

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)

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(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<sup>(1)</sup>, 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<sup>(2)</sup>, 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 be 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<sup>(3)</sup> 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 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<sup>(4)</sup>. 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<sup>(5)</sup>, 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.
- (13) Council Decision 90/424/EEC of 26 June 1990 on expenditure in the veterinary field<sup>(6)</sup> 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<sup>(7)</sup> 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<sup>(8)</sup>, 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.
- (19) Council Directive 64/432/EEC of 26 June 1964 on animal health problems affecting intra-Community trade in bovine animals and swine<sup>(9)</sup>, Council Directive 91/68/EEC of 28 January 1991 on animal health conditions governing intra-Community trade in ovine and caprine animals<sup>(10)</sup>, Council Directive 92/65/EEC of 13 July 1992 laying down animal health requirements governing trade in and imports into the Community of animals, semen, ova and embryos not subject to animal health requirements laid down in specific Community rules referred to in Annex A(I) to Directive 90/425/EEC<sup>(11)</sup> 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<sup>(12)</sup> 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:

## 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;
- (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.

### 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.

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).

4 For the animals referred to in paragraphs 1 and 2 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), indicate as appropriate) of Regulation (EC) No 1266/2007<sup>(13)</sup>.

### 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.

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;
- b the animals are transported under official supervision directly to the slaughterhouse for slaughter within 24 hours of arrival at the slaughterhouse of destination;
- 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.

6 For the animals, their semen, ova and embryos referred to in paragraphs 1 and 4 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 ... (Article 8(1)(a) or 8(1)(b) or 8(4), indicate as appropriate) of Regulation (EC) No 1266/2007<sup>(14)</sup>.*

#### *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;
  - c when a rest period is foreseen at a control post during the movement through a restricted zone, the animals are protected against any attacks by vectors.

2 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) at ... (insert time) in conformity with Regulation (EC) No 1266/2007<sup>(15)</sup>.*

3 Paragraph 1 of this Article shall no longer apply in an epidemiologically relevant geographical area of a bluetongue seasonally vector-free zone when more than 60 days have elapsed from the date of commencement of the seasonally vector-free period, defined in accordance with Annex V.

However, that exemption shall no longer apply after the end of the seasonally vector-free period, on the basis of the bluetongue monitoring programme.

#### 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.

Done at Brussels, 26 October 2007.

*For the Commission*

Markos KYPRIANOU

*Member of the Commission*

## 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 in restricted zones shall be aimed at providing information on the dynamics of bluetongue in a zone already subjected to restrictions.

The geographical unit of reference shall be defined by a grid of around  $45 \times 45$  km (approximately 2 000 km<sup>2</sup>) unless specific environmental conditions justify a different size. In certain Member States, the 'region' as defined in Article 2 of Directive 64/432/EEC may be used as the geographical unit of reference for monitoring purposes.

Bluetongue monitoring programmes must consist at least of the following elements:

- 1.1. Serological monitoring with sentinel animals:

- Serological monitoring with sentinel animals shall consist of an active annual programme of testing sentinel animals aimed at assessing the circulation of bluetongue virus within the restricted zones. Where possible, sentinel animals must be bovine animals. They must be free from antibodies as demonstrated by means of a preliminary seronegative test and 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 every 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 monthly throughout the year. However, the testing frequency may be adjusted to the seasonal variations of the epidemiological situation during the year to establish the beginning and the end of the circulation of bluetongue virus within the restricted zones,
- The minimum number of sentinel animals per geographical unit must be representative and sufficient in order to detect a monthly incidence of seroconversion<sup>(16)</sup> of 2 % with a 95 % confidence in each geographical unit.

- 1.2. Entomological monitoring

- Entomological monitoring shall consist of an active programme of vector catching by means of permanently sited traps intended to determine the population dynamics and overwintering features of the *Culicoides* species in the sampled site in order to determine the seasonally vector-free period in the bluetongue seasonally-free zone in accordance with Annex V,
- Only aspiration traps equipped with ultraviolet light shall 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 at least during the period of the year necessary to determine the beginning and the end of the seasonally vector free period. At least one trap must be placed in each geographical unit all over the restricted zone. The frequency of operation of the traps must be adjusted to the seasonal variations of the epidemiological situation during the year to optimise the determination of the population dynamics and overwintering features of the *Culicoides* and may be amended on the basis of the evidence obtained in the three first years

of operation of the traps. An adequate proportion of the midges collected in the insect traps must be sent to a specialised laboratory capable of counting and identifying *Culicoides* species on a routine basis.

