

CHAPTER 11.3.

USA COMMENTSINFECTION WITH *BRUCELLA ABORTUS*,
MELITENSIS AND *SUIS*

General Comment: Combining all *Brucella* organisms into one chapter creates confusion in regards to the appropriate conduct of some activities as relevant to a particular species. For example, herd or flock testing intervals are noted as all encompassing test interval ranges used for any and all species. The broad interval range is not necessarily appropriate for each species. For example, the text which reads “an interval of more than 6 and less than 12 months between each test” leads one to believe that a 6 month interval between tests for bovine would be appropriate which essentially means both tests could be completed in 12 months. This is not consistent with the eradication program activities of many countries. Should this new organizational format be used, it is our recommendation that species specific testing interval requirements be clearly noted.

Article 11.3.1.

General provisions

The aim of this chapter is to mitigate the risk of spread of, and the risk to human health from, *B. abortus*, *B. melitensis* and *B. suis* in *animals*.

For the purpose of this chapter, ‘*Brucella*’ means *B. abortus*, *B. melitensis* or *B. suis*.

For the purpose of this chapter, ‘*animals*’ means domestic and *captive wild* animal populations of the following categories:

1. Bovidae means cattle (*Bos taurus*, *B. indicus*, *B. frontalis* and *B. javanicus*), yak (*B. grunniens*), bison (*Bison bison* and *B. bonasus*) and water buffalo (*Bubalus bubalis*).
2. Ovidae and Capridae mean sheep (*Ovis aries*) and goats (*Capra aegagrus*).
3. Pigs means domestic pigs and ~~wild boars~~ feral swine (*Sus scrofa*).

Rationale: Brucellosis may be spread by both male and female swine.

4. *Camelidae* means dromedary (*Camelus dromedarius*), Bactrian camel (*Camelus bactrianus*), llama (*Lama glama*), alpaca (*Lama pacos*), guanaco (*Lama guanicoe*) and vicuna (*Vicugna vicugna*).
5. *Cervidae* means red deer, wapiti (elk), sika, samba, rusa, fallow deer, white-tailed, black-tailed, mule deer and reindeer (*Cervus elaphus*, *C. canadensis*, *C. nippon*, *C. unicolor unicolor*, *C. timorensis*, *Dama dama dama*, *Odocoileus virginianus borealis*, *Odocoileus hemionus columbianus*, *Odocoileus hemionus hemionus* and *Rangifer tarandus*).

Rationale: For clarity since wapiti are more commonly referred to as elk in North America.

6. European hare (*Lepus europaeus*).

The chapter deals not only with the occurrence of clinical signs caused by *Brucella infection*, but also with the presence of *Brucella infection* in the absence of clinical signs.

A *case* is an *animal* infected with *Brucella*.

The following defines a *case* of *Brucella infection*:

- *Brucella* has been isolated and/or identified as such from an *animal* or a product derived from that *animal*;

OR

- positive results to one or more tests (serological, bacteriological and/or molecular tests) have been obtained and there is epidemiological evidence of *Brucella infection*.

Rationale: This added text reflects that found in the *Manual of Diagnostic Tests and Vaccines for Terrestrial Animals 2011* which states, “There is no single test by which a bacterium can be identified as *Brucella*. A combination of growth characteristics, serological, bacteriological and/or molecular methods is usually needed.”

Standards for diagnostic tests and vaccines are described in the *Terrestrial Manual*. In the absence of sufficient scientific information, the prescribed tests for bovidae, except bovine specific indirect ELISAs, may be applied to *Cervidae* and *Camelidae*.

Article 11.3.2.

Safe commodities

When authorising import or transit of the following *commodities*, *Veterinary Authorities* should not require any *Brucella*-related conditions, regardless of the *Brucella* status of the animal population of the *exporting country, zone, herd or flock*:

1. skeletal muscle *meat*, brain and spinal cord, digestive tract, thymus, thyroid and parathyroid glands and derived products, provided that they are accompanied by an *international veterinary certificate* attesting that they are originating from *animals* that have been subjected to ante-mortem and post-mortem inspections as described in Chapter 6.2.;
2. cured hides and skins;
3. gelatine, collagen, tallow and *meat-and-bone meal*.

