[F1 ANNEX I

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

Textual Amendments

F1 Substituted by 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).

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[(1)] 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 %[(2)] 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.**]**

(1) **[**[F1]OJ L 59, 5.3.2005, p. 40.**]**

(2) **[**[F1]For a transitional period until 31 August 2012, the sample size of the survey may be calculated to detect a prevalence of 20 %.**]**

Textual Amendments

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Changes to legislation:
There are outstanding changes not yet made to Commission Regulation (EC) No 1266/2007. Any changes that have already been made to the legislation appear in the content and are referenced with annotations.
View outstanding changes

Changes and effects yet to be applied to the whole legislation item and associated provisions

- Annex 1 para. 3 heading word substituted by S.I. 2018/1410 reg. 14(11)(b)(i)
- Annex 1 para. 1 words substituted by S.I. 2018/1410 reg. 14(11)(a)
- Annex 1 para. 3(a) words substituted by S.I. 2018/1410 reg. 14(11)(b)(ii)(aa)
- Annex 1 para. 3(a) words substituted by S.I. 2018/1410 reg. 14(11)(b)(ii)(bb)
- Annex 1 para. 3(b) words substituted by S.I. 2018/1410 reg. 14(11)(b)(iii)(aa)
- Annex 1 para. 3(b) words substituted by S.I. 2018/1410 reg. 14(11)(b)(iii)(bb)
- Annex 1 para. 1 words substituted in earlier amending provision S.I. 2018/1410, reg. 14(11)(a) by S.I. 2020/1388 reg. 25(11)(f)(i)
- Annex 1 para. 3(a) words substituted in earlier amending provision S.I. 2018/1410, reg. 14(11)(b)(ii)(bb) by S.I. 2020/1388 reg. 25(11)(f)(ii)
- Annex 3 s. B word substituted in earlier amending provision S.I. 2018/1410, reg. 14(12)(b)(ii) by S.I. 2020/1388 reg. 25(11)(g)(ii)
- Annex 3 s. C word substituted in earlier amending provision S.I. 2018/1410, reg. 14(12)(c) by S.I. 2020/1388 reg. 25(11)(g)(ii)
- Annex 3 s. A words omitted by S.I. 2018/1410 reg. 14(12)(a)(i)(aa)
- Annex 3 s. A words omitted by S.I. 2018/1410 reg. 14(12)(a)(i)(bb)
- Annex 3 s. B words omitted by S.I. 2018/1410 reg. 14(12)(b)(i)
- Annex 3 s. A words substituted by S.I. 2018/1410 reg. 14(12)(a)(i)(cc) (This amendment not applied to legislation.gov.uk. Reg. 14(12)(a)(i)(cc) substituted immediately before IP completion day by S.I. 2020/1388, regs. 1(2)(a), 25(11)(g)(i)(aa))
- Annex 3 s. A words substituted by S.I. 2018/1410 reg. 14(12)(a)(ii) (This amendment not applied to legislation.gov.uk. Reg. 14(12)(a)(ii) substituted immediately before IP completion day by S.I. 2020/1388, regs. 1(2)(a), 25(11)(g)(i)(bb))
- Annex 3 s. A words substituted by S.I. 2018/1410 reg. 14(12)(a)(iii) (This amendment not applied to legislation.gov.uk. Reg. 14(12)(a)(iii) substituted immediately before IP completion day by S.I. 2020/1388, regs. 1(2)(a), 25(11)(g)(i)(cc))
- Annex 3 s. B words substituted by S.I. 2018/1410 reg. 14(12)(b)(ii)
- Annex 3 s. C words substituted by S.I. 2018/1410 reg. 14(12)(c)
- Annex 3 s. A words substituted by S.I. 2018/1410, reg. 14(12)(a)(i)(cc) (as substituted) by S.I. 2020/1388 reg. 25(11)(g)(i)(aa)
- Annex 3 s. A words substituted by S.I. 2018/1410, reg. 14(12)(a)(ii) (as substituted) by S.I. 2020/1388 reg. 25(11)(g)(i)(bb)
- Annex 3 s. A words substituted by S.I. 2018/1410, reg. 14(12)(a)(iii) (as substituted) by S.I. 2020/1388 reg. 25(11)(g)(i)(cc)
- Art. 2(b) substituted by S.I. 2018/1410 reg. 14(3)(a)
- Art. 2(c) substituted by S.I. 2018/1410 reg. 14(3)(b)
- Art. 2(c) words substituted in earlier amending provision S.I. 2018/1410, reg. 14(3)(b) by S.I. 2020/1388 reg. 25(11)(b)(i)
- Art. 2(e) substituted by S.I. 2018/1410 reg. 14(3)(c)
- Art. 2(e) words substituted in earlier amending provision S.I. 2018/1410, reg. 14(3)(c) by S.I. 2020/1388 reg. 25(11)(b)(ii)
- Art. 2(g)-(j) inserted by S.I. 2018/1410 reg. 14(3)(d)
- Art. 2(g) words substituted in earlier amending provision S.I. 2018/1410, reg. 14(3)(d) by S.I. 2020/1388 reg. 25(11)(b)(iii)(aa)
- Art. 2(j)(ii)(iii) Art. 2(j)(iii)(iv) renumbered as Art. 2(j)(ii)(iii) in earlier amending provision S.I. 2018/1410, reg. 14(3)(d) by S.I. 2020/1388 reg. 25(11)(b)(iii)(bb)

– Art. 2(j)(ii) omitted in earlier amending provision S.I. 2018/1410, reg. 14(3)(d) by S.I. 2020/1388 reg. 25(11)(b)(iii)(bb)