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on

Bluetongue monitoring and surveillance in the EU

This document does not necessarily represent the views of the Commission Services

Content

1. Introduction

Bluetongue (BT) is a non-contagious, insect-transmitted (only *Culicoides* species), viral disease of domestic and wild ruminants that does not affect humans. At present 24 serotypes of the virus are recognised. The virulence and mortality rate of the different serotypes and strains within the serotypes vary considerably.

BT virus (BTV) is currently distributed between latitudes of approximately 50°N and 34°S but is known to be expanding further into the northern hemisphere. In the last decade, BT has been confirmed in many areas in the Mediterranean region, including Greece, Spain (Balearic Islands, southern Spain), Italy (Sardinia, Sicily, southern and central Italy), Portugal (southern Portugal) and France (Corsica) where environmental conditions seem to occur that make the endemic persistence of the virus possible in at least some of the above mentioned areas. However, it is also the case that *Culicoides* midges, responsible for BTV transmission, may be found in many other areas of the European Union in the spring, summer and autumn. Recently, the disease has been detected in the Netherlands, Belgium, western Germany and north-eastern France. Further information on this recent outbreak is given in document SANCO/10588/2006[1].

The recent outbreak has highlighted the risks that many countries in Europe, not only in the Mediterranean area, may face in relation to BTV.

In order to improve the understanding of the epidemiological situation and of the risks for the EU posed by this disease and to establish proportionate measures leading to a minimum disruption of trade it is necessary to enhance monitoring[2] and surveillance[3] for BT in the EU, in accordance with harmonised principles and guidelines.

Efforts to improve BTV surveillance in some Member States (MSs) are also made in the framework of a co-ordinated action financed by the EU Sixth Framework Programme for Research and Technological Development.

Discussions have been held on BT surveillance in the EU with experts from the MSs and Third Countries[4] with the purpose of setting the objectives and principles for BT surveillance in free and non-free zones in the EU, so that an enhanced and harmonised approach can be established.

[1] Working Document SANCO/10588/2006 enhancing the preparedness of National Reference laboratories for BTV outbreaks in Europe (in annex to this document)

[2] The Terrestrial Animal Health Code of the OIE defines monitoring as the continuous investigation of a given population or subpopulation, and its environment, to detect changes in the prevalence of a disease or characteristics of a pathogenic agent. In this document, monitoring is used to refer to the actions and measures taken to assess the disease evolution in a BT restricted zone for the purpose of adaptation of Community legislation and in order to modulate restrictions on animal movements.

[3] The Terrestrial Animal Health Code of the OIE defines surveillance as the investigation of a given population or subpopulation to detect the presence of a pathogenic agent or disease; the frequency and type of surveillance will be determined by the epidemiology of the pathogenic agent or disease, and the desired outputs. In this document, surveillance is used to refer to the actions and measures taken to demonstrate BTV absence in a non-restricted zone and early detect possible virus incursions into the zone for the purpose of adaptation of Community legislation.

[4] Meeting organised by DG SANCO (EC) on Enhanced Bluetongue monitoring and surveillance in the EU held on 5 October 2006

1.1. Legal framework for Bluetongue surveillance and control

The Community legal framework on BT surveillance and control is laid down in Council Directive 2000/75/EC[5] and Commission Decision 2005/393/EC[6].

Directive 2000/75/EC lays down basic measures that must be taken in case of a suspected outbreak of BT: confinement of animals of the susceptible species to prevent contact with the vectors, insecticides treatment, restrictions to movement of animals to or from the infected holding or from the zones where virus is circulating. In addition to that, MSs must extend these measures to holdings located within a radius of 20 kilometres around the infected holding. Protection (100 km radius) and surveillance zones (depth of at least 50 km extending beyond the limits of the protection zone) around the infected holdings must also be established. Depending on the basis of epidemiological, geographical, ecological or meteorological circumstances the competent authority may adapt or take further measures.

Decision 2005/393/EC as recently amended to incorporate the new restricted zones in Belgium, Germany, France, Luxembourg and the Netherlands provides for, among other ancillary measures, derogations from the restrictions to animal movements (especially domestic movements or intra-Community trade within restricted zones). Animals can be moved out of the restricted zones in a case-by-case risk assessment scenario and under certain conditions such as vaccination, pre-movement isolation, protection from attack from *Culicoides* and laboratory testing. Similar conditions can be applied for the movement of semen, ova and embryos.