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 *Brucella* status of the animal population of the *exporting country, zone or herd or flock*.

Article 11.3.3.

Country or zone free from *Brucella* infection in animals without vaccination

A country or *zone* can be qualified free from *Brucella infection* without vaccination either in one or several of the animal categories listed in Article 11.3.1.

To qualify as free from *Brucella infection* without vaccination, a country or *zone* should satisfy for each relevant category of *animals* the following requirements:

1. *Brucella infection* in *animals* is a *notifiable disease* in the country;
2. a programme should be in place to ensure effective reporting of all *cases* suggestive of *Brucella infection*, particularly abortions, and regular submission of abortion material to diagnostic laboratories for investigation;
3. neither domestic nor *captive wild animals* have been vaccinated against *Brucella infection* for at least the past three years;
4. no *case* of abortion due to *Brucella infection* and no isolation of *Brucella* has been recorded in *animals* for at least the past three years;
5. except for pigs:

Rationale: 1) If declaring a country free of disease in a particular species of animal, then there should be on-going surveillance in that particular species to support the disease-free status, and 2) swine can be infected with and therefore be a source of infection of *B. abortus*.

- a) regular and periodic testing of all *herds* or *flocks* demonstrated that *Brucella infection* was not present in at least 99.8% of the *herds* or *flocks* and 99.9% of *animals* in the country or *zone* for the previous three consecutive years;

Rationale: The status should be based on current regular and periodic testing as opposed to any three consecutive year period since disease may have been identified since that three consecutive year period.

- b) a *surveillance* programme based on regular and periodic testing of *animals* should be in place in the country or *zone* to detect *Brucella infection* in accordance with Chapter 1.4.;
 - c) if a *surveillance* programme described in Points 2 and 5 a) and b) above has not detected *Brucella infection* for the past five years, *surveillance* should be maintained in accordance with Chapter 1.4.;
6. vaccinated *animals* should not be introduced. Unvaccinated *animals* and genetic materials should comply with the recommendations in Articles 11.3.8. to 11.3.12. The free status without vaccination of the country or *zone* for a specified animal category is not affected by the occurrence of *Brucella infection* in other animal categories or *feral* and *wild animals* provided that effective measures have been implemented to mitigate transmission of disease to the relevant animal population belonging to the specified animal category free from *Brucella infection* ~~is effectively separated~~ from the potential source of *infection*.

Rationale: It may not be possible to maintain effective separation of animal population in certain herd situations such as occurs in large cattle herds in the western region of the United States which utilize grazing rights during summer months. However, if effective mitigation measures are practiced, such as testing the herd for presence of disease, then adequate efforts have been made to mitigate disease transmission and establish the disease free status of those animals.

Country or zone free from *Brucella* infection in animals with vaccination

A country or *zone* can be qualified free from *Brucella infection* with vaccination either in bovidae or ovidae and capridae as listed in Article 11.3.1.

To qualify as free from *Brucella infection* with vaccination, a country or *zone* should satisfy for each relevant category of *animals* the following requirements:

1. *Brucella infection* in *animals* is a *notifiable disease* in the country;
2. vaccinated *animals* should be identified with a permanent mark;
3. a programme should be in place to ensure effective reporting of all *cases* suggestive of *Brucella infection*, particularly abortions, and regular submission of abortion material to diagnostic laboratories for investigation;
4. no *case* of abortion due to *Brucella infection* and no isolation of *Brucella* has been recorded in *animals* during at least the past three years;
5. regular and periodic testing of all *herds* or *flocks* demonstrated that *Brucella infection* was not present in at least 99.8% of the *herds* or *flocks* and 99.9% of *animals* in the country or *zone* for [the previous](#) three consecutive years;

Rationale: The status should be based on current regular and periodic testing as opposed to any three consecutive year period since disease may have been identified since that three consecutive year period.

6. a *surveillance* programme based on regular and periodic testing of *animals* should be in place in the country or *zone* to detect *Brucella infection* in accordance with Chapter 1.4.;
7. if a *surveillance* programme described in Points 3, 5 and 6 above has not detected *Brucella infection* for the past five years, *surveillance* should be maintained in accordance with Chapter 1.4.;
8. *animals* and genetic materials introduced should comply with the recommendations in Articles 11.3.8. to 11.3.12.

