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# REPORT OF THE ELECTRONIC CONSULTATION OF THE OIE TERRESTRIAL ANIMAL HEALTH STANDARDS COMMISSION ON BLUETONGUE

**Paris, 15–17 April 2009**

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As announced in the report of the Commission held in March, the OIE Terrestrial Animal Health Standards Commission (hereinafter referred to as the Code Commission) consulted electronically on the report of the *ad-hoc* Group on Bluetongue which met at the OIE Headquarters in Paris on 14 April 2009.

Dr Thiermann, President of the Code Commission, who attended the *ad hoc* Group meeting, agreed with the *ad hoc* Group's recommendations. Following the electronic consultation, the other members of the Code Commission also gave general agreement on the text reviewed by the *ad hoc* Group and decided to propose the chapter for adoption at the 77th General Session of the OIE in May 2009.

The revised text is presented at Annex I of this report for adoption.

.../Annexes

Annex I

# CHAPTER 8.3.

# BLUETONGUE

Article 8.3.1.

## General provisions

For the purposes of the *Terrestrial Code*, the *infective period* for bluetongue virus (BTV) shall be 60 days.

The global BTV distribution is currently ~~between the latitudes of approximately 53°N and~~ between the latitudes of approximately 53°N and north of 34°S with a ~~possible northern range~~ recent extension in Northern Europe ~~to the arctic (66.33°N) but is known to be expanding in the northern hemisphere~~.

In the absence of clinical *disease* in a country or *zone* within this part of the world, its BTV status should be determined by an ongoing *surveillance* programme (in accordance with Articles 8.3.16. to 8.3.21.). 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 enzootic or incursional zones as described in Articles 8.3.16. to 8.3.21.

All countries or *zones* adjacent to a country or *zone* not having free status should be subjected to similar *surveillance*. The *surveillance* should be carried out over a distance of at least 100 kilometres from the border with that country or *zone*, but a lesser distance could be acceptable if there are relevant ecological or geographical features likely to interrupt the transmission of BTV or a bluetongue *surveillance* programme (in accordance with Articles 8.3.16. to 8.3.21.) in the country or *zone* not having free status supports a lesser distance.

Standards for diagnostic tests and vaccines are described in the *Terrestrial Manual*.

~~Article 8.3.1.bis~~

## Trade in commodities

When authorising import or transit of the following *commodities*, *Veterinary Authorities* should not require any BTV related conditions, regardless of the BTV status of the ruminant population of the *exporting country* or *zone*:

1. *milk* and *milk products*;
2. *meat* and *meat products*;
3. hides and skins;
4. wool and fiber;
5. *in vivo* derived bovine embryos and oocytes collected, processed and stored in conformity with the provisions of Chapter 4.7.

When authorising import or transit of other *commodities* listed in this Chapter, *Veterinary Authorities* should require the conditions prescribed in this Chapter relevant to the BTV status of the ruminant population of the *exporting country* or *zone*.

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Article 8.3.2.

**BTV free country or zone**

1. A country or a *zone* may be considered free from BTV when bluetongue is notifiable in the whole country and either:

   a) the country or *zone* lies wholly ~~north of 53°N or~~ north of 53°N or south of 34°S, and is not adjacent to a country or *zone* not having a free status; or

   b) a *surveillance* programme in accordance with Articles 8.3.16. to 8.3.21. has demonstrated no evidence of BTV in the country or *zone* during the past 2 years; or

   c) a *surveillance* programme has demonstrated no evidence of *Culicoides* likely to be competent BTV vectors in the country or *zone*.

2. A BTV free country or zone in which *surveillance* has found no evidence that *Culicoides* likely to be competent BTV vectors are present will not lose its free status through the importation of vaccinated, seropositive or infective animals, or semen or embryos/ova from infected countries or *infected zones*.

3. A BTV free country or zone in which *surveillance* has found evidence that *Culicoides* likely to be competent BTV vectors are present will not lose its free status through the importation of vaccinated or seropositive animals from infected countries or *infected zones*, provided:

   a) the animals have been vaccinated, at least 60 days prior to dispatch, in accordance with the *Terrestrial Manual* ~~at least 60 30 days prior to dispatch~~ with a vaccine which covers all serotypes whose presence in the source population has been demonstrated through a *surveillance* programme in accordance with Articles 8.3.16. to 8.3.21., and ~~that~~ the animals are identified in the accompanying certification as having been vaccinated; ~~where live attenuated vaccine has been used, vaccination has been carried out at least 60 days prior to shipment;~~ or

   b) the animals are not vaccinated, and a *surveillance* programme in accordance with Articles 8.3.16. to 8.3.21. has been in place in the source population for a period of at least 60 days immediately prior to dispatch, and no evidence of BTV transmission has been detected.

