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)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Council Directive 2000/75/EC of 20 November 2000 laying down specific provisions for the control and eradication of bluetongue [1], and in particular, 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 and eradicate bluetongue. They include the establishment of protection and surveillance zones ('restricted zones'), the implementation of bluetongue monitoring and surveillance programmes, and an exit ban on animals leaving the restricted zones ('the exit ban').

(2) 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 [2] lays down rules to be applied in the event of an outbreak of that disease.

(3) Annex I to Regulation (EC) No 1266/2007 sets out the minimum requirements for the bluetongue monitoring and surveillance programmes. Annex III to that Regulation sets out the conditions for exemption from the exit ban with regard to animals, their semen, ova and embryos. Annex V to that Regulation sets out criteria for the purpose of determining a bluetongue seasonally-free zone.

(4) It is essential that appropriate bluetongue monitoring and surveillance programmes are in place to achieve, among others, the objectives of the detection of the presence of the bluetongue virus at the earliest possible stage, to demonstrate the absence of general or specific bluetongue virus serotypes, and for the determination of the seasonally vector-free period. The bluetongue monitoring and surveillance programmes should include minimum requirements for Member States, while ensuring sufficient flexibility to take account of local epidemiological conditions.

(5) A mass emergency vaccination campaign against various types of bluetongue is being implemented in the EU. The vaccination of animals against that disease represents a major change of the immune status of the susceptible species population and has implications for bluetongue surveillance and monitoring programmes. Therefore, certain modifications to the requirements for the programmes need to be made.

(6) Annex V to Regulation (EC) No 1266/2007 sets out criteria for the purpose of determining a bluetongue seasonally-free zone. For reasons of clarification and a more harmonized approach, the beginning and the end of the seasonally vector-free period should be based on standardized surveillance data.

(7) Section B of Annex III to Regulation (EC) No 1266/2007 sets out conditions for exemption from the exit ban with regard to semen. It provides that semen must have been obtained from donor animals which comply with certain conditions, in order to be exempted. In the interests of certainty of Community legislation, it is appropriate to clarify certain requirements as regards the testing regimes of semen donor animals, in particular as regards post-collection testing.

(8) Regulation (EC) No 1266/2007 should therefore be amended accordingly.

(9) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on the Food Chain and Animal Health,

HAS ADOPTED THIS REGULATION:

Article 1

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

1. Annex I is replaced by the text in the Annex to this Regulation;

[1] OJ L 327, 22.12.2000, p. 74.
[2] OJ L 283, 27.10.2007, p. 37.

2. in Section B of Annex III, points (d) and (e) are replaced by the following:

'(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.'

Article 2

This Regulation shall enter into force on the 20th 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, 7 November 2008.

For the Commission
Androulla VASSILIOU
Member of the Commission

ANNEX

'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.

1.1.2.1. Serological monitoring with sentinel animals:

— Serological monitoring with sentinel animals shall consist of an active annual programme of testing sentinel animals aimed at assessing the circulation of the bluetongue virus within the restricted zone. 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 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 of seroconversion [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 bluetongue serotype or serotypes expected to be present in the epidemiologically relevant geographical area necessary to ascertain the specific serotype circulating.

[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.

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 % [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 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;

[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.

— 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.

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.

[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.'