The free status with vaccination of the country or *zone* for a specified animal category is not affected by the occurrence of *Brucella infection* in other animal categories or *feral* and *wild animals* provided that [effective measures have been implemented to mitigate transmission of disease to](#) the relevant animal population belonging to the specified animal category free from *Brucella infection* ~~is effectively separated~~ from the potential source of *infection*.

Rationale: It may not be possible to maintain effective separation of animal populations in certain herd situations such occurs in large cattle herds in the western parts of the United States which utilize grazing rights during summer months. However, if effective mitigation measures are practiced, such as testing the herd for presence of disease, then adequate efforts have been made to mitigate disease transmission and establish the disease free status of those animals.

Article 11.3.5.

Herd or flock free from *Brucella* infection without vaccination

1. To qualify as free from *Brucella* infection without vaccination, a *herd* or *flock* of the relevant animal category should satisfy the following requirements:

- a). the *herd* or *flock* is in a country or *zone* free from *Brucella* infection without vaccination for the relevant animal category and is certified free without vaccination by the *Veterinary Authority*;

OR

- b). the *herd* or *flock* is in a country or *zone* free from *Brucella* infection with vaccination for the relevant animal category and is certified free without vaccination by the *Veterinary Authority*; and no *animal* of the *herd* or *flock* has been vaccinated in the past three years;

OR

- c) the *herd* or *flock* met the following conditions:

- i) *Brucella* infection in *animals* is a *notifiable disease* in the country;
- ii) no *animal* of the *herd* or *flock* has been vaccinated during the past three years;
- iii) the *herd* or *flock* has not shown evidence of *Brucella* infection for at least the **past nine months**;

Comment: The United States questions the relevance of a nine month period for all species of animals. Might it be more appropriate to base this time frame on birthing cycles (e.g. calving or kidding intervals) since 1) seroconversion is possible post-birthing, and 2) the most opportune time to test for brucellosis is post birthing

- iv) all suspect *cases* (such as *animals* which have aborted) have been subjected to the necessary clinical and laboratory investigations with negative results;
- v) all *animals* were subjected to a prescribed serological test with negative results on two occasions, at an interval of more than 6 and less than 12 months between each test, the first test being performed not before 3 months after the *slaughter* of the last *case*.

2. To maintain the free status, the following conditions should be met:

- a) regular prescribed tests, at a frequency depending on the prevalence of *herd* or *flock* infection in the country or *zone*, demonstrate the continuing absence of *Brucella* infection;
- b) *animals* introduced into the *herd* or *flock* should be accompanied by a certificate from an *Official Veterinarian* attesting that they come from:
- i) a country or *zone* free from *Brucella* infection without vaccination;

OR

- ii) a country or *zone* free from *Brucella* infection with vaccination and the *animals* have not been vaccinated during the last three years;

OR

- iii) a *herd* or *flock* free from *Brucella infection* with or without vaccination, provided that the *animals* have not been vaccinated in the last 3 years and negative results were shown to a prescribed test during the 30 days prior to shipment; in the case of females which have given birth during the past 30 days, the test should be carried out at least 30 days after the birth. This test is not required for sexually immature *animals* or vaccinated *animals* less than 18 months of age.
- c) There is no evidence of *infection* in other epidemiologically relevant animal species kept in the same *establishment*, or measures have been implemented to prevent any transmission of the *Brucella infection* from other species kept in the same *establishment*.

Article 11.3.6.

Herd or flock free from *Brucella* infection with vaccination

A *herd* or *flock* can be qualified free from *Brucella infection* with vaccination either in bovidae or ovidae and capridae as listed in Article 11.3.1.

