

# Office International des Épizooties international standards for bluetongue

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## Summary

Preventing the spread of disease through international trade is one of the primary objectives of the Office International des Épizooties (OIE), the World Organisation for Animal Health. This is accomplished by establishing international standards that facilitate trade while minimising the risk of introducing diseases such as bluetongue (BT). The OIE standards for BT are contained in the *Terrestrial animal health code (Code)* and the *Manual of diagnostic tests and vaccines for terrestrial animals (Manual)*. These standards include procedures for prompt reporting of BT outbreaks; requirements that should be met for a country or zone to be defined as free of bluetongue virus (BTV); recommendations for the safe importation of live animals, semen and embryos into a BTV-free country or zone; and the general provisions that countries should meet to reduce the risk of spread of BTV through trade. The *Manual* describes in detail the various tests for the diagnosis of BT. It provides a list of prescribed tests; these are the tests that are required by the *Code* for the testing of animals in connection with international trade.

There are 24 serotypes of BTV and infected countries have the right to restrict imports from countries that have different types of BTV. However, this should only be done if a surveillance and monitoring programme has confirmed that the other types are not present. Zoning for an arbovirus is difficult to apply but zoning for vectors is practicable. Some countries have demonstrated that there is no evidence of infection in their country or parts of their country even though there has been unrestricted animal movement between endemic zones and free zones. This freedom is due to the absence of vectors in the free zone. Based on this observation, free countries and zones can be established if an appropriate surveillance and monitoring programme is in place to define their boundaries. Consequently, there have been extensive changes in the *Code* to allow the establishment of BTV-free countries and zones and seasonally free countries and zones to provide the basis for safe trade, while minimising the risk of the introduction of BTV.

## Keywords

Bluetongue – International standards – Livestock – Office International des Épizooties – Trade.

Preventing the spread of disease through international trade is one of the primary objectives of the Office International des Épizooties (World Organisation for Animal Health). This is accomplished by establishing international standards that facilitate trade while minimising the risk of introducing diseases such as bluetongue (BT). The OIE was founded in 1924 as a result of an outbreak of rinderpest in Belgium. Initially, 24 countries signed a mandate to share information about disease outbreaks to allow them to take the appropriate action to prevent further spread of such diseases.

There are now 167 OIE member countries. Providing a mechanism for prompt reporting of disease outbreaks/occurrences is still one of the primary roles of the OIE.

In 1968 the OIE international committee, made up of the chief veterinary officers of the member countries, approved the first *International zoo-sanitary code* for the harmonisation of trade of animals and animal products (1). BT was one of the diseases for which standards were established. In 1995 the standards developed by the OIE were formalised as

international standards by the Agreement on the Application of Sanitary and Phytosanitary Measures (SPS Agreement) of the World Trade Organization (WTO) (4).

Developing BT standards that allow the safe trade of animals and animal products, has been very difficult as much of the world between latitudes of approximately 40°N and 35°S is infected or has the potential of being infected. These standards have taken on new importance as the infection has moved north and west in Europe. Another factor that has complicated the development and application of these standards is that there are 24 serotypes of BTV and many known and potential vectors of different competencies.

The OIE standards that have been and are being developed to promote safe trade in live animals, semen and embryos will be discussed.

### The World Trade Organization Sanitary and Phytosanitary Agreement

The OIE was identified by the WTO SPS Agreement as the competent international organisation for developing international standards, guidelines, and recommendations relating to animal diseases and zoonoses. In order to harmonise health measures, the Agreement states that governments should use these international standards, guidelines and recommendations. The goal of the Agreement is to remove unjustifiable sanitary (health) restrictions on international trade. The Agreement states that it is the sovereign right of a country to provide an appropriate level of animal health protection against pest or disease entry. However, this sovereign right is not to be misused for protectionist purposes and import sanitary measures can only be enforced if a similar level of protection against the disease is applied to all imports, and internally, by the importing country. Member countries can introduce standards providing a higher level of protection than provided by the OIE standards if there is a scientific justification but these national standards must be based on a risk analysis. With regard to a disease such as BT, a member country which is infected with one or several types of BTV has the right to adopt sanitary measures to prevent the entry of other types of BTV from which it is free. A monitoring and surveillance programme must be in place to demonstrate that the other types are not present.

