry of the susceptible ruminants.

If the Commission has not opposed the application within a period of seven days from the date of notification, the notifying Member State shall be entitled to apply those additional conditions forthwith. It shall inform the other Member States without delay.

3. The Commission shall make available to the public information regarding the application of additional conditions in accordance with paragraph 2.

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4. For the animals referred to in paragraph 1 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 in compliance with Article 9a(1) of Regulation (EC) No 1266/2007’.

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CHAPTER 4

FINAL PROVISIONS

Article 10

Repeal

Decision 2005/393/EC is repealed.

Article 11

Entry into force

This Regulation shall enter into force on the fifth 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.

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ANNEX I

Minimum requirements for bluetongue monitoring and surveillance programmes (referred to in Article 4)

1. *Minimum requirements for bluetongue monitoring programmes to be implemented by Member States in restricted zones*

Bluetongue monitoring programmes shall be aimed at providing information on the dynamics of bluetongue in a restricted zone. The objectives of bluetongue monitoring programmes are to detect the introduction of new bluetongue serotypes and to demonstrate the absence of certain bluetongue serotypes. Other objectives may include the demonstration of the absence of bluetongue virus circulation, the determination of the seasonally vector free period and identifying the vector species.

The geographical unit of reference for the purposes of bluetongue monitoring and surveillance shall be defined by a grid of around 45 × 45 km (approximately 2 000 km^2) unless specific environmental conditions justify a different size. Member States may also use the 'region' as defined in Article 2(p) of Directive 64/432/EEC as the geographical unit of reference for monitoring and surveillance purposes.

1.1. Bluetongue monitoring programmes shall consist of at least passive clinical surveillance and active laboratory-based surveillance, as set out in points 1.1.1 and 1.1.2.

1.1.1. Passive clinical surveillance shall:

— consist of a formal and properly documented ongoing system aimed at detecting and investigating any suspicions, including an early warning system for reporting suspicions. Owners or holders and veterinarians must promptly report any suspicion to the competent authority. All suspicions due to the presence of bluetongue serotypes not expected to be present in the epidemiologically relevant geographical area must be thoroughly investigated immediately by the competent authority in order to ascertain the bluetongue serotypes circulating;

— be specially reinforced during the season of vector activity;

— ensure that awareness campaigns are put in place and aimed, in particular, at enabling owners or holders and veterinarians in identifying clinical signs of bluetongue.

1.1.2. Active laboratory-based surveillance shall consist of at least one, or a combination of, serological monitoring with sentinel animals, serological/virological surveys, or targeted risk-based monitoring, as set out in points 1.1.2.1, 1.1.2.2 and 1.1.2.3.

▼M7

1.1.2.1. Monitoring with sentinel animals:

— monitoring with sentinel animals shall consist of an active annual programme of testing sentinel animals aimed at assessing the circulation of the bluetongue virus within the restricted zone. Where possible, sentinel animals must be bovine animals. They must be located in areas of the restricted zone where, following a risk analysis considering entomological and ecological evaluations, the presence of the vector has been confirmed or habitats suitable for the vector's breeding are present,

— sentinel animals shall be tested at least once a month during the period of activity of the vector involved, if known. In the absence of such information the sentinel animals shall be tested at least once a month throughout the year,

— the minimum number of sentinel animals per geographical unit of reference for the purposes of bluetongue monitoring and

▼M7

surveillance must be representative and sufficient in order to detect a monthly incidence [1] of 2 % with 95 % confidence in each geographical unit of reference,

— laboratory testing shall be designed in such a way that positive screening tests are followed by the specific serotype serological/-virological tests targeted to the appropriate bluetongue serotype or serotypes necessary to ascertain the specific serotype circulation in each epidemiologically relevant geographical area.

▼M8

1.1.2.2. Serological/virological surveys:

— shall consist of at least an active annual programme of serological/-virological testing of susceptible species populations, aimed at detecting evidence of bluetongue virus transmission through random serological and/or virological testing implemented in all epidemiologically relevant geographical areas and performed in the period of the year when infection or seroconversion is more likely to be detected;

— must be designed in such a way that the samples are representative and adjusted to the structure of the susceptible species population to be sampled in the epidemiologically relevant geographical area and the sample size has been calculated to detect a prevalence of 20 % with 95 % confidence in the susceptible species population of that epidemiologically relevant geographical area. For the purpose of demarcating a part of a protection zone as a 'lower risk area' in accordance to Article 7(2a) the survey must have a sample size calculated to detect a monthly prevalence of 2 % with 95 % confidence in the susceptible species population of that epidemiologically relevant geographical area;

— must ensure that seropositive animals from vaccinated or immunized populations do not interfere with the serological surveys,

— must ensure that laboratory testing is designed in such a way that positive screening tests are followed by the specific serotype serological/virological tests targeted to the bluetongue serotype or serotypes expected to be present in the epidemiologically relevant geographical area necessary to ascertain the specific serotype circulating;

— may also be designed to monitor vaccination coverage and distribution of different bluetongue serotypes present in the restricted zone,

— may include the testing of samples which are collected for other purposes, such as samples from slaughterhouses or from bulk milk.