1. To qualify as free from *Brucella infection* with vaccination, a *herd* or *flock* of the relevant animal category should satisfy the following requirements:
 - a) the *herd* or *flock* is in a country or *zone* free from *Brucella infection* with vaccination for the relevant animal category and is certified free with vaccination by the *Veterinary Authority*;

OR

- b) the *herd* or *flock* met the following conditions:
 - i) *Brucella infection* in *animals* is a *notifiable disease* in the country;
 - ii) vaccinated *animals* should be permanently identified;
 - iii) the *herd* or *flock* has not shown evidence of *Brucella infection* during at least the **past nine months**;

Comment: The United States questions the relevance of a nine month period for all species of animals. Might it be more appropriate to base this time frame on birthing cycles (e.g. calving or kidding intervals) since 1) seroconversion is possible post-birthing, and 2) the most opportune time to test for brucellosis is post birthing

- iv) all suspect *cases* (such as *animals* which have aborted) have been subjected to the necessary clinical and laboratory investigations with negative results;
 - v) all *animals* were subjected to a prescribed serological test with negative results on two occasions, at an interval of more than 6 and less than 12 months between each test, the first test being performed not before 3 months after the *slaughter* of the last *case*.
2. To maintain the free status, the following conditions should be met:
 - a) regular prescribed tests, at a frequency depending on the prevalence of *herd* or *flock infection* in the country or *zone*, demonstrate the continuing absence of *Brucella infection*;

- b) *animals* introduced into the *herd* or *flock* should be accompanied by a certificate from an *Official Veterinarian* attesting that they come from either:
- i) a country or *zone* free from *Brucella infection* with or without vaccination;
- OR
- ii) a *herd* or *flock* free from *Brucella infection* with or without vaccination, provided that negative results were shown to a prescribed test during the 30 days prior to shipment; in the case of females which have given birth during the past 30 days, the test should be carried out at least 30 days after the birth. This test is not required for sexually immature *animals* or vaccinated *animals* less than 18 months of age.
- c) There is no evidence of *infection* in other epidemiologically relevant animal species kept in the same *establishment*, or measures have been implemented to prevent any transmission of the *Brucella infection* from other species kept in the same *establishment*.

Article 11.3.7.

Recovery of the *Brucella* infection free status in a country or a zone

Should a *case* of *Brucella infection* in one or more animal categories occur in a free country or *zone*, the status is suspended and may not be recovered until:

1. all infected *animals* of the relevant category were slaughtered or destroyed as soon as the result of the diagnostic test was known;
2. in animal categories other than pigs, all remaining sexually mature *animals* in the *herd* or *flocks* have been subjected to a serological test, with negative results, on three occasions, at an interval of not less than two months, a further test six months later and a final test a year later.
3. in pig *herds*, where *cases* of *Brucella infection* have occurred, all pigs were slaughtered or destroyed.
4. An epidemiological investigation must be performed within 60 days of the date the case was detected and the investigation must confirm that brucellosis has not spread from the affected herd(s) or flock(s). All herds or flocks on premises adjacent to the affected herd(s) or flock(s) (adjacent herds or flocks), all herds or flocks from which animals may have been brought into the affected herd(s) or flock(s) (source herds or flocks), and all herds or flocks that may have had contact with or accepted animals from the affected herd(s) or flock(s) (contact herds or flocks), must be epidemiologically investigated and a complete herd or flock test conducted unless the investigating epidemiologist determines that a herd or flock blood test is not warranted.
5. After the close of the 60-day period following the date the case was detected, Veterinary Authorities must conduct a review to confirm that the investigation is complete and successfully closed.
6. Prior to re-establishing the *Brucella* infection free status in a country or a zone, Veterinary Authorities must conduct a review to confirm that all requirements for infection free status have been satisfied and document that the country or zone is in compliance with all applicable provisions of infection free status.

Rationale: Infection-free status is predicated on more than just removing the infected animals and testing their herd of origin. A complete and thorough epidemiologic investigation is a necessary component of demonstrating infection free status. Reviews to confirm adequate completion of all activities and documentation that all provisions of infection free status have been met is critical to demonstrating infection free status.

Article 11.3.8.

Recommendations for the importation of animals 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 clinical sign of *Brucella infection* on the day of shipment;

2. originate from:
 - a) a country or *zone* free from *Brucella infection*;

OR

- b) a *herd* or *flock* free from *Brucella infection* and were subjected to a prescribed serological test with negative results during the 30 days prior to shipment.

This test is not required for:

- pigs;

Comment: Since swine can be infected with and can spread *B. abortus*, as well as *B. suis*, the rationale for excluding them from test is unclear.

