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.

(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

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,

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:

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

ANNEX

Annexes I, II, III and V to Regulation (EC) No 1266/2007 are amended as follows:

(1) Annex I is replaced by the following:

‘ANNEX I

Minimum requirements for bluetongue monitoring and surveillance programmes (referred to in Article 4)

1. *General requirements*

Bluetongue monitoring and surveillance programmes shall be aimed at;

(a) detecting any possible incursions of the bluetongue virus and;

(b) where appropriate, demonstrating the absence of certain serotypes of that virus in a Member State or epidemiologically relevant geographical area; or

(c) determining the seasonally vector free period (entomological surveillance).

The geographical unit of reference for the purposes of bluetongue monitoring and surveillance shall be defined by a grid of around 45 x 45 km (approximately 2 000 km^2) unless specific environmental conditions justify a different size.

If appropriate, Member States may also use the “region” as defined in Article 2.2(p) of Directive 64/432/EEC or the regions as defined in Annex X to 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[(10)] as the geographical unit of reference for monitoring and surveillance purposes.

2. *Bluetongue monitoring and surveillance programmes aimed at detecting any possible incursions of the bluetongue virus*

Bluetongue monitoring and surveillance programmes aimed at detecting any possible incursions of the bluetongue virus shall consist of at least passive clinical surveillance and active laboratory-based surveillance.

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.

2.2. Active laboratory-based surveillance shall consist of an annual programme of at least one, or a combination of, serological/virological monitoring with sentinel animals, serological/virological surveys, or targeted monitoring and surveillance based on a risk assessment.

— Sampling may take place at pre-defined intervals throughout the year but shall at least be carried out once a year performed in the period of the year when infection or seroconversion is most likely to be detected.

— The bluetongue monitoring and surveillance programmes must be designed in such a way that the samples are taken from susceptible

animals (that is animals which have not been vaccinated and which have been exposed to the competent vector), which are representative for the structure of the susceptible species population in the epidemiologically relevant geographical area.

— The sample size must be calculated to detect the appropriate design prevalence based on the known risk of the target population with 95 % confidence in the susceptible species population of that epidemiologically relevant geographical area. In the absence of scientific information on the expected prevalence for the target population the sample size must be calculated to detect a prevalence of 20 %.

— Whenever the samples do not originate from individual animals, the sample size must be adjusted according to the sensitivity of the diagnostic procedures applied.

— Laboratory-based surveillance 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.

3. *Bluetongue monitoring and surveillance programmes aimed at demonstrating the absence of certain serotypes of the bluetongue virus in a Member State or epidemiologically relevant geographical area*

Bluetongue monitoring and surveillance programmes aimed at the demonstration of the absence of bluetongue virus circulation must comply with the conditions set out in points 2.1 and 2.2. The sample size used for the active laboratory-based surveillance must be calculated to detect a prevalence of 5 %[11] with 95 % confidence. In addition:

(a) for the purpose of removing an epidemiologically relevant geographical area from a restricted zone as referred to in Article 6(2), Member States must demonstrate the absence of bluetongue virus circulation during a period of at least two years, including two seasons of vector activity;

Member States shall submit to the Commission relevant historical epidemiological information on the monitoring and surveillance programme in place and its yearly results during the past three years, including at least:

(i) a description of the surveys currently being carried out and the type of diagnostic test performed (ELISA, serum neutralisation, PCR, virus isolation);

(ii) the sampled species and the number of samples taken per susceptible animal species; if pools of sera are used, an estimation of the numbers of animals corresponding to the pools tested must be reported;

(iii) the geographical coverage of the samples;

(iv) the frequency and timing of sampling;

(v) the number of positive results specified by animals species and geographical location.

(b) for the purpose of demarcating a "provisionally free area" as referred to in Article 7(2a), Member States must demonstrate the absence of bluetongue virus circulation during a period of at least one year, including one season of vector activity.

Member States shall submit to the Commission relevant historical epidemiological information on the monitoring and surveillance programme in place and its results during the past two years, including at least the information as laid down in points (a)(i) to (v).

4. *Bluetongue monitoring and surveillance programmes aimed at determining the seasonally vector free period (entomological surveillance)*

Entomological surveillance to determine the seasonally vector-free period as referred to in Annex V, shall meet the following requirements:

(a) it must 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;

(b) 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 the operation of the aspiration traps, the frequency of operation of those traps may be adjusted;

(c) 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.

(2) Annex II is replaced by the following:

'ANNEX II

Criteria for the "vector protected establishment" (referred to in points 2, 3and 4 of Section A of Annex III, point (b) of Section B and point 2(b) of Section C in that Annex)

1. A vector protected establishment shall at least comply with the following:

(a) it must have appropriate physical barriers at entry and exit points;

(b) openings of the vector protected establishment must be vector screened with mesh of appropriate gauge which must be impregnated regularly with an approved insecticide according to the manufacturers' instructions;

(c) vector surveillance and control must be carried out within and around the vector protected establishment;

(d) measures must be taken to limit or eliminate breeding sites for vectors in the vicinity of the vector protected establishment;

(e) standard operating procedures must be in place, including descriptions of back-up and alarm systems, for operation of the vector protected establishment and transport of animals to the place of loading.

