Commission Implementing Regulation (EU) No 456/2012 of 30 May 2012 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)

COMMISSION IMPLEMENTING REGULATION (EU) No 456/2012

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(Text with EEA relevance)

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

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 Article 9(1)(c), Articles 11 and 12 and the third paragraph of Article 19 thereof,

Whereas:

(1) 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 the restricted zones. It also 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, including rules on the use of vaccines against bluetongue.

(2) Under the current rules laid down in Directive 2000/75/EC, the use of vaccines against bluetongue is not permitted outside protection zones. Directive 2012/5/EU of the European Parliament and of the Council of 14 March 2012 amending Council Directive 2000/75/EC as regards vaccination against bluetongue[(3)] makes the rules on vaccination laid down in Directive 2000/75/EC more flexible in order to allow vaccination with inactivated vaccines against bluetongue also outside the areas subject to animal movement restrictions. As a consequence, Regulation (EC) No 1266/2007 should be amended. Furthermore, amendments are necessary to simplify the process of monitoring and surveillance and to adapt the procedures established by Regulation (EC) No 1266/2007 to recent scientific opinions.

(3) For the purpose of gathering and analysing epidemiological information on bluetongue, Regulation (EC) No 1266/2007 provides that Member States are to transmit to the BlueTongue NETwork application (BT-Net system) information on bluetongue gathered in the course of the implementation of the bluetongue monitoring and surveillance programmes.

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(4) However, experience shows that there is sufficient information available in the framework of other existing Union disease notification and reporting obligations. The obligation to exchange information through the BT-Net system is therefore no longer necessary.

(5) Regulation (EC) No 1266/2007, as amended by Commission Regulation (EC) No 123/2009[(4)] introduced the possibility for Member States to demarcate, under certain conditions, 'lower risk areas' to facilitate preventive vaccination in parts of their territory without virus circulation. As a consequence of the entry into force of Directive 2012/5/EU, whereby vaccination against bluetongue may be performed also outside restricted zones the provisions for the demarcation of 'lower risk areas' are no longer necessary.

(6) In accordance with Article 6(2) of Regulation (EC) No 1266/2007, a Member State may decide to remove an epidemiological geographical relevant area from a restricted zone, and thereby claim freedom from disease in that area after two years of absence of virus circulation as proven by monitoring.

(7) However, those parts of a restricted zone where for at least one year, including a full vector activity season, monitoring and surveillance show that no virus circulation of a specific bluetongue serotype or serotypes has taken place, are at risk of reintroduction of the disease by introduction of infectious animals from other parts of the same restricted zone where the bluetongue virus is still circulating. For these situations, in order to provide for a safe transition towards freedom from disease under favourable epidemiological conditions, Member States should be allowed to demarcate a 'provisionally free area' subject to the condition that monitoring and surveillance to ascertain the absence of virus circulation is carried out.

(8) According to the Scientific Opinion of the Panel on Animal Health and Welfare of the EFSA on the 'Risk of Bluetongue Transmission in Animal Transit', adopted on 11 September 2008[(5)], there is a theoretical possibility that infectious midges co-travel with the animals. That risk might be controlled by cleaning the vehicle and treating it with insecticides or repellents before loading the animals or when moving animals through areas known to be at low risk or at a period of time when the risk is known to be low. In order to limit undesired effects to the environment of those substances and to avoid possible problems as regards waiting periods and possible residues in the animals, the treatment of animals with authorised insecticides or repellents should no longer be required as this treatment provides for limited additional safety.

(9) Regulation (EC) No 1266/2007, as amended by Implementing Regulation (EU) No 648/2011[(6)], allows, for a transitional period, Member States of destination, in which the introduction of non-immune animals under certain circumstances could pose a risk for animal health, to require that the movement of such animals is subject to certain additional conditions. As rules on criteria for vector protected establishments are laid down in this Regulation, that transitional provision is no longer necessary.

(10) Due to the different levels of virus circulation, environmental conditions and different vaccination strategies in the Member States, the epidemiological situations as regards

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bluetongue may differ considerably in different areas of the Union. Experience has shown that different surveillance strategies may be successfully implemented to achieve the desired objectives. Therefore, the minimum harmonised requirements for monitoring and surveillance as laid down in Annex I to Regulation (EC) No 1266/2007 should be simplified to allow for more flexibility for the Member States to design their national monitoring and surveillance programmes, taking into account the Scientific Opinion of the EFSA Panel on Animal Health and Welfare on bluetongue monitoring and surveillance[7].

(11) Based on the abovementioned Scientific Opinion, the minimum sample size to detect a prevalence of 5 % with 95 % confidence in the susceptible species population should be sufficient for surveillance for the purpose of demonstrating the absence of virus circulation in an epidemiological relevant geographical area during a period of two years.