4. A BTV free country or zone adjacent to an infected country or *infected zone* should include a *zone* as described in Article 8.3.1. in which *surveillance* is conducted in accordance with Articles 8.3.16. to 8.3.21. Animals within this *zone* must be subjected to continuing *surveillance*. The boundaries of this *zone* must be clearly defined, and must take account of geographical and epidemiological factors that are relevant to BTV transmission.

Article 8.3.3.

**BTV seasonally free zone**

A BTV seasonally free zone is a part of an infected country or an *infected zone* for which for part of a year, *surveillance* demonstrates no evidence either of BTV transmission or of adult *Culicoides* likely to be competent BTV vectors.

For the application of Articles 8.3.6., 8.3.9. and 8.3.13., the seasonally free period is taken to commence the day following the last evidence of BTV transmission (as demonstrated by the *surveillance* programme), and of the cessation of activity of adult *Culicoides* likely to be competent BTV vectors.

For the application of Articles 8.3.6., 8.3.9. and 8.3.13., the seasonally free period is taken to conclude either:

1. at least 28 days before the earliest date that historical data show bluetongue virus activity has recommenced; or

2. immediately if current climatic data or data from a *surveillance* programme indicate an earlier resurgence of activity of adult *Culicoides* likely to be competent BTV vectors.

A BTV seasonally free zone in which *surveillance* has found no evidence that *Culicoides* likely to be competent BTV vectors are present will not lose its free status through the importation of vaccinated, seropositive or infective animals, or semen or embryos / ova from infected countries or *infected zones*.

Article 8.3.4.

**BTV infected country or zone**

A BTV infected country or *infected zone* is a clearly defined area where evidence of BTV has been reported during the past 2 years.

Article 8.3.5.

**Recommendations for importation from BTV free countries or zones**

for ruminants and other BTV susceptible herbivores

*Veterinary Authorities* should require the presentation of an *international veterinary certificate* attesting that:

1. the animals were kept in a BTV free country or *zone* since birth or for at least 60 days prior to shipment; or

2. the animals were kept in a BTV free country or *zone* for at least 28 days, then were subjected, with negative results, to a serological test to detect antibody to the BTV group according to the *Terrestrial Manual* and remained in the BTV free country or *zone* until shipment; or

3. the animals were kept in a BTV free country or *zone* for at least 7 days, then were subjected, with negative results, to an agent identification test according to the *Terrestrial Manual*, and remained in the BTV free country or *zone* until shipment; or

4. the animals:

   a) were kept in a BTV free country or *zone* for at least 7 days;

   b) were vaccinated, at least 60 days before the introduction into the free country or zone, in accordance with the *Terrestrial Manual* ~~60~~ at least 30 ~~days before the introduction into the free country or zone~~ against all serotypes whose presence in the source population has been demonstrated through a *surveillance* programme as described in Articles 8.3.16. to 8.3.21.; ~~where live attenuated vaccine has been used, vaccination has been carried out at least 60 days prior to shipment;~~

   c) were identified as having been vaccinated; and

   d) remained in the BTV free country or *zone* until shipment;

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AND

5. if the animals were exported from a free *zone*, either:

   a) did not transit through an *infected zone* during transportation to the *place of shipment*; or

   b) were protected from attack from *Culicoides* likely to be competent BTV vectors at all times when transiting through an *infected zone*; or

   c) had been vaccinated in accordance with point 4 above.

Article 8.3.6.

**Recommendations for importation from BTV seasonally free zones**

for ruminants and other BTV susceptible herbivores

*Veterinary Authorities* should require the presentation of an *international veterinary certificate* attesting that the animals:

1. were kept during the seasonally free period in a BTV seasonally free zone since birth or for at least 60 days prior to shipment; or

2. were kept during the BTV seasonally free period in a BTV seasonally free zone for at least 28 days prior to shipment, and were subjected during the residence period in the *zone* to a serological test to detect antibody to the BTV group according to the *Terrestrial Manual*, with negative results, carried out at least 28 days after the commencement of the residence period; or

3. were kept during the BTV seasonally free period in a BTV seasonally free zone for at least 14 days prior to shipment, and were subjected during the residence period in the *zone* to an agent identification test according to the *Terrestrial Manual*, with negative results, carried out at least 14 days after the commencement of the residence period; or

4. were kept during the seasonally free period in a BTV seasonally free zone, and were vaccinated, at least 60 days before the introduction into the free country or *zone*, in accordance with the *Terrestrial Manual* ~~60 at least 30 days before the introduction into the free country or zone~~ against all serotypes whose presence in the source population has been demonstrated through a *surveillance* programme in accordance with Articles 8.3.16. to 8.3.21. and were identified as having been vaccinated and remained in the BTV free country or zone until shipment; ~~where live attenuated vaccine has been used, vaccination has been carried out at least 60 days prior to shipment;~~

AND

5. if the animals were exported from a free zone, either:

   a) did not transit through an *infected zone* during transportation to the *place of shipment*; or

   b) were protected from attack from *Culicoides* likely to be competent BTV vectors at all times when transiting through an *infected zone*; or

   c) were vaccinated in accordance with point 4 above.