### OIE standards for bluetongue

The OIE standards are contained in the *Terrestrial animal health code (Code)* (2) and the *Manual of diagnostic*

*tests and vaccines for terrestrial animals (Manual)* (3). The *Code* provides the chief veterinary officers of the OIE member countries with recommendations for establishing national or regional sanitary measures or rules applicable to the importation of animals and animal products. The *Manual* describes the diagnostic methods that are to be used and the methods for the production and control of biological products. The *Code* and *Manual* are developed by the OIE specialist commissions made up of experts elected by the OIE member countries. Proposed new or revised standards are submitted to the member countries for review and comment. These comments are included as appropriate in the proposed standards which are then submitted to the international committee of these member countries for approval. A revised version of the *Code* is published annually and a revised *Manual* is published every four years; the current edition of the *Manual* was published in 2004.

### Terrestrial animal health code on bluetongue

Chapter 2.1.9 of the *Code* outlines the requirements that should be met for a country or zone to be defined as free of BTV and the sanitary measures that should be applied when importing live animals, semen and embryos into a BTV-free country or zone. Prior to 1999, this chapter of the *Code* stated that BTV-susceptible species could only be imported from an infected country into a free country if they were negative for antibodies and were held in quarantine for 40 days. Requests from member countries to modify the bluetongue chapter of the *Code* resulted in the formation of an ad hoc group which developed a new chapter which was approved by the international committee in 1999. Refinements to the chapter have been approved each subsequent year. Some of the key components of the chapter as published in the 2003 version of the *Code* (2) are summarised here.

The first article of the chapter includes some general, very important information. It states that for the purposes of the *Code*, the infective period for BTV shall be 100 days. This article specifies that the BTV distribution historically has been between latitudes of approximately 40°N and 35°S. It also outlines the surveillance and monitoring requirements that are to supplement the general provisions of the *Code*, which will be described later. It states that, if a country or zone lies between 40°N and 35°S and does not have confirmed clinical BTV infection, it should establish a surveillance and monitoring programme to demonstrate its BTV status. This programme should be adjusted for local conditions such as historical, geographical and climatic factors, ruminant and *Culicoides* population data, or proximity to enzootic or incursional zones. Random and targeted

serological surveillance should provide at least a 95% level of confidence of detecting an annual seroconversion incidence of 2% in cattle (or other ruminant species if sufficient cattle are not available). It continues to state that countries or zones located outside this part of the world but adjacent to a country or zone not having free status should be subjected to similar surveillance; this surveillance should be carried out over a distance of at least 100 km from the border with that country or zone. An appendix to the *Code* is being drafted that will provide a more detailed standard for BTV surveillance and monitoring. The chapter defines a free country or zone as:

- 1) a country or zone that lies wholly north of 40°N or south of 35°S, and is not adjacent to a country or zone not having free status; or
- 2) a country or zone that has a surveillance and monitoring programme, as outlined above, which has demonstrated that there is no evidence of BTV in the country or zone during the past two years and there has been no vaccination against BT during the previous twelve months; or
- 3) a country or zone that has a surveillance and monitoring programme that demonstrated no evidence of *Culicoides*.

The chapter provides three approaches for moving live animals, based on the epidemiology of BT. It states that:

- 1) animals kept in a BTV-free country or zone or protected from *Culicoides* since birth or for at least the 100 days prior to shipment can move without further restriction into a free country or zone
- 2) animals that have been in a BTV-free country or zone or protected from *Culicoides* for 28 days should be tested for BTV antibody using the agar gel immunodiffusion (AGID) test or the enzyme-linked immunosorbent assay (ELISA) and, if negative, can be imported into a free country or zone
- 3) after 7 days in the free country or zone the animal can be tested for BTV nucleic acid using the polymerase chain reaction (PCR) or virus isolation and, if negative by one of these procedures, can be imported into a free country; in the case of import from infected countries or zones, the animals must be protected from *Culicoides* for the 14 days prior to shipment and subjected twice to such testing.

In addition, the chapter states that the importation of animals from an infected country or zone will not affect the status of a free country or zone in which surveillance and monitoring have found no evidence

of BTV vectors; this was a significant change that was added in the 1999 revision.

The 1999 revision of the chapter added an article describing a BTV seasonally free zone. This is an infected country or zone in which, for part of a year, surveillance and monitoring demonstrate no evidence either of BTV transmission or of adult *Culicoides*. The seasonally free status is applicable up to 28 days before the earliest date when historical data indicate that virus activity would recommence. Animals can be imported into a free country after 100 days in a seasonally free zone; however, in many countries or zones this is not feasible as they do not have a free period of 100 days and the *Code* states that animals in the seasonally free zone during the free period can be imported if they have had two negative AGID or ELISA tests seven days apart after 21 days of residence or two negative PCR tests seven days apart after 7 days of residence.

