Changes to legislation: *Commission Regulation (EC) No 1108/2008 is up to date with all changes known to be in force on or before 27 December 2020. There are changes that may be brought into force at a future date. Changes that have been made appear in the content and are referenced with annotations. (See end of Document for details) View outstanding changes*

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)

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.

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(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;

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.

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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

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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;