Article 8.3.7.

**Recommendations for importation from BTV infected countries or zones**

for ruminants and other BTV susceptible herbivores

*Veterinary Authorities* should require the presentation of an *international veterinary certificate* attesting that the animals:

1. were protected ~~in a *quarantine station* from attack~~ from attack from *Culicoides* likely to be competent BTV vectors ~~since birth or~~ in an insect proof *establishment* for at least 60 days prior to shipment and during transportation to the *place of shipment*; or

2. were protected ~~in a *quarantine station* from attack~~ from attack from *Culicoides* likely to be competent BTV vectors in an insect proof *establishment* for at least 28 days prior to shipment and during transportation to the *place of shipment*, and were subjected during that period to a serological test according to the *Terrestrial Manual* to detect antibody to the BTV group, with negative results, carried out at least 28 days after introduction into the *quarantine station*; or

3. were protected ~~in a *quarantine station* from attack~~ from attack from *Culicoides* likely to be competent BTV vectors in an insect proof *establishment* for at least 14 days prior to shipment and during transportation to the *place of shipment*, and were subjected during that period to an agent identification test according to the *Terrestrial Manual*, with negative results, carried out at least 14 days after introduction into the *quarantine station*; or

4. were vaccinated, at least 60 days before shipment, in accordance with the *Terrestrial Manual* ~~60 at least 30 days before shipment, and demonstrated to have antibodies~~ against all serotypes whose presence in the source population has been demonstrated through a *surveillance* programme in accordance with Articles 8.3.16. to 8.3.21., and were identified in the accompanying certification as having been vaccinated or, if demonstrated to have antibodies, have been protected from vectors for at least 60 days prior to shipment; ~~where live attenuated vaccine has been used, vaccination has been carried out at least 60 days prior to shipment;~~ or

5. are not vaccinated, a *surveillance* programme in accordance with Articles 8.3.16. to 8.3.21. has been in place in the source population for a period of at least 60 days immediately prior to shipment, and no evidence of BTV transmission has been detected and~~;~~

~~AND~~

~~6.~~ were protected from attack from *Culicoides* likely to be competent BTV vectors during transportation to the *place of shipment*.~~; or~~

~~7. were vaccinated in accordance with the *Terrestrial Manual* 60 days before shipment or had antibodies against all serotypes whose presence in the zones of transit has been demonstrated through a *surveillance* programme in accordance with Articles 8.3.16. to 8.3.21.~~

Article 8.3.8.

**Recommendations for importation from BTV free countries or zones**

for semen of ruminants and other BTV susceptible herbivores

*Veterinary Authorities* should require the presentation of an *international veterinary certificate* attesting that:

Annex I (contd)

1. the donor animals:

   a) were kept in a BTV free country or *zone* for at least 60 days before commencement of, and during, collection of the semen; or

   b) were subjected to a serological test according to the *Terrestrial Manual* to detect antibody to the BTV group, between 21 and 60 days after the last collection for this consignment, with negative results; or

   c) were subjected to an agent identification test according to the *Terrestrial Manual* on blood samples collected at commencement and conclusion of, and at least every 7 days (virus isolation test) or at least every 28 days (PCR test) during, semen collection for this consignment, with negative results;

2. the semen was collected, processed and stored in conformity with the provisions of Chapter 4.5.

Article 8.3.9.

**Recommendations for importation from BTV seasonally free zones**

for semen of ruminants and other BTV susceptible herbivores

*Veterinary Authorities* should require the presentation of an *international veterinary certificate* attesting that:

1. the donor animals:

   a) were kept during the BTV seasonally free period in a seasonally free zone for at least 60 days before commencement of, and during, collection of the semen; or

   b) were subjected to a serological test according to the *Terrestrial Manual* to detect antibody to the BTV group, with negative results, at least every 60 days throughout the collection period and between 21 and 60 days after the final collection for this consignment; or

   c) were subjected to an agent identification test according to the *Terrestrial Manual* on blood samples collected at commencement and conclusion of, and at least every 7 days (virus isolation test) or at least every 28 days (PCR test) during, semen collection for this consignment, with negative results;

2. the semen was collected, processed and stored in conformity with the provisions of Chapter 4.5.

Article 8.3.10.

**Recommendations for importation from BTV infected countries or zones**

for semen of ruminants and other BTV susceptible herbivores

*Veterinary Authorities* should require the presentation of an *international veterinary certificate* attesting that:

1. the donor animals:

   a) were protected from attack from *Culicoides* likely to be competent BTV vectors for at least 60 days before commencement of, and during, collection of the semen; or

b) were subjected to a serological test according to the *Terrestrial Manual* to detect antibody to the BTV group, with negative results, at least every 60 days throughout the collection period and between 21 and 60 days after the final collection for this consignment; or

c) were subjected to an agent identification test according to the *Terrestrial Manual* on blood samples collected at commencement and conclusion of, and at least every 7 days (virus isolation test) or at least every 28 days (PCR test) during, semen collection for this consignment, with negative results;

2. the semen was collected, processed and stored in conformity with the provisions of Chapter 4.5.