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

Bluetongue surveillance programmes outside restricted zones shall be aimed at the detection of virus circulation in a bluetongue-free Member State or epidemiologically relevant geographical area and must consist at least of the following elements:

- 2.1. Passive clinical surveillance:

- shall consist of a formal and ongoing system aimed at detecting and investigating suspicions of bluetongue including an early warning system for reporting suspicious cases. Owners or holders of animals as well as veterinarians must report promptly any suspicion of bluetongue to the competent authority. All suspected cases of bluetongue must be investigated immediately,
- must be specially reinforced during the season of vector activity, and in particular at its beginning,
- must ensure that awareness campaigns are put in place and aimed, in particular, at enabling veterinarians and farmers in identifying clinical signs of bluetongue.

- 2.2. Serological surveillance:

- shall consist of an active annual programme of serological testing of susceptible species populations, aimed at detecting evidence of the bluetongue virus transmission through random or targeted serological and/or virological testing proportional to the risk of infection of the Member State or epidemiologically relevant geographical area and performed in the period of the year when seroconversion is more likely to be detected,
- must be designed in such a way that the samples are representative of the bovine population in the Member State or in an epidemiologically relevant geographical area and the sample size has been calculated to detect a prevalence of 0,5 % with 95 % confidence in the bovine population of that Member State or geographical area,
- must ensure that samples sizes are adjusted to the structure of the bovine population to be sampled and for the use of targeted surveillance, focusing the sampling for the surveillance on high-risk populations in which specific commonly known risk factors exist. The design of the targeted surveillance must ensure that seropositive animals from vaccinated or immunised populations referred to in points 5, 6 and 7 of Part A of Annex III do not interfere with the bluetongue surveillance programme.

- 2.3. Entomological surveillance:

- shall consist of an active annual programme of vector catching aimed at gathering information on the proven and potential vector species in the Member State or in an epidemiologically relevant geographical area, their distribution and seasonal profiles,
- shall be implemented in all Member States where information on the proven and potential vector species, their distribution and seasonal profiles in the Member State is lacking.

## 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<sup>(17)</sup>
  - (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)
- (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.

### 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)<sup>(18)</sup> (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;

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;

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;
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;
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*) on ... (*insert date*) in conformity with Regulation (EC) No 1266/2007<sup>(19)</sup>.

6. The animals 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 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) in compliance with Annex IV(6) to Regulation (EC) No 1266/2007<sup>(20)</sup>.

7. The animals 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) in compliance with Annex IV(7) to Regulation (EC) No 1266/2007<sup>(21)</sup>.

#### 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.
- C. Ova and embryos of animals
1. *In vivo* derived embryos and ova of bovine animals must be collected in accordance with Council Directive 89/556/EEC<sup>(22)</sup>.
  2. *In vivo* derived 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.

#### 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<sup>(23)</sup>;
6. the location of the slaughterhouse as regards livestock holdings;
7. the biosecurity measures in place at the slaughterhouse.

#### 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.

- (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).
- (4) OJ L 59, 5.3.2005, p. 40. Decision as amended by Decision 2006/924/EC (OJ L 354, 14.12.2006, p. 48).
- (5) The EFSA Journal (2007) 480, 1-20.
- (6) 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).
- (7) OJ L 139, 31.5.2007, p. 30.
- (8) The EFSA Journal (2007) 479, 1-29.
- (9) OJ 121, 29.7.1964, p. 1977/1964. Directive as last amended by Directive 2006/104/EC.
- (10) OJ L 46, 19.2.1991, p. 19. Directive as last amended by Directive 2006/104/EC.
- (11) 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).
- (12) OJ L 208, 19.8.1993, p. 34.
- (13) OJ L 283, 27.10.2007, p. 37.'
- (14) OJ L 283, 27.10.2007, p. 37.'
- (15) OJ L 283, 27.10.2007, p. 37.'
- (16) 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.
- (17) If pools of sera are used, an estimation of the number of animals corresponding to the pools tested must be reported.
- (18) [http://www.oie.int/eng/normes/en\\_mcode.htm?e1d10](http://www.oie.int/eng/normes/en_mcode.htm?e1d10)
- (19) OJ L 283, 27.10.2007, p. 37.'
- (20) OJ L 283, 27.10.2007, p. 37.'
- (21) OJ L 283, 27.10.2007, p. 37.'
- (22) 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).
- (23) OJ L 125, 23.5.1996, p. 10. Directive as last amended by Directive 2006/104/EC.