▼M5

1.1.2.3. Targeted risk-based monitoring:

— shall consist of a formal and properly documented ongoing system aimed at demonstrating the absence of certain specific bluetongue serotypes;

— applies to a target population of susceptible animals at a relative high risk, based on their location, the geographical situation and the epidemiology of the bluetongue serotype or serotypes expected to be present in the epidemiologically relevant geographical area;

— must have a sampling strategy that is adjusted to the defined target population. The sample size has been calculated to detect the design prevalence (based on the known risk of the target population) with 95 % confidence in the target population of that epidemiologically relevant geographical area. Whenever the samples do not originate from individual animals, sample size must be adjusted according to the sensitivity of the diagnostic procedures applied.

[1] It has been estimated that 20 % is the normal annual rate of seroconversion in an infected zone. However, in the Community, virus circulation mainly takes place in a period of around six months (end of spring/mid-autumn). Therefore 2 % is a conservative estimation of the expected monthly rate of seroconversion.

▼M5

1.2. To determine the seasonally vector-free period as referred to in Annex V to this Regulation, entomological surveillance must meet the following requirements:

— it shall consist of at least an active annual programme of vector catching by means of permanently sited aspiration traps intended to determine the population dynamics of the vector;

— aspiration traps equipped with ultraviolet light must be used in accordance with pre-established protocols. The traps must be operated throughout the night and operate at a rate of at least:

  — one night per week during the month before the expected beginning and during the month before the expected end of the seasonally vector-free period;

  — one night per month during the seasonally vector-free period;

  — on the basis of the evidence obtained in the three first years of their operation, the frequency of operation of the aspiration traps may be adjusted;

— at least one aspiration trap must be placed in each epidemiologically relevant area all over the bluetongue seasonally-free zone. A proportion of the midges collected in the aspiration traps must be sent to a specialised laboratory capable of counting and identifying the suspected vector species.

1.3. Monitoring in order to provide the Commission with substantiated information demonstrating the absence of bluetongue virus circulation in an epidemiological relevant geographical area during a period of two years, as referred to in Article 6(2):

— shall consist of at least one, or a combination of, serological monitoring with sentinel animals, serological/virological surveys and targeted risk-based monitoring, as set out in points 1.1.2.1, 1.1.2.2 and 1.1.2.3;

— must be designed in such a way that the samples are representative and adjusted to the structure of the susceptible species population to be sampled in the epidemiologically relevant geographical area and the sample size has been calculated to detect a prevalence of 20 % ([1]) with 95 % confidence in the susceptible species population of that epidemiologically relevant geographical area if mass vaccination has not been implemented; or

— must be designed in such a way that the samples are representative and adjusted to the structure of the susceptible species population to be sampled in the epidemiologically relevant geographical area and the sample size has been calculated to detect a prevalence of 10 % ([2]) with 95 % confidence in the susceptible species population of that epidemiologically relevant geographical area if mass vaccination has been implemented.

2. *Minimum requirements for bluetongue surveillance programmes to be implemented by the Member States outside restricted szones*

Bluetongue surveillance programmes shall be aimed at detecting any possible incursions of the bluetongue virus and at demonstrating the absence of that virus in a bluetongue-free Member State or epidemiologically relevant geographical area.

Bluetongue surveillance programmes shall consist of at least passive clinical surveillance and active laboratory-based surveillance, as set out in points 2.1 and 2.2.

2.1. Passive clinical surveillance:

— shall consist of a formal and properly documented ongoing system aimed at detecting and investigating any suspicions including an

([1]) It has been estimated that 20 % is the normal annual rate of seroconversion in an infected zone. However, if there is evidence that the annual rate of seroconversion in the epidemiologically relevant geographical area is lower than 20 % the sample size has to be calculated to detect the lower estimated prevalence.

([2]) It has been assumed that 10 % is the normal annual rate of seroconversion in a vaccinated zone. However, if there is evidence that the annual rate of seroconversion in the epidemiologically relevant vaccinated geographical area is lower than 10 % the sample size has to be calculated to detect the lower estimated prevalence.

