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)

COMMISSION REGULATION (EC) No 1266/2007

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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[(1)], 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[(2)], 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 de 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[(3)] 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

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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[(4)]. 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[(5)], 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

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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[(6)] 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[(7)] 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.

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(18) According to the opinion of the Scientific Panel on Animal Health and Welfare of the EFSA on vectors and vaccines[8], 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[9], Council Directive 91/68/EEC of 28 January 1991 on animal health conditions governing intra-Community trade in ovine and caprine animals[10], 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[11] 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[12] 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:

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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;