2. The competent authority shall approve an establishment as vector protected, if the criteria in point 1 are met. It shall verify at the appropriate frequency, but at least three times during the required protection period (at the beginning, during and at the end of the period) the effectiveness of the measures carried out by means of a vector trap inside the vector protected establishment.';

(3) Annex III is amended as follows:

(a) Section A is amended as follows:

(i) in point 2, the first subparagraph is replaced by the following:

The animals have been kept, until dispatch, protected against attacks by vectors in a vector protected establishment in accordance with the criteria set out in Annex II for a period of at least 60 days prior to the date of dispatch.;

(ii) in point 3, the first subparagraph is replaced by the following:

The animals have been kept, until dispatch, in a bluetongue seasonally free zone during the seasonally vector-free period, defined in accordance with Annex V, or have been protected against attacks by vectors in a vector protected establishment in accordance with the criteria set out in Annex II for a period of at least 28 days and were subjected during that period to a serological test according to the OIE Terrestrial Manual to detect antibodies to the bluetongue virus group, with negative results, carried out on samples collected from that animal at least 28 days following the date of the commencement of the period of protection against attacks by vectors or the seasonally vector-free period.;

(iii) in point 4, the first subparagraph is replaced by the following:

The animals have been kept, until dispatch, in a bluetongue seasonally free zone during the seasonally vector-free period, defined in accordance with Annex V, or have been protected against attacks by vectors in a vector protected establishment in accordance with the criteria set out in Annex II for a period of at least 14 days and were subjected during that period to an agent identification test according to the OIE Terrestrial Manual, with negative results, carried out on samples collected from that animal at least 14 days following the date of commencement of the period of protection against attacks by vectors or the seasonally vector-free period.;

(iv) point 5 is replaced by the following:

5. The animals have been vaccinated against the serotype(s) present or likely to be present in an epidemiologically relevant geographical area of origin, the animals are still within the immunity period of time guaranteed in the specifications of the vaccine and the animals meet at least one of the following requirements:

   (a) they have been vaccinated more than 60 days before the date of movement;

   (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 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;

   (c) they were previously vaccinated and they have been revaccinated with an inactivated vaccine within the immunity period of time guaranteed in the specifications of the vaccine;

   (d) they were kept during the seasonally vector-free period, defined in accordance with Annex V, in a bluetongue seasonally free zone, since birth or for a period of at least 60 days before the date of vaccination and 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.

   Where animals referred to in this point are intended for intra-Union trade, 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:

   Animal(s) vaccinated against bluetongue serotype/s … *(insert serotype/s)* with … *(insert name of the vaccine)* with a inactivated/modified live vaccine *(indicate, as appropriate)* in conformity with Annex III.A(5) to Regulation (EC) No 1266/2007.’; ;

(v) in point 6, the introductory phrase is replaced by the following:

   6. The animals were always kept in an epidemiologically relevant geographical area of origin where not more than one serotype was or is present or likely to be present and:;

(vi) point 7 is amended as follows:

— the introductory phrase is replaced by the following:

> 7. The animals were subjected with positive results to two adequate serological tests according to the OIE Terrestrial Manual able to detect specific antibodies against all the bluetongue virus serotypes present or likely to be present, in the epidemiologically relevant geographical area of origin, and:;

— the third subparagraph is replaced by the following:

> For pregnant animals being moved from a restricted zone for bluetongue virus serotype 8, at least one of the conditions set out in points 5, 6 and 7 must have been 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.;

(b) in Section B, point (b) is replaced by the following:

> (b) they have been protected against attacks by vectors in a vector protected establishment in accordance with the criteria set out in Annex II for a period of at least 60 days before commencement of, and during, collection of the semen;;

(c) in Section C, in point 2, (b) is replaced by the following:

> (b) they have been protected against attacks by vectors in a vector protected establishment in accordance with the criteria set out in Annex II for at least 60 days before commencement of, and during, collection of the embryos/ova;;

(4) in Annex V, the title is replaced by the following:

ANNEX V

Criteria for the definition of the seasonally vector-free period (referred to in Article 9(2))

(**1**) OJ L 327, 22.12.2000, p. 74.

(**2**) OJ L 283, 27.10.2007, p. 37.

(**3**) OJ L 81, 21.3.2012, p. 1.

(**4**) OJ L 40, 11.2.2009, p. 3.

(**5**) *EFSA Journal* 2008; 795, 18-65.

(**6**) OJ L 176, 5.7.2011, p. 18.

(**7**) *EFSA Journal* 2011; 9(6): 2192.

(**8**) OJ L 116, 30.4.2008, p. 3.

(**9**) *EFSA Journal* 2011; 9(5): 2189.

(**10**) OJ L 59, 5.3.2005, p. 40.

(**11**) For a transitional period until 31 August 2012, the sample size of the survey may be calculated to detect a prevalence of 20 %.';

Changes to legislation:
Commission Implementing Regulation (EU) No 456/2012 is up to date with all changes known to be in force on or before 27 October 2023. 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.
View outstanding changes

Changes and effects yet to be applied to :

– Regulation implicit repeal by EUR 2020/689 Regulation