In accordance to Community legislation, disease surveillance is indeed of fundamental importance to assess the actual risk posed by animal movements and modulate trade restrictions accordingly. As a consequence of the increased threat posed by BT, there is an increasing need for a harmonised EU approach to monitoring and surveillance.

The two legal acts are in line with the recently reviewed chapter on BT of the Terrestrial Animal Health Code of the World Organisation for Animal Health (OIE).

In accordance with the Terrestrial Animal Health Code, in the absence of clinical disease in a country or zone, except those located wholly north of 50°N[7] or south of 34°S, and not adjacent to a country or zone not having a free status, its BTV status should be determined by an ongoing surveillance programme. The programme may need to be adapted to target parts of the country or zone at a higher risk due to historical, geographical and climatic factors, ruminant population data and *Culicoides* ecology, or proximity to endemic or incursional zones. All countries or zones located below 50°N or adjacent to a country or zone not having free status should be subjected to similar surveillance.

[5] Council Directive 2000/75/EC of 20 November 2000 laying down specific provisions for the control and eradication of bluetongue (OJ L 327, 22.12.2000, p. 74–83)

[6] 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 (OJ L 130, 24.5.2005, p. 22–28). Decision as last amended by Decision 2006/650/EC (OJ L 267, 27.9.2006, p. 45-47)

[7] It has to be noted that most of the recent outbreaks of BTV-8 in North-Western Europe have occurred in farms located northern than 50°N (aprox 53°N). It is likely that the reference to 50°N in the OIE Code will be changed.

1.2. Legal base for EU financial support to BT control, monitoring and surveillance

EU expenditure on BT is specifically foreseen under Article 3 and Article 24 of Council Decision 90/424/EEC[8] on expenditure on the veterinary field.

- Article 3 of 90/424/EEC provides for the Community's financial contribution towards the emergency measures in the event of occurrence of BT in the territory of a MS. The MSs shall obtain a Community contribution for the eradication of the disease up to 50% of certain cost (compensation for slaughter, destruction of carcasses, disinfection…) incurred by the MS and up to 100% of the costs of the supply of vaccine doses and 50% of vaccination.

  It also provides for a Community financial contribution where, on the outbreak, two or more MSs collaborate closely to control the epidemic particularly in carrying out an epidemiological survey and disease surveillance measures.

  Commission Decision 2006/78/EC[9] entitled Portugal to a financial contribution from the Community amounting to 50 % of the expenditure incurred for the costs of the laboratory tests for serological and virological surveillance and for the costs of entomological surveillance, including the purchase of traps up to a certain preliminary maximum of 600.000 EUR

- Article 24 of 90/424/EEC provides for Community financial support to eradication and monitoring programmes that aim at progressively eliminating animal diseases (BT in endemic or high risk areas) that are endemic in certain areas of the Community.

  Surveillance programmes have been implemented from 2002 in several MSs and they have received Community financial contribution as follows:

	EU contribution (co-financing at a rate of 50%)				
MSs	**2002**	**2003**	**2004**	**2005**	**2006**
ES	200000	30000	355000	875000	2200000
FR	300000	200000	225000	95000	150000
IT	450000	600000	1205000	675000	1000000
PT					1250000
	950000	**830000**	**1785000**	**1645000**	**4600000**

- In addition, Article 19 of Council decision 90/424/EEC provides for Community financial support to technical and scientific measures. In this framework the Community can financially assist the MSs in undertaking the technical and scientific measures necessary for the development of Community veterinary legislation. This legal basis should be considered for the design of the necessary epidemiological or entomological studies that are needed and will enable the Community to update EU legislation as regards BT (in particular Decision 2005/393/EC) or develop new legislation.

The procedure of the Standing Committee on the Food Chain and Animal Health is mentioned for the financial decisions to be taken on the basis of article 3, 19 or 24 of Decision 90/424/EEC

[8] Council Decision 90/424/EEC of 26 June 1990 on expenditure in the veterinary field (OJ L 224, 18.8.1990, p. 19). Decision as last amended by Council Decision 2006/53 (OJ L 29, 2.2.2006, p. 37).