(12) Keeping bluetongue susceptible animals in a vector proof establishment for a specified period of time is an important requirement for certain conditions for exemptions from the exit ban as set out in Annex III to Regulation (EC) No 1266/2007. Experience shows that it is difficult for Member States to establish proper criteria for the implementation of a vector proof establishment for regular movements for trade in animals of susceptible species such as cattle, sheep and goats.

(13) In order to improve the effectiveness of vector proof establishments and to assist the Member States in their implementation of that control measure, a number of criteria should be established. Those criteria should be based on experiences of the Member States and the Terrestrial Animal Health Code of the World Organisation for Animal Health (OIE). To align the terminology with the OIE, the term ‘vector proof establishment’, currently used in Regulation (EC) No 1266/2007, should be replaced by ‘vector protected establishment’.

(14) In response to new scientific information which indicates the possibility of transplacental transmission of the bluetongue virus, in particular for bluetongue virus serotype 8, precautionary measures to prevent the possible spread of bluetongue by pregnant animals or certain newborn animals were introduced in Regulation (EC) No 1266/2007, as amended by Regulation (EC) No 384/2008[8].

(15) According to the Scientific Opinion of the Panel on Animal Health and Welfare of the EFSA on bluetongue serotype 8[9], there is scientific evidence for transplacental transmission of bluetongue virus serotype 8 which was introduced in the Union in 2006. However, transplacental transmission of other serotypes of the bluetongue virus in affected areas where no modified live vaccines have been used has not been shown. In the light of the conclusions of that opinion, the precautionary measure as regards the movement of pregnant animals should only apply for zones which are restricted for bluetongue virus serotype 8.

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

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

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HAS ADOPTED THIS REGULATION:

Article 1

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

(1) Article 4 is replaced by the following:

Article 4

Bluetongue monitoring and surveillance programmes

Member States shall implement bluetongue monitoring and surveillance programmes in accordance with the minimum requirements set out in Annex I.;

(2) Article 5 is deleted;

(3) in Article 6, paragraph 2 is replaced by the following:

2. Before taking any decision to remove an epidemiologically relevant geographical area from a restricted zone, Member States shall provide the Commission with substantiated information demonstrating the absence of bluetongue virus circulation in that area during a period of two years, including two full vector activity seasons, following the implementation of the bluetongue monitoring and surveillance programme in accordance with point 3 of Annex I.;

(4) in Article 7, paragraph 2a is replaced by the following:

2a. Member States may demarcate an epidemiological relevant geographical area in a restricted zone as a "provisionally free area" provided that for a period of one year, including one full vector season, monitoring and surveillance in accordance with point 3 of Annex I has demonstrated the absence of bluetongue virus circulation in that part of the restricted zone for that specific bluetongue serotype or combination of serotypes.

A Member State which intends to demarcate a restricted zone or part of a restricted zone as a "provisionally free area" shall notify its intention to the Commission. That notification shall be accompanied by the information referred to in point 3 of Annex I.

The Commission shall inform the Member States in the framework of the Standing Committee on the Food Chain and Animal Health of the list of "provisionally free areas".

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 "provisionally free 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.;

(5) in Article 8(5), the third subparagraph is replaced by the following:

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Information on the designated slaughterhouses shall be made available to the other Member States and to the public.;

(6) Article 9 is replaced by the following:

Article 9

Further conditions for the transit of animals

1 The transit of animals shall be allowed by the competent authority provided that:

a after adequate cleansing and disinfection at the place of loading, the means in which the animals are transported are treated with authorised insecticides and/or repellents. This treatment must in any case take place prior to leaving or entering the restricted zone;

b when a rest period of more than one day is foreseen at a control post during the movement through a restricted zone, the animals are protected against attacks by vectors in a vector protected establishment in accordance with the criteria set out in Annex II.

2 Paragraph 1 shall not apply if the transit takes place:

a exclusively from or through epidemiologically relevant geographical areas of the restricted zone during the bluetongue seasonally vector-free period defined in accordance with Annex V; or

b from or through parts of the restricted zone demarcated as a "provisionally free area" in accordance with Article 7(2a).

3 For the animals referred to in paragraph 1 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: "Insecticide/repellent treatment with … *(insert name of the product)* on … *(insert date)* in conformity with Article 9 of Regulation (EC) No 1266/2007.";

(7) Article 9a is deleted;

(8) Annexes I, II, III and V are amended in accordance with the Annex to this Regulation.

Article 2

This Regulation shall enter into force on the fifth 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, 30 May 2012.

For the Commission

The President

José Manuel BARROSO