~~Article 8.3.11.~~

~~**Recommendations for the importation of *in vivo* derived bovine embryos/oocytes**~~

~~Regardless of the bluetongue status of the *exporting country*, *Veterinary Authorities* of *importing countries* should require the presentation of an *international veterinary certificate* attesting that the embryos/oocytes were collected, processed and stored in conformity with the provisions of Chapter 4.7.~~

Article 8.3.12.

**Recommendations for importation from BTV free countries or zones**

for *in vivo* derived embryos of ruminants (other than bovines) and other BTV susceptible herbivores and for *in vitro* produced bovine embryos

*Veterinary Authorities* should require the presentation of an *international veterinary certificate* attesting that:

1. the donor females:

   a) were kept in a BTV free country or *zone* for at least the 60 days prior to, and at the time of, collection of the embryos; or

   b) were subjected to a serological test according to the *Terrestrial Manual* to detect antibody to the BTV group, between 21 and 60 days after collection, with negative results; or

   c) were subjected to an agent identification test according to the *Terrestrial Manual* on a blood sample taken on the day of collection, with negative results;

2. the embryos were collected, processed and stored in conformity with the provisions of Chapter 4.7. , Chapter 4.8. or Chapter 4.9., as relevant.

Article 8.3.13.

**Recommendations for importation from BTV seasonally free zones**

for *in vivo* derived embryos/oocytes of ruminants (other than bovines) and other BTV susceptible herbivores and for *in vitro* produced bovine embryos

*Veterinary Authorities* should require the presentation of an *international veterinary certificate* attesting that:

1. the donor females:

Annex I (contd)

a) were kept during the seasonally free period in a seasonally free zone for at least 60 days before commencement of, and during, collection of the embryos/oocytes; or

b) were subjected to a serological test according to the *Terrestrial Manual* to detect antibody to the BTV group, between 21 and 60 days after collection, with negative results; or

c) were subjected to an agent identification test according to the *Terrestrial Manual* on a blood sample taken on the day of collection, with negative results;

2. the embryos/oocytes were collected, processed and stored in conformity with the provisions of Chapter 4.7., Chapter 4.8. or Chapter 4.9., as relevant.

Article 8.3.14.

**Recommendations for importation from BTV infected countries or zones**

for *in vivo* derived embryos/oocytes of ruminants (other than bovines) and other BTV susceptible herbivores and for *in vitro* produced bovine embryos

*Veterinary Authorities* should require the presentation of an *international veterinary certificate* attesting that:

1. the donor females:

a) were protected from attack from *Culicoides* likely to be competent BTV vectors for at least 60 days before commencement of, and during, collection of the embryos/oocytes; or

b) were subjected to a serological test according to the *Terrestrial Manual* to detect antibody to the BTV group, between 21 and 60 days after collection, with negative results; or

c) were subjected to an agent identification test according to the *Terrestrial Manual* on a blood sample taken on the day of collection, with negative results;

2. the embryos/oocytes were collected, processed and stored in conformity with the provisions of Chapter 4.7., Chapter 4.8. or Chapter 4.9., as relevant.

Article 8.3.15.

**Protecting animals from *Culicoides* attack**

When transporting animals through BTV infected countries or *infected zones*, *Veterinary Authorities* should require strategies to protect animals from attack from *Culicoides* likely to be competent BTV vectors during transport, taking into account the local ecology of the vector.

Potential *risk management* strategies include:

1. treating animals with ~~chemical~~ insect repellents prior to and during transportation;

2. *loading*, transporting and *unloading* animals at times of low vector activity (i.e. bright sunshine, low temperature);

3. ensuring *vehicles* do not stop en route during dawn or dusk, or overnight, unless the animals are held behind insect proof netting;

4. darkening the interior of the *vehicle*, for example by covering the roof and/or sides of *vehicles* with shadecloth;

5. *surveillance* for vectors at common stopping and offloading points to gain information on seasonal variations;

6. using historical, ongoing and/or BTV modelling information to identify low risk ports and transport routes.

Article 8.3.16.

**Surveillance: introduction**

Articles 8.3.16. to 8.3.21. define the principles and provide a guide on the *surveillance* for BT complementary to Chapter 1.4., applicable to Members seeking to determine their BT status. This may be for the entire country or *zone*. Guidance for Members seeking free status following an *outbreak* and for the maintenance of BT status is also provided.

BT is a vector-borne infection transmitted by different species of *Culicoides* insects in a range of ecosystems. An important component of BT epidemiology is vectorial capacity which provides a measure of *disease risk* that incorporates vector competence, abundance, biting rates, survival rates and extrinsic *incubation period*. However, methods and tools for measuring some of these vector factors remain to be developed, particularly in a field context. Therefore, *surveillance* for BT should focus on transmission in domestic ruminants.