▼M5

early warning system for reporting suspicions. Owners or holders and veterinarians must promptly report any suspicion to the competent authority. All suspicions must be thoroughly investigated by the competent authority immediately in order to confirm or rule out any outbreak of bluetongue;

— must be specially reinforced during the season of vector activity in areas having a specific relative higher risk, based on geographical and epidemiological data;

— must ensure that awareness campaigns are put in place and aimed, in particular, at enabling owners or holders and veterinarians in identifying clinical signs of bluetongue.

2.2. Active laboratory-based surveillance shall consist of at least one, or a combination of serological monitoring with sentinel animals, or serological/virological surveys, or targeted risk-based surveillance, as set out in points 2.2.1, 2.2.2 and 2.2.3.

2.2.1. Serological monitoring with sentinel animals

— Serological monitoring with sentinel animals shall consist of an active annual programme of testing sentinel animals, aimed at detecting the evidence of bluetongue virus transmission outside the restricted zones. Specific attention must be given to areas at high risk, based on geographical and epidemiological data;

— Sentinel animals shall be tested at least once a month during the period of activity of the vector involved, if that period is known. In the absence of such information, the sentinel animals shall be tested at least once a month throughout the year;

— The minimum number of sentinel animals per geographical unit of reference for the purposes of bluetongue monitoring and surveillance must be representative and sufficient in order to detect a monthly incidence of seroconversion [1] of 2 % with 95 % confidence in each geographical unit of reference.

▼M8

2.2.2. Serological/virological surveys:

— shall consist of at least an active annual programme of serological/-virological testing of susceptible species populations, aimed at detecting evidence of bluetongue virus transmission through random serological and/or virological testing implemented in all epidemiologically relevant geographical areas and performed in the period of the year when infection or seroconversion is more likely to be detected;

— must be designed in such a way that the samples are representative and adjusted to the structure of the susceptible species population to be sampled in the epidemiologically relevant geographical area and the sample size has been calculated to detect a prevalence of 20 % with 95 % confidence in the susceptible species population of that epidemiologically relevant geographical area;

— must ensure that seropositive animals from vaccinated or immunized populations do not interfere with the serological surveys,

— may include the testing of samples which are collected for other purposes, such as samples from slaughterhouses or from bulk milk.

▼M5

2.2.3. Targeted risk-based surveillance

— shall consist of a formal and well documented ongoing system aimed at demonstrating the absence of certain specific bluetongue serotypes;

— must be based on substantial knowledge of the local risk factors; such knowledge must allow the identification of the specific relative higher risk target population to be sampled;

[1] It has been estimated that 20 % is the normal annual rate of seroconversion in an infected zone. However, in the Community, virus circulation mainly takes place in a period of around six months (end of spring/mid autumn). Therefore 2 % is a conservative estimation of the expected monthly rate of seroconversion.

▼**M5**

— must ensure that the targeted sampling strategy is adjusted to the target population defined at relative higher risk and the sample size has been calculated to detect the design prevalence (based on the known risk of the target population) with 95 % confidence in the target population of that epidemiologically relevant geographical area.

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ANNEX II

Information to be transmitted by the Member States to the BT-Net system (referred to in Article 5(2))

The information to be transmitted by the Member States to the BT-Net system shall include at least the following:

1. **Bluetongue serological/virological data**

   (a) Administrative division/unit

   (b) Animal species tested

   (c) Type of surveillance system scheme (sentinel system or periodical survey)

   (d) Type of diagnostic tests performed (ELISA, Serum-neutralisation, PCR, virus isolation)

   (e) Month and year

   (f) Number of tested animals ([1])

   (g) Number of positive animals

   (h) Serotype serologically or virologically determined (data to be provided in case of positive results to serum-neutralization or virus isolation tests)

2. **Bluetongue entomological data**

   (a) Administrative division

   (b) Site unique identity (a unique code for each trapping site)

   (c) Collection date

   (d) Latitude and longitude

   (e) Total number of *Culicoides* spp. collected

   (f) Number of *C. imicola* collected, if available

   (g) Number of *C. obsoletus Complex* collected, if available

   (h) Number of *C. obsoletus sensu strictu* collected, if available

   (i) Number of *C. scoticus* collected, if available

   (j) Number of *C. Pulicaris Complex* collected, if available

   (k) Number of *C. Nubeculosus complex* collected, if available

   (l) Number of *C. dewulfii* collected, if available

   (m) Other relevant data

3. **Bluetongue vaccination data**

   (a) Administrative division

   (b) Year/semester

   (c) Type of vaccine

   (d) Serotype combination

   (e) Animal species vaccinated

   (f) Total number of herds in the Member State

   (g) Total number of animals in the Member State

   (h) Total number of herds under the vaccination programme

   (i) Total number of animals under the vaccination programme

   (j) Total number of herds vaccinated

   (k) Number of animals vaccinated (where the vaccination type is vaccination of young animals)

([1]) If pools of sera are used, an estimation of the number of animals corresponding to the pools tested must be reported.