A BTV-infected country or zone is a country or zone that does not meet the requirements to be free or seasonally free. The 1999 revision provided more methods to import from an infected country or zone to a free country. It states that, if the animals were protected from *Culicoides* attack, they can be imported to a free country using about the same three approaches as outlined above for importing from a seasonally free zone.

Semen can be imported into a free country or zone using a similar approach. Semen from animals that have been in a free country for 100 days at the time of collection can be imported without further restriction. Semen from other animals can be imported into a free country after two negative AGID or ELISA tests on blood samples from donors taken 28 and 60 days after collection, or one negative PCR or virus isolation test on a blood sample taken at the time of collection.

In accordance with International Embryo Transfer Society (IETS) recommendations, *in vivo* derived bovine embryos are considered not to present a risk of BTV transmission. Embryos from other susceptible species should meet criteria similar to those for the importation of semen.

### **Terrestrial animal health code: general provisions**

The chapters in part 1 of the *Code*, general provisions provide the basic standards underpinning the disease specific chapters (2). Some of the more significant points included in these chapters are given below.

### Diseases in 'Lists A and B'

The OIE has designated 15 diseases, including BT, as being 'List A' diseases. List A diseases are transmissible diseases which have the potential for very serious and rapid spread, irrespective of national borders, and consequently are of major importance in the international trade of animals and animal products. There are also 67 List B diseases, which are considered to be less significant in international trade. A single list of diseases, replacing Lists A and B, will become operational in January 2005.

### Notification and epidemiological information

Member countries of the OIE are obliged to make available to other countries through the OIE whatever information is available that will help prevent the spread of important animal diseases. Member countries must report outbreaks of List A diseases, including BT, to the OIE within 24 hours if they were previously considered free. They also need to report a provisional diagnosis of BT if this represents important new information of epidemiological significance to other countries. Following the initial report, monthly reports need to be provided. The OIE forwards this information to member countries. Several countries have reported to the OIE every year that BT is endemic in cattle, sheep, goats, wildlife and camels; as they are not considered free, there is no requirement to report each new case within 24 hours. New notification requirements, based on the single list of diseases, will also become operational in January 2005.

### Evaluation of veterinary services

This chapter provides guidelines for the evaluation of veterinary services, which is an important element in the risk analysis process of an importing country. The results of this evaluation can help provide the importing country with the assurance that information on the animal health situation provided by the veterinary services of an exporting country is objective, meaningful and correct.

### Obligations and ethics in international trade

The obligations of the importing and exporting countries are described. As stated in the SPS Agreement, commodities imported should comply with the national level of protection that the importing country has established. The requirements applying to pathogens or diseases subject to official control programmes in a country or zone should not provide a higher level of protection on imports than that provided for the same pathogens or diseases within that country or zone. For most diseases, a country that has endemic infection and no programme to monitor and perhaps control the disease cannot apply import restrictions. However,

since there are 24 types of BTV that do not cross-protect, restrictions on exotic types can be justified. Before these restrictions are put in place, surveillance and monitoring programmes should be conducted to determine what types of BT are present in the country.

### Surveillance and monitoring of animal health

This chapter outlines the minimum requirements for a surveillance and monitoring programme that will substantiate elements of a report from a country on its animal health situation, and is the basis for a country to be able to claim a certain status for a disease. Information provided by the surveillance and monitoring programme of the exporting country is a key component of the application of OIE standards and of the risk analysis conducted by an importing country. As outlined above, obtaining freedom of BT requires documented evidence that an effective system of surveillance for BTV infection is in operation. The OIE is developing general guidelines on surveillance for diseases and a *Code* appendix on surveillance for BTV.

### Zoning and regionalisation

The procedure for designating a zone is provided. Zoning provides a country that has the disease in one portion of the country a method of establishing a disease-free zone in another portion of the country. The size, location and delineation of a zone will depend on the epidemiology of the disease, environmental factors, the surveillance conducted and applicable control measures. The extent of zones and their limits should be established by the veterinary administration on the basis of natural, artificial, or legal boundaries and made public through official channels. The chapter encourages importing countries to recognise the zones that an exporting country develops. Several countries have succeeded in defining a BTV-free zone from which animals can be exported with fewer restrictions.