[9] Commission Decision 2006/78/EC of 31 January 2006 concerning a financial contribution by the Community for the implementation of an epidemiological survey and bluetongue surveillance measures in the context of the emergency measures taken to combat this disease in Portugal in 2004 and 2005 (OJ L 36, 8.2.2006, p. 45–47)

1.3. Basic principles and tools of BT monitoring and surveillance

1.3.1. Main objectives

The main objectives and principles of BT monitoring and surveillance can be summarised as follows:

1. Monitoring the dynamics of the disease in restricted[10] (non-free) zones
2. Surveillance to confirm the absence of the disease or to early detect the entry of virus into free zones. Surveillance may have also the purpose to substantiate the country declaration of BTV-freedom in the framework of the OIE Code.
3. Gathering data for the assessment of the risk of entry and/or spread of virus into free or infected areas in order and to enhance disease prevention and implement appropriate control measures, including restrictions to animal movements accordingly. This data should include epidemiological, geographical and meteorological data, as well as information of the vector(s) in the areas.

1.3.2. Fundamental tools

BT monitoring and surveillance must be based on three fundamental tools:

1. Serological and virological surveillance on domestic ruminants (mainly cattle)
2. Entomological surveillance
3. Supplementary measures: Clinical surveillance (BT is a notifiable disease), wildlife[11] surveillance, etc.

1.3.3. Geographical unit

- The epidemiological unit of concern for BT is neither the single animal nor the herd but a *geographical unit* that has to be defined taking into account mainly environmental characteristics.
- For the purpose of this document, the geographical unit is to be defined by a grid of around 45 x 45 Km (approx. 2.000 Km^2) unless specific environmental conditions justify a different size. In certain MSs, the "region" as defined in Article 2 of Council Directive 64/432/EEC could be used as geographical unit for surveillance purposes making a correspondence between geographical unit for BT and administrative unit. For other MSs, those administrative areas do not appear suitable for this purpose.

[10] Restricted zones as described in Article 2 of Commission Decision 2005/393/EC as last amended

[11] In this context "wildlife mean those wild species, which can be potential reservoirs and which are sensitive to BTV infection. It should be specially considered where they can meet a defined need that is not properly addressed by the serological entomological surveillance

1.4. Purpose of this document

The purpose of this document is:

- to provide for a harmonised approach to monitoring BT in restricted zones[12] (see also footnote 2), and
- to provide guidelines for surveillance in non-restricted zones adjacent to restricted zones (see also footnote 3).

In accordance to the OIE, all countries should have a BT surveillance in place except those countries (or zones) that lie wholly north of 50°N or south of 34°S, and are not adjacent to a country (or zone) not having a free status[13].

However, pending the adoption of specific standards on surveillance by the OIE, this document will not deal in detail with the surveillance required to substantiate the disease-free status of a country or zone for the purpose of international trade. Nevertheless, MSs are encouraged to make progress towards the establishment of such surveillance in their territories in line with the existing OIE standards, taking also into account the increasing threat for Europe posed by BT.

2. Monitoring BT in restricted (non-free) zones in the EU

2.1. Description

Monitoring consists of veterinary measures and strategies intended to provide information on BT situation in an infected, suspected or restricted zone.

The purpose is to provide follow up information on the situation as regards the behaviour of the disease in a zone already subjected to restrictions in the movements of domestic animals susceptible to BT due to the risk attributed to this zone.

The objectives are:

1. to detect possible progress in virus circulation in the restricted zone that would lead to the extension of this restricted zone.
2. to assess the circulation of the virus within the infected and restricted zones:
    a. to better define the appropriate extent of the infected and restricted zones
    b. to define the temporal and geographical distribution and progress of BTV
3. to gather information on the presence of:
    a. vector species involved and their competence
    b. quantitative estimation of vectors
    c. identification of the vector-free season or periods with the lowest risk of viral transmission

[12] Restricted zones as defined in Article 2 of Commission Decision 2005/393/EC as last amended.