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(l) Number of young animals vaccinated (where the vaccination type is mass vaccination)

(m) Number of adults vaccinated (where the vaccination type is mass vaccination)

(n) Doses of vaccine administered.

▼M1

ANNEX III

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

▼M4

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. ►M8 The animals have been kept, until dispatch, protected against attacks by vectors in a vector proof establishment 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. ►M8 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 in a vector proof establishment 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 on samples collected from that animal 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.'

▼M4

4. ►M8 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 in a vector proof establishment 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 on samples collected from that animal 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(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;

▼M7

   (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; however, that agent identification test is not necessary for movements of animals from a part of a restricted zone demarcated as a 'lower-risk area' in accordance with Article 7 (2a) of this Regulation;

▼M4

   (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

▼M4

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.'

▼M7

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. In case a serological test, as set out in point 3, is carried out, that test shall be carried out not earlier than seven days before the date of movement.

▼M4

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*)'.

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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;

▼M8

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

▼M1

(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;

▼M5

(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 of the semen to be consigned;

(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 of the semen to be consigned; and

(ii) during the period of semen collection:

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

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

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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 ([1]) and Commission Decision 95/388/EC ([2]), 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'.

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;

▼M8

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

([1]) OJ L 194, 22.7.1988, p. 10.
([2]) OJ L 234, 3.10.1995, p. 30.

▼M1

(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 [1] 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.

[1] OJ L 302, 19.10.1989, p. 1.

▼B

ANNEX IV

Criteria for the designation of slaughterhouses for exemption from the exit ban (referred to in the second paragraph of Article 8(4))

For the purpose of the risk assessment for the designation of slaughterhouses for the channelling of movements of animals from a holding located in a restricted zone for immediate slaughter, the competent authority of destination shall use at least the following criteria:

1. the data available through the monitoring and surveillance programmes, especially as regards the vector's activity;
2. the distance from the point of entry in the non-restricted zone to the slaughterhouse;
3. the entomological data on the route;
4. the period of the day during which the transport takes place in relation to the hours of activity of the vectors;
5. the possible use of insecticides and repellents in compliance with Council Directive 96/23/EC ([1]);
6. the location of the slaughterhouse as regards livestock holdings;
7. the biosecurity measures in place at the slaughterhouse.

([1]) OJ L 125, 23.5.1996, p. 10. Directive as last amended by Directive 2006/104/EC.

▼B

ANNEX V

Criteria for the definition of the seasonally vector-free period (referred to in Article 9(3))

For the purpose of determining a bluetongue seasonally-free zone, the seasonally vector-free period for a determinate epidemiologically relevant geographical area of a Member State (epidemiologically relevant geographical area) shall be defined by the competent authority using at least the following criteria:

1. **General criteria**

   (a) A bluetongue monitoring and/or surveillance programme must be in place.

   (b) The specific criteria and thresholds used for the determination of the seasonally vector-free period shall be defined considering the *Culicoides* species proven or suspected to be the main vectors in the epidemiologically relevant geographical area.

   (c) The criteria used for the determination of the seasonal vector-free period shall be applied considering data from current and previous years (historical data). In addition, the aspects linked to surveillance data standardization shall be taken into consideration.

2. **Specific criteria**

   (a) No bluetongue virus circulation within the epidemiologically relevant geographical area, as demonstrated by bluetongue surveillance programmes or other evidence suggesting a halt in bluetongue virus.

   (b) Cessation of vector and likely vector activity, as demonstrated through entomological surveillance as part of the bluetongue monitoring and/or surveillance programmes.

   (c) Captures of *Culicoides* species proven or suspected to be the vectors of the serotype present in the epidemiologically relevant geographical area below a maximum threshold of vectors collected that shall be defined for the epidemiologically relevant geographical area. In the absence of sound evidence supporting the determination of the maximum threshold, total absence of *Culicoides imicola* specimens and less than five parous *Culicoides* per trap must be used.

3. **Additional criteria**

   (a) Temperature conditions that impact on the behaviour of the vectors activity for the epidemiologically relevant geographical area. The temperature thresholds shall be defined in consideration of the ecological behaviour of *Culicoides* species proven or suspected to be the vectors of the serotype present in the epidemiologically relevant geographical area.