Susceptible wild ruminant populations should be included in *surveillance* when these animals are intended for trade.

The impact and epidemiology of BT differ widely in different regions of the world and therefore it is impossible to provide specific recommendations for all situations. It is incumbent upon Members to provide scientific data that explain the epidemiology of BT in the region concerned and adapt the *surveillance* strategies for defining their infection status (free, seasonally free or infected country or *zone*) to the local conditions. There is considerable latitude available to Members to justify their infection status at an acceptable level of confidence.

*Surveillance* for BT should be in the form of a continuing programme.

Article 8.3.17.

**Surveillance: case definition**

For the purposes of *surveillance*, a *case* refers to an animal infected with BT virus (BTV).

For the purposes of *international trade*, a distinction must be made between a *case* as defined below and an animal that is potentially infectious to vectors. The conditions for trade are defined in Articles 8.3.1. to 8.3.15. of this ~~*Terrestrial Code*~~ Chapter.

The purpose of *surveillance* is the detection of virus circulation in a country or *zone* and not determination of the status of an individual animal or *herds*. *Surveillance* deals not only with the occurrence of clinical signs caused by BTV, but also with the evidence of *infection* with BTV in the absence of clinical signs.

The following defines the occurrence of BTV infection:

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1. BTV has been isolated and identified as such from an animal or a product derived from that animal, or

2. viral antigen or viral ribonucleic acid (RNA) specific to one or more of the serotypes of BTV has been identified in samples from one or more animals showing clinical signs consistent with BT, or epidemiologically linked to a confirmed or suspected *case*, or giving cause for suspicion of previous association or contact with BTV, or

3. antibodies to structural or nonstructural proteins of BTV that are not a consequence of vaccination have been identified in one or more animals that either show clinical signs consistent with BT, or epidemiologically linked to a confirmed or suspected *case*, or give cause for suspicion of previous association or contact with BTV

Article 8.3.18.

**Surveillance: general conditions and methods**

1. A *surveillance* system in accordance with Chapter 1.4. should be under the responsibility of the *Veterinary Authority*. In particular:

   a) a formal and ongoing system for detecting and investigating *outbreaks of disease* should be in place;

   b) a procedure should be in place for the rapid collection and transport of samples from suspect *cases* of BT to a *laboratory* for BT diagnosis as described in the *Terrestrial Manual*;

   c) a system for recording, managing and analysing diagnostic and *surveillance* data should be in place.

2. The BT *surveillance* programme should:

   a) in a country/*zone* free or seasonally free, include an early warning system for reporting suspicious *cases*. Farmers and workers, who have day-to-day contact with domestic ruminants, as well as diagnosticians, should report promptly any suspicion of BT to the *Veterinary Authority*. They should be supported directly or indirectly (e.g. through private *veterinarians* or *Veterinary para-professionals*) by government information programmes and the *Veterinary Authority*. An effective *surveillance* system will periodically identify suspicious *cases* that require follow-up and investigation to confirm or exclude that the cause of the condition is BTV. The rate at which such suspicious *cases* are likely to occur will differ between epidemiological situations and cannot therefore be predicted reliably. All suspected *cases* of BT should be investigated immediately and samples should be taken and submitted to an approved *laboratory*. This requires that sampling kits and other equipment are available for those responsible for *surveillance*;

   b) conduct random or targeted serological and virological *surveillance* appropriate to the infection status of the country or *zone.*

Generally, the conditions to prevent exposure of susceptible animals to BTV infected vectors will be difficult to apply. However, under specific situations, in establishments such as *artificial insemination centres* or *quarantine stations* exposure to vectors may be preventable. The testing requirements for animals kept in these facilities are described in Articles 8.3.10. and 8.3.14.

Article 8.3.19.

**Surveillance strategies**

The target population for *surveillance* aimed at identification of *disease* and/or *infection* should cover susceptible domestic ruminants within the country or *zone*. Active and passive *surveillance* for BTV infection should be ongoing. *Surveillance* should be composed of random or targeted approaches using virological, serological and clinical methods appropriate for the infection status of the country or *zone.*

The strategy employed may be based on *surveillance* using randomised sampling that would demonstrate the absence of BTV infection at an acceptable level of confidence. The frequency of sampling should be dependent on the epidemiological situation. Random *surveillance* is conducted using serological tests described in the *Terrestrial Manual*. Positive serological results may be followed up with virological methods as appropriate.

Targeted *surveillance* (e.g. based on the increased likelihood of *infection* in particular localities or species) may be an appropriate strategy. Virological and serological methods may be used concurrently to define the BTV status of targeted populations.

