Annex XXIX

CHAPTER 11.7.

# BOVINE TUBERCULOSIS

# **EU** position

The EU could support the adoption of the modified chapter, but the current wording "tuberculin tests or gamma interferon tests" is not acceptable.

The EU would not accept the free status of herds or countries or zones, or importation of bovine animals based only on the gamma interferon test (as made possible by the current wording proposal), as there is not sufficient scientific and field information to prove that they give the equivalent level of guarantees. In addition, as a matter of principle, all tests should be referred to in the Manual and not in the Code.

Thus, the words "tuberculin tests or gamma interferon tests" should be replaced by "tests used in accordance with the *Terrestrial Manual*".

Moreover, in general, the Manual should only recommend "prescribed" tests, and the Code should always refer to these tests. The meaning of "alternative" is not clear: either the test is reliable for trade and then should be prescribed, or it is not, and then it should be clearly and expressly restricted for other purposes.

Article 11.7.1.

## **General provisions**

The recommendations in this chapter are intended to manage the human and animal health risks associated with *Mycobacterium bovis* (*M. bovis*) infection in domestic (permanently captive and owned freerange) bovines including cattle (*Bos taurus*, *B. indicus* and *B. grunniens*), water buffaloes (*Bubalus bubalis*) and wood bison<sup>s</sup> (*Bison bison* and *B. bonasus*).

Standards for diagnostic tests are described in the Terrestrial Manual.

Article 11.7.2.

#### Country or zone free from bovine tuberculosis

To qualify as free from bovine tuberculosis, a country or *zone* should satisfy the following requirements:

- 1. *M. bovis* infection in domestic (permanently captive and owned free-range) bovines including cattle, water buffalo and wood bison is a *notifiable disease* in the country;
- 2. an on-going awareness programme should be in place to encourage reporting of all cases suggestive of bovine tuberculosis;
- 3. regular and periodic testing of all cattle, water buffalo, and wood bison *herds* demonstrated that *M. bovis* infection was not present in at least 99.8% of the *herds* and 99.9% of the cattle, water buffalo and wood bison in the country or *zone* for 3 consecutive years;
- 4. a *surveillance* programme should be in place to detect bovine tuberculosis in the country or *zone* through ante-mortem and post-mortem inspection as described in Chapter 6.2.;

- 5. if the *surveillance* programme described in points 3 and 4 above has not detected infection with demonstrated that *M. bovis* infection was not present in at least 99.8% of the *berds* and 99.9% of the <u>cattle</u>, water buffalo and wood bison in the country or <u>zone</u> for 5 consecutive years, *surveillance* may be maintained through ante-mortem and post-mortem inspection as described in Chapter 6.2.;
- 6. cattle, water buffalo and wood bison introduced into a country or *zone* free from bovine tuberculosis should be accompanied by a certificate from an *Official Veterinarian* attesting that they come from a country, *zone, compartment* or *herd* free from bovine tuberculosis or comply with the relevant provisions in Article 11.7.5. or in Article 11.7.6.

### Article 11.7.3.

## Compartment free from bovine tuberculosis

To qualify as a *compartment* free from bovine tuberculosis, <u>all</u> cattle, water buffalo or wood bison in a *compartment* should be certified by the *Veterinary Authority* as satisfying the following requirements:

- 1. <u>the</u> cattle, water buffalo and wood bison:
  - a) showed no sign of bovine tuberculosis or lesions at ante-mortem or post-mortem inspection for at least 3 consecutive years;
  - b) were over 6 weeks of age at the time of the first test and have shown a negative result to at least two tuberculin tests or gamma interferon tests carried out at an interval of a minimum of 6 months, the first test being performed at least 6 months following the *slaughter* of the last affected animal;
  - c) met one of the following conditions:
    - i) showed a negative result to a biannual <u>twice yearly</u> tuberculin test or <u>gamma interferon test</u> to ensure the continuing absence of bovine tuberculosis if the annual percentage of *herds* confirmed as infected with tuberculosis is more than 1% of all *herds* in the country or *zone* during the last 2 years; or
    - ii) showed a negative result to an annual tuberculin test or gamma interferon test to ensure the continuing absence of bovine tuberculosis if the annual percentage of *herds* confirmed as infected with tuberculosis is more than 0.2% but not more than 1% of all *herds* in the country or *zone* during the last 2 years; or
    - iii) showed a negative result to a tuberculin test or gamma interferon test every 3 years to ensure the continuing absence of bovine tuberculosis if the annual percentage of *herds* confirmed as infected with tuberculosis is not more than 0.2% of all *herds* in the country or *zone* during the last 4 years; or
    - iv) showed a negative result to a tuberculin test <u>or gamma interferon test</u> every 4 years to ensure the continuing absence of bovine tuberculosis if the annual percentage of *herds* confirmed as infected with tuberculosis is not more than 0.1% of all *herds* in the country or *zone* during the last 6 years;
- 2. cattle, water buffalo and wood bison introduced into the *compartment* come from a *herd* free from bovine tuberculosis. This condition may be waived for animals which have been isolated for at least 90 days and which, prior to entry into the *compartment*, were subjected to at least two tuberculin tests or gamma interferon tests carried out at a 6-month interval with negative results with the second tuberculin test or gamma interferon test performed during the 30 days prior to entry into the *compartment*;
- 3. cattle, water buffalo and wood bison in a *compartment* free from bovine tuberculosis are protected from

contact with wildlife reservoirs of bovine tuberculosis and are managed under a common biosecurity plan protecting them from contamination with *M. bovis*, and the *compartment* has been approved by the *Veterinary Authority* in accordance with Chapters 4.3. and 4.4.

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Article 11.7.4.
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## Herd free from bovine tuberculosis

To qualify as free from bovine tuberculosis, a *herd* of cattle, water buffalo, or wood bisons should satisfy the following requirements:

- 1. the *herd* is in a country, *zone* or *compartment* free from bovine tuberculosis and is certified free by the *Veterinary Authority*; or
- 2. cattle, water buffalo and wood bison in the *herd*:
  - a) showed no signs of bovine tuberculosis or lesions at ante-mortem or post-mortem inspection for at least <del>3 consecutive</del> <u>one</u> years;
  - b) were over 6 weeks of age at the time of the first test and have shown a negative result to at least two tuberculin tests or gamma interferon tests carried out at an interval of a minimum interval of 6 months; in case of regaining of free status after an *outbreak*, the first test being should be performed at least 6 months following the *slaughter* of the last affected animal;
  - c) <u>to maintain the free status</u>, met one of the following conditions:
    - i) showed a negative result to an annual tuberculin test <u>or gamma interferon test</u> to ensure the continuing absence of bovine tuberculosis; or
    - ii) showed a negative result to a tuberculin test <u>or gamma interferon test</u> every 2 years to ensure the continuing absence of bovine tuberculosis if the annual percentage of *herds* confirmed as infected with tuberculosis is not more than 1% of all *herds* in the country or *zone* during the last 2 years; or
    - iii) showed a negative result to a tuberculin test <u>or gamma interferon test</u> every 3 years to ensure the continuing absence of bovine tuberculosis if the annual percentage of *herds* confirmed as infected with tuberculosis is not more than 0.2% of all *herds* in the country or *zone* during the last 4 years; or
    - iv) showed a negative result to a tuberculin test <u>or gamma interferon test</u> every 4 years to ensure the continuing absence of bovine tuberculosis if the annual percentage of *herds* confirmed as infected with tuberculosis is not more than 0.1% of all *herds* in the country or *zone* during the last 6 years;
- 3. cattle, water buffalo and wood bison introduced into the *herd* come from a *herd* free from bovine tuberculosis. This condition may be waived for animals which have been isolated for at least 90 days and which, prior to entry into the *herd*, were subjected to at least two tuberculin tests or gamma interferon tests carried out at a 6-month interval with negative results with the second tuberculin test or gamma interferon test performed during the 30 days prior to entry into the *herd*.

## Article 11.7.5.

# Recommendations for the importation of cattle, water buffalo and wood bison for breeding or rearing

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

- 1. showed no signs of bovine tuberculosis on the day of shipment;
- 2. originate from a *herd* free from bovine tuberculosis that is in a country, *zone* or *compartment* free from bovine tuberculosis; or
- 3. were subjected to the tuberculin test <u>or gamma interferon test</u> for bovine tuberculosis with negative results during the 30 days prior to shipment and come from a *herd* free from bovine tuberculosis; or
- 4. have been isolated for at least 90 days prior to entry into the *herd*, including protection from contact with wildlife reservoirs of bovine tuberculosis and were subjected to at least two tuberculin tests or gamma interferon tests carried out at a six-month interval with negative results with the second tuberculin test or gamma interferon test performed during the 30 days prior to entry into the *herd*.