[13] It is to be noted that recent outbreaks of BTV-8 in the EU have occurred as north as 53°N. It appears likely that the OIE Code will change accordingly.

2.2. Measures

2.2.1. Serological and virological monitoring (sentinel animals)

Serological monitoring of ruminants is aimed at assessing the circulation of BTV within the infected and restricted zones.

In restricted zones and also where the circulation of the virus is reasonably suspected or has been demonstrated it is necessary to differentiate newly infected animals from the seropositive animals due to past exposure to the virus. Therefore, sentinel animals should be established.

The sentinel animals should be tested at least every month during the period of activity of the vector involved if known. In the absence of such information the sentinel animals should be tested at least monthly all over the year.

Once a sentinel animal has seroconverted, it should not be tested again for surveillance purposes. New sentinels replacing such useless sentinels should be set as soon as possible.

However, the seroconverted sentinel animals are suitable for virological investigation in order to provide further information on the strain circulating.

As preliminary step, prior to setting the network of sentinel animals, a cross-sectional serological study should be performed in the first winter after the entrance of the BTV in a new territory to gain additional information on the definition of the infected zone.

Characteristics of the sentinel animals

1. Sentinel animal must be preferably bovine animals and must be individually identified
2. Sentinel animals must be free from antibodies by means of a preliminary seronegative test that can be performed to the individual sentinel animals or to all ruminants in the farm. This is especially important if vaccination is carried out in the restricted zone. Farms with a high rate of animal turnover should not be considered as sentinel and preferably sentinel farms should keep autochthonous animals.
3. Sentinel animals should be located within the geographical unit[14] taking into account the following criteria:

   - areas of the geographical unit 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.

   - areas of the geographical unit close to the borders of the restricted zone

   However, the sites for the sentinel animals must be chosen carefully in order to maximise the chance of detecting BTV activity at the geographical unit for which the sentinel animal/site acts as a sampling point.

Sample size

- The number of sentinel animals should be estimated for each geographical unit of reference unless any other evidence justifies a bigger or smaller density of sentinel animals. However, considering that an increased sensitivity of the system might be required at the periphery of the zone, an increased density and/or frequency of testing of sentinels in the peripheral geographic units may be useful.

[14] As defined previously in 1.3.3.

- The minimum number of sentinel animals per geographical unit should be representative and sufficient in order to detect a monthly incidence of seroconversion[15] of 2% with a 95% confidence in the geographical unit.

Test to be used

Basic test: the serological test recommended for surveillance is the ELISA[16]. ELISAs having, shown highest sensitivity should be preferably used for monitoring[17].

In addition, samples from the seroconverted sentinel animals may be tested with PCR and /or other virological or serological[18] methods to further confirm the serotype circulating in the zone.

2.2.2. Entomological monitoring

The entomological surveillance by means of permanently sited (permanent) traps is intended to determine mainly the population dynamics and over-wintering features of the *Culicoides* species in the sampled site.

Use of mobile (non-permanent) traps are intended to define the geographical distribution and abundance of various *Culicoides* species in the sampled zone.

Characteristics of the entomological monitoring

- Entomological surveillance is based on "vector catching". For this purpose only aspiration traps equipped with ultraviolet light should be used (South African model or equivalent). Placing and maintaining the traps and collection of midges and information that should accompany the samples should be carried out in accordance with pre-established protocols[19].Insecticides should not be used in the vicinity of the traps sites.
- The traps should be run throughout the night (from dusk to dawn) and operate at a rate of at least one night per week throughout the year. Midges should be retrieved from each trap on the day following its operation. The frequency of operation of the traps could however be amended on the basis of the evidence obtained in the first years of operation of the traps.
- Placing the traps close to sentinel animals (see 2.2.1. above) could allow comparison of the results between entomological and serological surveillance and provide useful additional information.
- Additional mobile (non-permament) traps may be used to obtain additional information. These traps may be placed on farm/holding where virus transmission has been just

[15] It has been estimated that 20% is the normal annual rate of seroconversion in an infected zone. However, under EU conditions, 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

[16] In consideration of its characteristics of high sensitivity, the serological test recommended is the competitive ELISA (c-ELISA). Positive c-ELISA results may be confirmed by seroneutralization assay to identify the infecting serotype(s).