### Import risk analysis

Detailed procedures for conducting an import risk analysis are provided. The components of risk analysis are: hazard identification, BTV in this case; risk assessment, which is the evaluation of the likelihood and consequences of entry, establishment, and spread of BTV and includes release assessment, exposure assessment, consequence assessment, and risk estimation; risk management, which describes the determination of the measures necessary to reduce the level of risk to a level acceptable for the importing country; and risk communication, which is the exchange of information with stakeholders during the risk analysis.

### ***Manual of diagnostic tests and vaccines for terrestrial animals***

The *Manual* is a companion volume to the *Code* and provides a uniform approach to the diagnosis of BT. The purpose is to facilitate international trade in animals and animal products by describing internationally agreed laboratory methods for diagnosis and requirements for the production and control of BT vaccines. The methods described also form the basis for effective BTV surveillance and monitoring. The *Manual* describes in detail the various tests for the diagnosis of BT. It provides a list of prescribed tests; these are the tests that are required by the *Code* for the testing of animals in connection with international trade. The 2004 edition of the *Manual* specifies that agent identification, AGID, ELISA and PCR tests are the prescribed tests and these tests are described in detail. The agent identification procedures described are intravenous inoculation of embryonating chicken eggs and sheep inoculation. The *Manual* states that isolation can be attempted in cell culture but the success rate is often much lower than in eggs or sheep. These procedures require 3 to 5 weeks; consequently, they are usually not practical to meet the import requirements outlined above. The 1999 changes in the *Code* allowed the use of PCR to qualify animals for importation. The following is a quote from the *Manual* concerning the use of PCR for BTV. 'Primer-directed amplification of viral nucleic acid has revolutionised BT diagnosis. Results to date indicate that polymerase chain reaction techniques may be used, not only to detect the presence of viral nucleic acid, but also to 'serogroup' orbiviruses and provide information on the serotype and possible geographical source (topotype or genotype) of BTV isolates within a few days of receipt of a clinical sample such as infected sheep blood.' It goes on to provide complete details for conducting the test, including the suggested primers for a conserved region of the gene.

The AGID and ELISA are prescribed serological tests for BTV and are described in detail in the *Manual*. Both tests are group-specific and can detect all types of BTV with one test. The AGID was described about 30 years ago but is still used by many countries. The lack of specificity of this test is a limitation as it can detect antibodies to other orbiviruses, particularly those in the epizootic haemorrhagic disease (EHD) serogroup; however, the sensitivity is adequate. A competitive or blocking ELISA (c-ELISA) procedure is described. The monoclonal antibodies that can be used for this test have been derived in a number of laboratories, and appear to bind to the major core protein VP7. In the c-ELISA, antibodies in test sera compete with the

monoclonal antibody for binding to antigen. The c-ELISA has been standardised after comparative studies in a number of international laboratories. Advantages of the ELISA over AGID are its adaptability to automation and less subjectivity exercised in reading the results. Virus neutralisation is designated as an alternative test. An alternative test is one that is suitable for the diagnosis of disease within a local setting, and can also be used in the import/export of animals after bilateral agreement. The virus neutralisation test is specific for each type of virus; consequently each virus type must be included in the test. This makes the test difficult and usually impractical for use as an export test.

### **Discussion and conclusions**

The 2003 edition of the BT chapter of the *Code* and the 2004 edition of the *Manual* have attempted to address the need to establish methods for safe importation from BTV-infected, seasonally free, as well as free countries or zones. These changes take into account the fact that much of the world is infected or potentially infected with some of the 24 serotypes of BTV and should not be restricted unnecessarily from trading BTV-susceptible animals. Another issue that is addressed in the revised *Code* is the need for surveillance to determine the distribution of BTV. BTV often does not produce clinical disease in many susceptible animals; consequently, surveillance must be conducted to determine the extent of the distribution of the virus in the potentially infected countries or zones. The continuing spread of the virus north and west in Europe will require increased surveillance in the region. BTV surveillance and monitoring procedures are described in the *Code* and will be expanded upon in the new chapter that is being developed as an appendix to the *Code*. Zoning for an arbovirus is difficult to apply but zoning for vectors is practicable. Two countries (Australia and the United States of America) have demonstrated that there is no evidence of infection in part of their countries due to the absence of vectors in the free zone even though there has been unrestricted animal movement between the endemic and free zones. Based on this observation, free zones can be established if an appropriate surveillance and monitoring programme is in place to define their boundaries.

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