A Member should justify the *surveillance* strategy chosen as being adequate to detect the presence of BTV infection in accordance with Chapter 1.4. and the prevailing epidemiological situation. It may, for example, be appropriate to target clinical *surveillance* at particular species likely to exhibit clinical signs (e.g. sheep). Similarly, virological and serological testing may be targeted to species that rarely show clinical signs (e.g. cattle).

In vaccinated populations, serological and virological *surveillance* is necessary to detect the BTV types circulating to ensure that all circulating types are included in the vaccination programme.

If a Member wishes to declare freedom from BTV infection in a specific *zone*, the design of the *surveillance* strategy would need to be aimed at the population within the *zone.*

For random surveys, the design of the sampling strategy will need to incorporate epidemiologically appropriate design prevalence. The sample size selected for testing will need to be large enough to detect evidence of *infection* if it were to occur at a predetermined minimum rate. The sample size and expected prevalence determine the level of confidence in the results of the survey. The Member must justify the choice of design prevalence and confidence level based on the objectives of *surveillance* and the epidemiological situation, in accordance with Chapter 1.4. Selection of the design prevalence in particular needs to be based on the prevailing or historical epidemiological situation.

Irrespective of the survey approach selected, the sensitivity and specificity of the diagnostic tests employed are key factors in the design, sample size determination and interpretation of the results obtained. Ideally, the sensitivity and specificity of the tests used should be validated for the vaccination/*infection* history and the different species in the target population.

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Irrespective of the testing system employed, *surveillance* system design should anticipate the occurrence of false positive reactions. If the characteristics of the testing system are known, the rate at which these false positives are likely to occur can be calculated in advance. There needs to be an effective procedure for following up positives to ultimately determine with a high level of confidence, whether they are indicative of *infection* or not. This should involve both supplementary tests and follow-up investigation to collect diagnostic material from the original sampling unit as well as those which may be epidemiologically linked to it.

The principles involved in *surveillance* for *disease / infection* are technically well defined. The design of *surveillance* programmes to prove the absence of BTV *infection* / circulation needs to be carefully followed to avoid producing results that are either insufficiently reliable to be accepted by international trading partners, or excessively costly and logistically complicated. The design of any *surveillance* programme, therefore, inputs from professionals competent and experienced in this field.

1. Clinical surveillance

   Clinical *surveillance* aims at the detection of clinical signs of BT at the *flock / herd* level. Whereas significant emphasis is placed on the diagnostic value of mass serological screening, *surveillance* based on clinical inspection should not be underrated, particularly during a newly introduced *infection*. In sheep and occasionally goats, clinical signs may include oedema, hyperaemia of mucosal membranes, coronitis and cyanotic tongue.

   BT suspects detected by clinical *surveillance* should always be confirmed by *laboratory* testing.

2. Serological surveillance

   An active programme of *surveillance* of host populations to detect evidence of BTV transmission is essential to establish BTV status in a country or *zone*. Serological testing of ruminants is one of the most effective methods of detecting the presence of BTV. The species tested depends on the epidemiology of BTV infection, and the species available, in the local area. Cattle are usually the most sensitive indicator species. Management variables that may influence likelihood of *infection*, such as the use of insecticides and animal housing, should be considered.

   *Surveillance* may include serological surveys, for example *abattoir* surveys, the use of cattle as sentinel animals (which must be individually identifiable), or a combination of methods. *Surveillance* may also be conducted by sampling and testing of bulk milk using an ELISA, as prescribed in the *Manual*.

   The objective of serological *surveillance* is to detect evidence of BTV circulation. Samples should be examined for antibodies against BTV using tests prescribed in the *Terrestrial Manual*. Positive BTV antibody tests results can have four possible causes:

   a) natural *infection* with BTV,

   b) vaccination against BTV,

   c) maternal antibodies,

d) positive results due to the lack of specificity of the test.

It may be possible to use sera collected for other survey purposes for BTV *surveillance*. However, the principles of survey design described in these recommendations and the requirements for a statistically valid survey for the presence of BTV infection should not be compromised.

The results of random or targeted serological surveys are important in providing reliable evidence that no BTV infection is present in a country or *zone*. It is, therefore, essential that the survey is thoroughly documented. It is critical to interpret the results in light of the movement history of the animals being sampled.

Serological *surveillance* in a free *zone* should target those areas that are at highest risk of BTV transmission, based on the results of previous *surveillance* and other information. This will usually be towards the boundaries of the free *zone*. In view of the epidemiology of BTV infection, either random or targeted sampling is suitable to select *herds* and/or animals for testing.

A ~~*surveillance*~~ *protection zone* within a free country or *zone* should separate it from a potentially infected country or *infected zone*. Serological *surveillance* in a free country or *zone* should be carried out over an appropriate distance from the border with a potentially infected country or *infected zone*, based upon geography, climate, history of *infection* and other relevant factors.

Serological *surveillance* in *infected zones* will identify changes in the boundary of the zone, and can also be used to identify the BTV types circulating. In view of the epidemiology of BTV infection, either random or targeted sampling is suitable.

