[F1 ANNEX I

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

Textual Amendments

F1 Substituted by Commission Regulation (EC) No 1108/2008 of 7 November 2008 amending Regulation (EC) No 1266/2007 as regards the minimum requirements for bluetongue monitoring and surveillance programmes and the conditions for exempting semen from the exit ban provided for in Council Directive 2000/75/EC (Text with EEA relevance).

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.

[F2 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 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.**]**

Textual Amendments

F2 Substituted by Commission Regulation (EC) No 123/2009 of 10 February 2009 amending Regulation (EC) No 1266/2007 as regards conditions for movements of animals within the same restricted zone and the conditions for exempting animals from the exit ban provided for in Council Directive 2000/75/EC (Text with EEA relevance).

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 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;

— 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.

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.

1.2. 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 %[(2)] 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 %[(3)] 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 zones

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 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[(4)] of 2 % with 95 % confidence in each geographical unit of reference.

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 the bluetongue virus transmission outside the restricted zones through random serological and/or virological testing implemented in all epidemiologically relevant geographical areas and performed in the period of the year when seroconversion is most 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.

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;

— 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.**]**

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[(5)]

(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.

[F3ANNEX III

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

Textual Amendments

F3 Substituted by Commission Regulation (EC) No 289/2008 of 31 March 2008 amending Regulation (EC) No 1266/2007 on implementing rules for Council Directive 2000/75/EC as regards the control, monitoring, surveillance and restrictions on movements of certain animals of susceptible species in relation to bluetongue (Text with EEA relevance).

[F4A.Animals

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

5. The animals originate from a herd vaccinated according to a vaccination programme adopted by the competent authority and the animals have been vaccinated against the serotype(s) present or likely to be present in an epidemiologically relevant geographical area of origin, the animals are still within the immunity period of time guaranteed in the specifications of the vaccine approved in the vaccination programme and the animals meet at least one of the following requirements:

(a) they have been vaccinated more than 60 days before the date of movement;

(b) **[**[F2]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;**]**

(c) they were previously vaccinated and they have been re-vaccinated with an inactivated vaccine within the immunity period of time guaranteed in the specifications of the vaccine approved in the vaccination programme;

(d) they were kept during the seasonally vector-free period, defined in accordance with Annex V, in a bluetongue seasonally-free zone, since birth or for a period of at least 60 days before the date of vaccination and have been vaccinated with an inactivated vaccine before at least the number of days necessary for the onset of the immunity protection set in the specifications of the vaccine approved in the vaccination programme.

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

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

6. The animals have never been vaccinated against bluetongue and were always kept in an epidemiologically relevant geographical area of origin where not more than one serotype was or is present or likely to be present and:

(a) they were subjected to two serological tests according to the OIE Terrestrial Manual to detect antibodies against the bluetongue virus serotype, with positive results; the first test must be carried out on samples taken between 60 and 360 days before the date of movement and the second test being carried out on samples taken not earlier than seven days before the date of the movement; or

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

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

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

7. The animals have never been vaccinated against the bluetongue virus and were subjected with positive results to two adequate serological tests according to the OIE Terrestrial Manual able to detect specific antibodies against all the bluetongue virus serotypes present or likely to be present, in the epidemiologically relevant geographical area of origin, and:

(a) the first test must have been carried out on samples that were taken between 60 and 360 days before the date of movement and the second test must have been carried out on samples that were taken not earlier than seven days before the date of movement; or

(b) the specific serotype serological test must have been carried out at least 30 days before the date of the movement and the animals were subjected to an agent identification test according to the OIE Terrestrial Manual, with negative results, carried out not earlier than seven days before the date of movement.

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

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

[[F2]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.**]**

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*)’.**]**

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) **[**[F1]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.**]**

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[(6)] and Commission Decision 95/388/EC[(7)], 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;

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

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

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

3. Where the ova and embryos referred to in points 1 and 2 are intended for intra-Community trade or export to a third country, the following additional wording shall be added to the corresponding health certificates laid down in Council Directive 89/556/EEC[8] 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.**]**

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[9];

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) **[**[F1]**[**[F2]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.**]]**

(2) **[**[F1]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.**]**

(3) **[**[F1]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.**]**

(4) **[**[F1]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.**]**

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

(6) **[**[F3]OJ L 194, 22.7.1988, p. 10.**]**

(7) **[**[F3]OJ L 234, 3.10.1995, p. 30.**]**

(8) **[**[F3]OJ L 302, 19.10.1989, p. 1.**]**

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

Textual Amendments

F1 Substituted by Commission Regulation (EC) No 1108/2008 of 7 November 2008 amending Regulation (EC) No 1266/2007 as regards the minimum requirements for bluetongue monitoring and surveillance programmes and the conditions for exempting semen from the exit ban provided for in Council Directive 2000/75/EC (Text with EEA relevance).

F2 Substituted by Commission Regulation (EC) No 123/2009 of 10 February 2009 amending Regulation (EC) No 1266/2007 as regards conditions for movements of animals within the same restricted zone and the conditions for exempting animals from the exit ban provided for in Council Directive 2000/75/EC (Text with EEA relevance).

F3 Substituted by Commission Regulation (EC) No 289/2008 of 31 March 2008 amending Regulation (EC) No 1266/2007 on implementing rules for Council Directive 2000/75/EC as regards the control, monitoring, surveillance and restrictions on movements of certain animals of susceptible species in relation to bluetongue (Text with EEA relevance).

Status:
Point in time view as at 14/02/2009.

Changes to legislation:
There are outstanding changes not yet made to Commission Regulation (EC) No 1266/2007. Any changes that have already been made to the legislation appear in the content and are referenced with annotations.