### Article 11.7.6.

## Recommendations for the importation of cattle, water buffalo and wood bison for slaughter

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

- 1. showed no signs of bovine tuberculosis on the day of shipment;
- originated from a *herd* free from bovine tuberculosis or were subjected to a tuberculin test or <u>gamma</u> <u>interferon test</u> for bovine tuberculosis with negative results during the 30 days prior to shipment;
- 3. were not being eliminated as part of an eradication programme against bovine tuberculosis.

## Article 11.7.7.

## Recommendations for the importation of semen of cattle, water buffalo and wood bison

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

- 1. the donor animals showed no signs of bovine tuberculosis on the day of collection of the semen and either:
  - a) were kept in an *artificial insemination centre* free from bovine tuberculosis in a country, *zone* or *compartment* free from bovine tuberculosis and which only accepts animals from free *herds* in a free country, *zone* or *compartment*; or
  - b) showed negative results to tuberculin tests <u>or gamma interferon tests</u> carried out annually and were kept in a *herd* free from bovine tuberculosis;
- 2. the semen was collected, processed and stored in conformity with the provisions of Chapter 4.5. and Chapter 4.6.

#### Article 11.7.8.

## Recommendations for the importation of embryos/ova of cattle, water buffalo and wood bison

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

1. the donor females and all other susceptible animals in the *herd* of origin showed no signs of bovine tuberculosis during the 24 hours prior to embryo collection; and either

- a) originated from a *herd* free from bovine tuberculosis in a country, *zone* or *compartment* free from bovine tuberculosis; or
- b) were kept in a *herd* free from bovine tuberculosis, and were subjected to a tuberculin test or gamma interferon test for bovine tuberculosis with negative results during an isolation period of 30 days in the *establishment* of origin prior to collection;
- 2. the embryos/ova were collected, processed and stored in conformity with the provisions of Chapters 4.7., 4.8. and 4.9., as relevant.

#### Article 11.7.9.

# Recommendations for the importation of fresh meat and meat products of cattle, water buffalo, and wood bison

Veterinary Authorities of importing countries should require the presentation of an international veterinary certificate attesting that the entire consignment of *meat* comes from animals which have been subjected to antemortem and post-mortem inspections as described in Chapter 6.2.

#### Article 11.7.10.

# Recommendations for the importation of milk and milk products of cattle, water buffalo and wood bison

Veterinary Authorities of importing countries should require the presentation of an international veterinary certificate attesting that the consignment:

- 1. has been derived from animals in a *herd* free from bovine tuberculosis; or
- 2. was subjected to pasteurization; or
- 3. was subjected to a combination of control measures with equivalent performance as described in the Codex Alimentarius Code of Hygienic Practice for Milk and Milk Products.

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# CHAPTER 11.8.

# BOVINE TUBERCULOSIS OF FARMED CERVIDAE

## **EU** position

# The EU supports the adoption of the modified chapter.

Article 11.8.1.

## **General provisions**

The recommendations in this chapter are intended to manage the human and animal health risks associated with *Mycobacterium bovis* (*M. bovis*) infection in domestic (permanently captive and owned freerange) farmed cervidae (red deer, wapiti, sika, samba, rusa, fallow deer, white-tailed, black-tailed and mule deer [*Cervus elephus, C. canadensis, C. nippon, C. unicolor unicolor, C. timorensis, Dama dama dama, Odocoileus virginianus borealis, Odocoileus hemionus columbianus* and *Odocoileus hemionus*]). The chapter does not address the management of tuberculosis in wild cervid populations.

Standards for diagnostic tests are described in the Terrestrial Manual.

Article 11.8.2.