3. Virological surveillance

Isolation and genetic analysis of BTV from a proportion of infected animals is beneficial in terms of providing information on serotype and genetic characteristics of the viruses concerned.

Virological *surveillance* using tests described in the *Terrestrial Manual* can be conducted:

a) to identify virus circulation in at risk populations,

b) to confirm clinically suspect *cases*,

c) to follow up positive serological results,

d) to better characterize the genotype of circulating virus in a country or *zone*.

Annex I (contd)

4. Sentinel animals

Sentinel animals are a form of targeted *surveillance* with a prospective study design. They are the preferred strategy for BTV *surveillance*. They comprise groups of unexposed animals managed at fixed locations and sampled regularly to detect new BTV *infections*.

The primary purpose of a sentinel animal programme is to detect BTV infections occurring at a particular place, for instance sentinel groups may be located on the usual boundaries of *infected zones* to detect changes in distribution of BTV. In addition, sentinel animal programmes allow the timing and dynamics of *infections* to be observed.

A sentinel animal programme should use animals of known source and history of exposure, control management variables such as use of insecticides and animal housing (depending on the epidemiology of BTV in the area under consideration), and be flexible in its design in terms of sampling frequency and choice of tests.

Care is necessary in choosing the sites for the sentinel groups. The aim is to maximise the chance of detecting BTV activity at the geographical location for which the sentinel site acts as a sampling point. The effect of secondary factors that may influence events at each location, such as climate, may also be analysed. To avoid bias, sentinel groups should comprise animals selected to be of similar age and susceptibility to BTV infection. Cattle are the most appropriate sentinels but other domestic ruminant species may be used. The only feature distinguishing groups of sentinels should be their geographical location.

Sera from sentinel animal programmes should be stored methodically in a serum bank to allow retrospective studies to be conducted in the event of new serotypes being isolated.

The frequency of sampling will depend on the reason for choosing the sampling site. In endemic areas, virus isolation will allow monitoring of the serotypes and genotypes of BTV circulating during each time period. The borders between infected and non infected areas can be defined by serological detection of *infective period*. Monthly sampling intervals are frequently used. Sentinels in declared free *zones* add to confidence that BTV *infections* are not occurring unobserved. In such cases, sampling prior to and after the possible period of transmission is sufficient.

Definitive information on BTVs circulating in a country or *zone* is provided by isolation and identification of the viruses. If virus isolation is required, sentinels should be sampled at sufficiently frequent intervals to ensure that samples are collected during the period of viraemia.

5. Vector surveillance

BTV is transmitted between ruminant hosts by species of *Culicoides* which vary across the world. It is therefore important to be able to identify potential vector species accurately although many such species are closely related and difficult to differentiate with certainty.

The main purpose of vector *surveillance* is to define high, medium and low-risk areas and local details of seasonality by determining the various species present in an area, their respective seasonal occurrence, and abundance. Vector *surveillance* has particular relevance to potential areas of spread. Long term *surveillance* can also be used to assess vector suppression measures.

The most effective way of gathering this information should take account of the biology and behavioural characteristics of the local vector species of *Culicoides* and may include the use of Onderstepoort-type light traps or similar, operated from dusk to dawn in locations adjacent to domestic ruminants, or the use of drop traps over ruminant animals.

Vector *surveillance* should be based on scientific sampling techniques. The choice of the number and type of traps to be used in vector *surveillance* and the frequency of their use should take into account the size and ecological characteristics of the area to be surveyed.

The operation of vector *surveillance* sites at the same locations as sentinel animals is advisable.

The use of a vector *surveillance* system to detect the presence of circulating virus is not recommended as a routine procedure as the typically low vector infection rates mean that such detections can be rare. Other *surveillance* strategies (e.g. the use of sentinel animals of domestic ruminants) are preferred to detect virus circulation.

Article 8.3.20.

**Documentation of BTV infection free status**

1. Members declaring freedom from BTV infection for the country or zone: additional surveillance procedures

In addition to the general conditions described in the above-mentioned articles, a Member declaring freedom from BTV infection for the entire country or a *zone* should provide evidence for the existence of an effective *surveillance* programme. The strategy and design of the *surveillance* programme will depend on the prevailing epidemiological circumstances and should be planned and implemented according to general conditions and methods described in this Chapter, to demonstrate absence of BTV infection during the preceding 24 months in susceptible domestic ruminant populations. This requires the support of a *laboratory* able to undertake identification of BTV infection through virus detection and antibody tests described in the *Terrestrial Manual*. This *surveillance* should be targeted to non-vaccinated animals. Clinical *surveillance* may be effective in sheep while serological *surveillance* is more appropriate in cattle.