[17] Working Document SANCO/10588/2006 enhancing the preparedness of National Reference laboratories for BTV outbreaks in Europe provides for additional information

[18] Serum-neutralisation or other tests referred in the OIE Manual of Diagnostic Tests and Vaccines for Terrestrial Animals

[19] Document "Sampling, timetable and protocol for entomological surveillance" provided by the Bluetongue Community Reference Laboratory is attached in the annex to this document as an example. Other valid examples are available in the literature (Vet. Ital., 40 (3), 260-265, available on line at http://www.izs.it/vet_italiana/2004/03/51.pdf)

confirmed to obtain additional information on the of *Culicoides* species responsible of BTV transmission).

Sample size

- In the restricted zone at least one trap should be placed in each geographical unit[20] all over the restricted zone.

Test to be used

- Midges collected in the insect traps should be sent to a specialised laboratory capable of counting and identifying *Culicoides* species on a routine basis.

2.2.3. Supplementary monitoring

2.2.3.1. Enhanced passive clinical surveillance

Bluetongue is a notifiable disease. Clinical surveillance is intended to early detect the circulation of the virus.

Characteristics of the passive clinical surveillance

- Clinical surveillance should be targeted to the ruminant species that is known to present more evident signs of BT for the BTV serotype(s), strain(s) circulating in the restricted zone. Usually, these ruminants are sheep, however the recently introduced BTV-8 has been able to induce clinical disease in cattle, too.
- Clinical surveillance must be specially reinforced during the season of vector activity, and in particular at its beginning.
- Passive surveillance is based on the reporting by the farmers to the veterinary authorities of clinical signs suggesting BT .Therefore, awareness campaigns should be put in place especially when the serotype(s) or strain(s) circulating in the zone produce mild or not clearly identifiable symptoms.
- An effective passive surveillance requires that reporting by farmers is not discouraged. In this regard, the adoption of restriction measures only[21] on the infected holding might be a disincentive to the farmers to notify disease signs.
- In addition, active clinical surveillance performed by trained veterinarians may be an ancillary system adequate for certain circumstances, specially in areas considered to be at potential risk. This active clinical surveillance may be performed in conjunction with other visits or inspections in the farm.

2.2.3.2. Wildlife monitoring

This supplementary monitoring should be put in place where wildlife is likely to play a significant role in the epidemiology of BT.

Surveillance of wildlife is intended to obtain additional information on the circulation of the virus among receptive animals of other susceptible (ruminant) species in order to complete the relevant epidemiological investigations and make predictions on the behaviour of the virus. This activity is particularly important in areas with high wild ruminant density.

[20] As described in 1.3.3.

[21] Provisions in article 6 paragraph 1.c) of Directive 2000/75/EC foresee the extension of all measures provided for in article 4 to holdings located within a radius of 20 km from the infected one.

Sample size

Samples from the maximum possible variety of susceptible wildlife representative of the restricted zone should be analysed.

Test to be used

PCR targeted at the BTV strain circulating is the test recommended for wildlife but ELISA is preferably[22] used in case the quality of the sera is adequate.

3. Surveillance for BT in non-restricted zones the EU

3.1. Introduction

The objective of this surveillance is to detect as early as possible BTV circulation in a free (non-restricted) zone and to confirm the absence of BTV.

3.2. Measures

3.2.1. Serological surveillance

Two differentiated strategies should be used for sero-surveillace in free zones:

- Routine surveillance is to be carried out by adequate sampling all over the free zones adjacent to a MS (or zone) not having a free status.

- Targeted reinforced surveillance is to be carried out by means of sentinel animals in free MSs (or zones) in the geographical units bordering the non-free restricted MSs (or zones), or in zones identified as at risk of long distance incursion due to other factors.

3.2.1.1.Routine serological surveillance

Sampling and testing herds/animals is adequate in free zones where the circulation of the virus has not been demonstrated in the recent past years [23].

