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)

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 9(1)(c), 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, including rules on the establishment of protection and surveillance zones, the implementation of vaccination programmes, and an exit ban on animals leaving those zones.

(2) Commission Regulation (EC) No 1266/2007 [2] lays down rules for the control, monitoring, surveillance and restrictions on movements of animals, in relation to bluetongue, in and from a protection and surveillance zone (restricted zone).

(3) Annex III to that Regulation establishes the conditions for exemptions from the exit ban applicable to movements of susceptible animals, their semen, ova and embryos provided for in Directive 2000/75/EC.

(4) According to the opinion of the Scientific Panel on animal health and welfare of the EFSA on vectors and vaccines [3], adopted on 27 April 2007, vaccination is a suitable tool for the control of bluetongue and for avoiding clinical outbreaks and therefore to limit the losses of farmers.

(5) The vaccination of animals against bluetongue represents a major change of the immune status of the susceptible population. The proof of the absence of general or specific bluetongue virus serotype or serotypes circulation in a part of the restricted zone should be made by the Member States by means of the results of the bluetongue monitoring programmes in place pursuant to Regulation (EC) No 1266/2007. Such monitoring programmes should include passive clinical surveillance and active laboratory-based surveillance by means of at least monitoring with sentinel animals.

(6) Laboratory-based surveillance by means sentinel animals should not be restricted only to serological test but it may also be carried out by other diagnostic methods, namely agent identification tests.

(7) Vaccination in the absence of virus circulation should not be discouraged and preventive vaccination in restricted zones without virus circulation should not be impeded. However, pursuant to Directive 2000/75/EC, vaccination against bluetongue is only permitted within the protection zone. Article 7(1) of Regulation (EC) No 1266/2007 provides that movements of animals within the same restricted zone where the same bluetongue virus serotype or serotypes are circulating are to 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, assuming that these animals do not pose an additional risk to animal health.

(8) Areas where vaccination has been applied and where there is no circulation of specific bluetongue virus serotype or serotypes present a lower risk than the other areas which are part of the restricted zone where there is virus circulation. Therefore, Member States should be permitted to demarcate, within the protection zone areas where vaccination has been applied and where there is no circulation of specific bluetongue virus serotype or serotypes. The intention to demarcate these areas should be notified to the Commission, together with all information demonstrating that it is justified. The other Member States should be also informed of such demarcation.

[1] OJ L 327, 22.12.2000, p. 74.
[2] OJ L 283, 27.10.2007, p. 37.
[3] The EFSA Journal (2007) 479, 1-29.

(9) Article 7(2) of that Regulation permits movements of animals from a protection zone to a surveillance zone, subject to certain conditions. Movements of animals within the same restricted zone, from a part of that zone with virus circulation to a part with vaccination and without virus circulation should be permitted under conditions similar to those required for movements of animals from a protection zone to a surveillance zone within the same restricted zone to limit the risk of virus spread into the part of the restricted zone with vaccination and without virus circulation. Therefore, the current rules for movements of animals within the same restricted zone where the same bluetongue virus serotype or serotypes are circulating should be amended.

(10) Movements of animals from a part of a restricted zone with vaccination and without virus circulation to an area outside the restricted zone are currently permitted subject to the same conditions as those applied when animals are moved from a restricted zone with virus circulation to an area outside the restricted zone. However, taking into account the relative low level of risk of movements of animals from a part of a restricted zone with vaccination and without virus circulation, it is appropriate to permit such movements under less strict conditions as regards the virus identification test that is required for certain categories of vaccinated animals. Annex III to Regulation (EC) No 1266/2007 should therefore be amended accordingly.

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

(12) 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. Article 7 is amended as follows:

(a) the following paragraph 2a is inserted:

'2a. Member States may, on the basis of the outcome of a risk assessment which must take into account sufficient epidemiological data obtained following the implementation of monitoring with sentinel animals in accordance with point 1.1.2.1 of Annex I, demarcate a part of a protection zone as a "restricted zone with vaccination and without circulation of bluetongue virus of a specific serotype or serotypes" (lower-risk area), subject to the following conditions:

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

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

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

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

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

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

(c) the animals are destined for immediate slaughter.';

(b) paragraphs 3 and 4 are replaced by the following:

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

4. For the animals referred to in paragraphs 1, 2 and 2a of this Article, the following additional wording shall be added to the corresponding health certificates laid down in Directives 64/432/EEC, 91/68/EEC and 92/65/EEC, or referred to in Decision 93/444/EEC:

"Animals in compliance with ..... (Article 7(1), or 7(2)(a), or 7(2)(b), or 7(2)(c), or 7(2a)(a) or 7(2a)(b), or 7(2a)(c), indicate as appropriate) of Regulation (EC) No 1266/2007".';

2. in Annex I, point 1.1.2.1. is replaced by the following:

'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 (*) 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.;

(*) 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.'

3. in Annex III, Section A is amended as follows:

(a) point 5(b) is replaced by the following:

'(b) they have been vaccinated with an inactivated vaccine before at least the number of days necessary for the onset of the immunity protection set in the specifications of the vaccine approved in the vaccination programme and were subjected to an agent identification test according to the OIE Terrestrial Manual, with negative results, carried out at least 14 days after the onset of the immunity protection set in the specifications of the vaccine approved in the vaccination programme; however, that agent identification test is not necessary for movements of animals from a part of a restricted zone demarcated as a "lower-risk area" in accordance with Article 7(2a) of this Regulation.';

(b) the third paragraph is replaced by the following:

'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.'.

Article 2

This Regulation shall enter into force on the third day following 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, 10 February 2009.

For the Commission
Androulla VASSILIOU
Member of the Commission