2. Additional requirements for countries or zones that practise vaccination

Vaccination to prevent the transmission of BTV may be part of a disease control programme. The level of *flock* or *herd* immunity required to prevent transmission will depend on the *flock* or *herd* size, composition (e.g. species) and density of the susceptible population. It is therefore impossible to be prescriptive. The vaccine must also comply with the provisions stipulated for BTV vaccines in the *Terrestrial Manual*. Based on the epidemiology of BTV *infection* in the country or *zone*, it may be that a decision is reached to vaccinate only certain species or other subpopulations.

Annex I (contd)

In countries or *zones* that practise vaccination, there is a need to perform virological and serological tests to ensure the absence of virus circulation. These tests should be performed on non-vaccinated subpopulations or on sentinels. The tests have to be repeated at appropriate intervals according to the purpose of the *surveillance* programme. For example, longer intervals may be adequate to confirm endemicity, while shorter intervals may allow on-going demonstration of absence of transmission.

Article 8.3.21.

**The use and interpretation of serological and virus detection tests**

1. Serological testing

Ruminants infected with BTV produce antibodies to structural and non-structural viral proteins, as do animals vaccinated with current modified live virus vaccines. Antibodies to the BTV serogroup antigen are detected with high sensitivity and specificity by competitive ELISA (c-ELISA) and to a lesser extent by AGID as described in the *Terrestrial Manual*. Positive c-ELISA results can be confirmed by neutralization assay to identify the infecting serotype(s); however, BTV infected ruminants can produce neutralizing antibodies to serotypes of BTV other than those to which they were exposed (false positive results), especially if they have been infected with multiple serotypes.

2. Virus detection

The presence of BTV in ruminant blood and tissues can be detected by virus isolation or polymerase chain reaction (PCR) as described in the *Terrestrial Manual*.

Interpretation of positive and negative results (both true and false) differs markedly between these tests because they detect different aspects of BTV *infection*, specifically (1) infectious BTV (virus isolation) and (2) nucleic acid (PCR). The following are especially relevant to interpretation of PCR assays:

a) The nested PCR assay detects BTV nucleic acid in ruminants long after the clearance of infectious virus. Thus positive PCR results do not necessarily coincide with active *infection* of ruminants. Furthermore, the nested PCR assay is especially prone to template contamination, thus there is considerable risk of false positive results.

b) PCR procedures other than real time PCR allow sequence analysis of viral amplicons from ruminant tissues, insect vectors or virus isolates. These sequence data are useful for creating data bases to facilitate important epidemiological studies, including the possible distinction of field and vaccine virus strains of BTV, genotype characterization of field strains of BTV, and potential genetic divergence of BTV relevant to vaccine and diagnostic testing strategies.

It is essential that BTV isolates are sent regularly to the OIE Reference Laboratories for genetic and antigenic characterization.

*Fig. 1. Application of laboratory tests in serological surveillance*

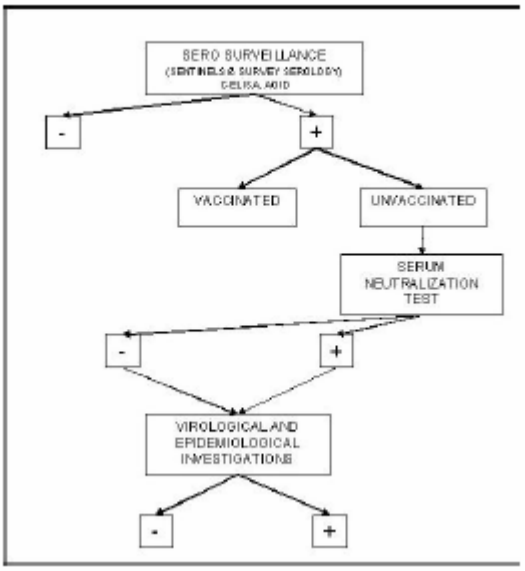
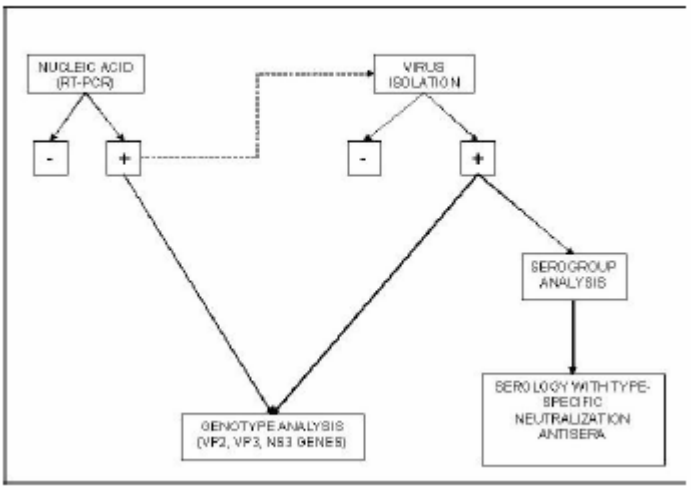



*Fig. 2. Application of laboratory tests in virological surveillance*

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