## Country or zone free from bovine tuberculosis of farmed cervidae

To qualify as free from bovine tuberculosis of farmed cervidae, a country or *zone* should satisfy the following requirements:

- 1. *M. bovis* infection in domestic bovines and in farmed cervidae as specified in Article 11.8.1. is a *notifiable disease* in the country;
- 2. an on-going awareness programme should be in place to encourage reporting of all *cases* suggestive of tuberculosis;
- 3. regular and periodic testing of all *herds* of farmed cervidae has demonstrated that *M. bovis* infection was not present in at least 99.8% of the *herds* and 99.9% of the farmed cervidae in the country or *zone* for 3 consecutive years;
- 4. a *surveillance* programme should be in place to detect bovine tuberculosis in the country or *zone* through ante-mortem and post-mortem inspection as described in Chapter 6.2.;
- 5. if the *surveillance* programme described in points 3 and 4 above has not detected infection with demonstrated that *M. bovis* infection was not present in at least 99.8% of the *herds* and 99.9% of the <u>farmed cervidae</u> in the country or <u>zone</u> for 5 consecutive years, *surveillance* may be maintained through ante-mortem and post-mortem inspection as described in Chapter 6.2.;
- 6. farmed cervidae introduced into a country or *zone* free from bovine tuberculosis should be accompanied by a certificate from an *Official Veterinarian* attesting that they come from a country, *zone*, *compartment* or *herd* free from bovine tuberculosis or comply with the relevant provisions in Article 11.8.5. or in Article 11.8.6.

#### Article 11.8.3.

#### Compartment free from bovine tuberculosis of farmed cervidae

To qualify as a *compartment* free from bovine tuberculosis of farmed cervidae, the *Veterinary Authority* should be able to certify that the following requirements are satisfied:

- 1. all farmed cervidae:
  - a) showed no sign of bovine tuberculosis or lesions at ante-mortem or post-mortem inspection for at least 3 consecutive years;
  - b) were over 6 weeks of age at the time of the first test and have shown a negative result to at least two tuberculin tests carried out at an interval of a minimum of 6 months, the first test being performed at least 6 months following the *slaughter* of the last affected animal;
  - c) met one of the following conditions:
    - i) showed a negative result to a biannual <u>twice yearly</u> tuberculin test to ensure the continuing absence of bovine tuberculosis if the annual percentage of *herds* confirmed as infected with tuberculosis is more than 1% of all *herds* in the country or *zone* during the last 2 years; or
    - ii) showed a negative result to an annual tuberculin test to ensure the continuing absence of bovine tuberculosis if the annual percentage of *herds* confirmed as infected with tuberculosis is more than 0.2% but not more than 1% of all *herds* in the country or *zone* during the last 2 years; or
    - iii) showed a negative result to a tuberculin test every 3 years to ensure the continuing absence of bovine tuberculosis if the annual percentage of *herds* confirmed as infected with tuberculosis is not more than 0.2% of all *herds* in the country or *zone* during the last 4 years; or
    - iv) showed a negative result to a tuberculin test every 4 years to ensure the continuing absence of bovine tuberculosis if the annual percentage of *herds* confirmed as infected with tuberculosis is not more than 0.1% of all *herds* in the country or *zone* during the last 6 years;
- 2. farmed cervidae introduced into the *compartment* come from a *herd* free from bovine tuberculosis. This condition may be waived for animals which have been isolated for at least 90 days and which, prior to entry into the *compartment*, were subjected to at least two tuberculin tests carried out at a 6-month interval with negative results with the second tuberculin test performed during the 30 days prior to entry into the *compartment*;
- 3. farmed cervidae in a *compartment* free from bovine tuberculosis are protected from contact with wildlife reservoirs of bovine tuberculosis and are managed under a common biosecurity plan protecting them from contamination with *M. bovis*, and the *compartment* has been approved by the *Veterinary Authority* in accordance with Chapters 4.3. and 4.4.

Article 11.8.4.

#### Herd free from bovine tuberculosis

To qualify as free from bovine tuberculosis, a *herd* of farmed cervidae should satisfy the following requirements:

- 1. the *herd* is in a country, a *zone* or a *compartment* free from bovine tuberculosis and is certified free by the *Veterinary Authority*; or
- 2. farmed cervidae in the *herd*:
  - a) showed no sign of bovine tuberculosis or lesions at ante-mortem or post-mortem inspection for at least 3 consecutive years;
  - b) were over 6 weeks of age at the time of the first test and have shown a negative result to at least two tuberculin tests carried out at an interval of a minimum interval of 6 months, in case of regaining of free status after an *outbreak*, the first test being should be performed at least 6 months following the *slaughter* of the last affected animal;
  - c) <u>to maintain the free status</u>, met one of the following conditions:
    - i) showed a negative result to an annual tuberculin test to ensure the continuing absence of bovine tuberculosis; or
    - ii) showed a negative result to a tuberculin test every 2 years to ensure the continuing absence of bovine tuberculosis if the annual percentage of *herds* confirmed as infected with tuberculosis is not more than 1% of all *herds* in the country or *zone* during the last 2 years; or
    - iii) showed a negative result to a tuberculin test every 3 years to ensure the continuing absence of bovine tuberculosis if the annual percentage of *herds* confirmed as infected with tuberculosis is not more than 0.2% of all *herds* in the country or *zone* during the last 4 years; or
    - iv) showed a negative result to a tuberculin test every 4 years to ensure the continuing absence of bovine tuberculosis if the annual percentage of *herds* confirmed as infected with tuberculosis is not more than 0.1% of all *herds* in the country or *zone* during the last 6 years;
- 3. farmed cervidae introduced into the *herd* come from a *herd* free from bovine tuberculosis. This condition may be waived for animals which have been isolated for at least 90 days and which, prior to entry into the *herd*, were subjected to at least two tuberculin tests carried out at a 6-month interval with negative results with the second tuberculin test performed during the 30 days prior to entry into the *herd*.

# Article 11.8.5.

## Recommendations for the importation of farmed cervidae for breeding or rearing

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

- 1. showed no signs of bovine tuberculosis on the day of shipment;
- 2. originate from a *herd* free from bovine tuberculosis of farmed cervidae that is in a country, *zone* or *compartment* free from bovine tuberculosis of farmed cervidae; or
- 3. were subjected to the tuberculin test for bovine tuberculosis with negative results during the 30 days prior to shipment and come from a *herd* free from bovine tuberculosis of farmed cervidae; or
- 4. have been isolated for at least 90 days prior to entry into the *herd*, including protection from contact with wildlife reservoirs of bovine tuberculosis and were subjected to at least two tuberculin tests carried out at a six-month interval with negative results with the second tuberculin test performed during the 30 days prior to entry into the *herd*.

#### Article 11.8.6.

### Recommendations for the importation of farmed cervidae for slaughter

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

- 1. showed no signs of bovine tuberculosis on the day of shipment;
- 2. originated from a *herd* free from bovine tuberculosis of farmed cervidae or were subjected to a tuberculin test for bovine tuberculosis with negative results during the 30 days prior to shipment;
- 3. were not being eliminated as part of an eradication programme against bovine tuberculosis.

Article 11.8.7.

## Recommendations for the importation of semen of farmed cervidae

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

- 1. the donor animals showed no signs of bovine tuberculosis on the day of collection of the semen; and either:
  - a) were kept in a *herd* free from bovine tuberculosis in any species, in a country, *zone* or *compartment* free from bovine tuberculosis of farmed cervidae, and which only accepts animals from free *herds* in a free country, *zone* or *compartment*; or
  - b) showed negative results to tuberculin tests carried out annually and were kept in a *herd* free from bovine tuberculosis;
- 2. the semen was collected, processed and stored in conformity with the provisions of Chapter 4.5. and Chapter 4.6.

#### Article 11.8.8.

#### Recommendations for the importation of embryos/ova of farmed cervidae

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

- 1. the donor females and all other susceptible animals in the *herd* of origin showed no signs of bovine tuberculosis during the 24 hours prior to embryo collection; and either
  - a) originated from a *herd* free from bovine tuberculosis of farmed cervidae in a country, *zone* or *compartment* free from bovine tuberculosis; or
  - b) were kept in a *herd* free from bovine tuberculosis of farmed cervidae and were subjected to a tuberculin test for bovine tuberculosis with negative results during an isolation period of 30 days in the *establishment* of origin prior to collection;
- 2. the embryos/ova were collected, processed and stored in conformity with the provisions of Chapters 4.7., 4.8. and 4.9., as relevant.

## Article 11.8.9.

## Recommendations for the importation of fresh meat and meat products of farmed cervidae

Veterinary Authorities of importing countries should require the presentation of an international veterinary certificate attesting that the entire consignment of meat comes from animals which have been subjected to ante-mortem and post-mortem inspections as described in Chapter 6.2.

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