Characteristics of the routine sampling

- Sampling should be representative of the population (species) under surveillance.
- Different strategies for sampling are acceptable:
    - Random sampling: simple, systematic, stratified or multistage sampling
    - Non-probability sampling: Specific sampling procedures taking into account the most relevant factors ensuring no undesired bias occurs.
    - Samples taken for other purposes are valid as long as they do not introduce an undesired bias.

Sample size

[22] PCR provides information on animals recently infected but ELISA gives retrospective information on the presence of the infection in the wild population

[23] This is related to the possible presence of seropositive animals due to outbreaks that occurred in the past. The presence of such seropositive animals that would interfere with this routine serological surveillance in a territory depends on the ruminant species, the husbandry practices in the territory, with particular reference to the replacement rate.

- The adequate number of sentinel animals should be estimated for each geographical unit and the minimum number of samples to be taken at least annually per each geographical unit must be sufficient to demonstrate no evidence of BTV.

  The possible causes of positive serological results should be taken into consideration when interpreting the results, such as natural infection with BTV, vaccination against BTV, maternal antibodies or false positive results due to the lack of specificity of the test.

  It is important, therefore, to interpret the results in light of the available epidemiological information on the tested animals.

Test to be used

Basic test: the serological test recommended for surveillance is the ELISA[24]. ELISAs having, shown highest sensitivity should be preferably used for monitoring[25].

3.2.1.2.Targeted reinforced surveillance on sentinel animals in free zones

Targeted reinforced surveillance based on sentinel animals should be established in the free zones bordering the restricted zones. The principles of monitoring in sentinel animals in restricted zones should be also applied (point 2.2.1.).

Therefore in the geographical units bordering the restricted zones, or in zones identified as at risk of long distance incursion due to other risk factors, a targeted reinforced surveillance consisting of a similar scheme to that on sentinel animals in the restricted zones (same number of animals, characteristics and procedures) should be in place.

3.2.2. Entomological surveillance

Entomological surveillance should be in place specially in the geographical units bordering a MS (or zone) not having a free status.

The purpose, the characteristics, procedures and minimum requirements should be similar to the characteristics of entomological monitoring in the restricted zones (point 2.2.2.).

4. Conclusions

1. It is necessary to rapidly put in place a harmonised BT monitoring and surveillance scheme in the EU. This harmonised system will allow the full and secure implementation of the measures foreseen in Decision 2005/393/EC ensuring transparency among the MSs and also as regards Third Countries.

   The strategy proposed in this document is to be considered by the MSs that need to implement this harmonised system and should be considered as the minimum level of monitoring and surveillance that should be established as soon as possible in all affected MS as well as in MSs at immediate risk of BTV incursions.

   Taking into account the diversity of epidemiological and environmental conditions and husbandry systems in the EU, it is necessary to ensure that the system implemented in each MS fits in with the prevailing local epidemiological and environmental situations.

[24] In consideration of its characteristics of high sensitivity, the serological test recommended is the competitive ELISA (c-ELISA). Positive c-ELISA results may be confirmed by seroneutralization assay to identify the infecting serotype(s).

[25] Working Document SANCO/10588/2006 enhancing the preparedness of National Reference laboratories for BTV outbreaks in Europe provides for additional information

The legal and financial contexts are to be taken into account in order to guarantee an equal treatment of all MSs thereby avoiding any discrimination.

2. In order to enhance preparedness as regards possible further spread of BT or the incursion of new BTV serotypes and strains in the EU, epidemiological data should be collected, gathered and analysed at EU level. This also applies to the MSs not infected or not considered at high risk.

   In addition, specific studies should be designed in order to address the lack of information in many areas of the EU on vectors distribution and biology related to BT or other arbovirus, taking account the reports on the disease situation and the epidemiological follow up analysis in relation to the ongoing outbreak of BTV-8 carried out by EFSA. This may include activities in MSs that are not geographically close to an ongoing outbreak. In such areas an inventory of the climate condition and vector ecology is recommended in order to be able to assess the risk of a possible introduction and transmission of BT.

5. Annex

- SANCO/10588/2006 Working document on Enhancing the preparedness of National Reference Laboratories for Bluetongue virus outbreaks in Europe

Microsoft Word Document

- Sampling Timetable and Protocol for entomological surveillance (as provided by the BT CRL)

Sampling timetable & protocol.doc