- young bovidae before the age of 12 months;
- young ovidae and capridae before the age of 6 months;
- young *Camelidae* and *Cervidae* before the age of sexual maturity;

OR

- c) with the exception of pigs, a *herd* or *flock* not qualified free from *Brucella infection*:
 - i) in which no *Brucella infection* has been reported during the nine months prior to shipment;
 - ii) were isolated for 30 days prior to shipment and subjected during that period to a prescribed serological test with negative results. In the case of females which have given birth during the past 30 days, the test should be carried out at least 30 days after the birth. This test is not required for sexually immature *animals* or vaccinated *animals* less than 18 months of age.

Article 11.3.9.

Recommendations for the importation of animals for slaughter

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

1. showed no clinical signs of *Brucella infection* on the day of shipment;
2. originate from a country, *zone* or *herd* free from *Brucella infection* with or without vaccination;

OR

3. were subjected to a prescribed test for *Brucella infection* with negative results during the 30 days prior to shipment and are not being eliminated as part of an eradication programme against *Brucella infection*.

Article 11.3.10

Recommendations for the importation of captive European hares (*Lepus europaeus*) for restocking

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

1. the *animals* showed no clinical signs of *Brucella infection* on the day of shipment;
2. a programme is in place to ensure effective investigation and reporting of all *cases* suggestive of *Brucella infection* in *establishments* keeping hares.

3. The animals being imported originate from an established population that has been under appropriate management and care and maintained under appropriate sanitary measures to assure adequate observation for presence of infection.

Rationale: Appropriate and adequate sanitary measures should be in place to assure the risk of importing disease from any susceptible species is mitigated.

Article 11.3.11.

Recommendations for the importation of semen

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

1. the donor *animals* have been under the husbandry and care of the establishment for a time period appropriate for observation of infection free status and the donor animals showed no clinical signs of *Brucella infection* on the day of collection of the semen;

Rationale: An established period of observation is necessary to assure that no clinical signs of infection are present.

2. the donor *animals* were not vaccinated against *Brucella infection* and either:
- a) were kept in an *artificial insemination centre* free from *Brucella infection*;
- OR
- b) were kept in a *herd* or *flock* free from *Brucella infection* and are subjected every six months to a prescribed test with negative results;
3. the semen was collected, processed and stored in conformity with the provisions of Chapter 4.5. and Chapter 4.6.

Article 11.3.12

Recommendations for the importation of embryos and oocytes

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

1. the donor *animals* have been under the husbandry and care of the establishment for a time period appropriate for observation of infection free status and the donor animals showed no clinical signs of *Brucella infection* on the day of collection;

Rationale: An established period of observation is necessary to assure that no clinical signs of infection are present.

2. the donor *animals* were not vaccinated against *Brucella infection* during the past three years and either:
- a) were kept in a country or *zone* free from *Brucella infection*;

OR

- b) were kept in a *herd* or *flock* free from *Brucella infection* and are subjected every six months to a prescribed test with negative results;
3. the embryos and oocytes were collected, processed and stored in conformity with the provisions of Chapter 4.7. to Chapter 4.9.

Article 11.3.13.

Recommendations for the importation of fresh meat and meat products other than mentioned in Article 11.3.2.

Veterinary Authorities of importing countries should require the presentation of an *international veterinary certificate* attesting that the *meat* and *meat products* come from *animals*:

1. which have been subjected to ante-mortem and post-mortem inspections as described in Chapter 6.2.;

2. which:
- a) originate from a *herd* or *flock* free from *Brucella infection*;
- OR
- b) have not tested positive to a prescribed test for *Brucella infection*.

Article 11.3.14.

Recommendations for the importation of milk and milk products

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

- 1. have been derived from *animals* of a *herd* or *flock* free from *Brucella infection*;
- OR
- 2. were subjected to pasteurization or any combination of control measures with equivalent performance as described in the Codex Alimentarius Code of Hygienic Practice for Milk and Milk Products.

Article 11.3.15

Recommendations for importation of wool and hair

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

- 1. have not been derived from *Brucella* infected *animals*;
- OR
- 2. have been processed to ensure the destruction of the *Brucella*.
-