

TERRESTRIAL ANIMAL HEALTH STANDARDS COMMISSION

FEBRUARY 2013 REPORT

USA COMMENTS AND SUGGESTIONS - SHOWN IN BLUE FONT

CHAPTER 8.X.

**INFECTION WITH *BRUCELLA ABORTUS*,
MELITENSIS AND *SUIS***

General Comment : The United States continues to have serious concerns with combining the three *Brucella* species into one Code Chapter. As separate Chapters, they speak to species-specific *Brucella* organism for the traditional host species. As a combined Chapter, this is lost each time the term « *Brucella* » is used throughout the Chapter. The United States again strongly urges the OIE to keep these three species-specific *Brucella* organism separate and to develop a unique code chapter for each.

Article 8.X.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~~ refers to *B. abortus* for bovids, *B. melitensis* for sheep and goats, or *B. suis* for pigs, excluding vaccine strains.

Rationale: The recognition of a country or *zone* as free from *Brucella* infection should reflect freedom from the *Brucella* organism specific to the traditional host species of animals because irrefutable scientific evidence does not currently exist that demonstrates that all species of *Brucella* have the same degree of infectivity in the non-traditional host species of animals. If the term "*Brucella*," when used in this Chapter, means all three species of *Brucella* organisms, a country or *zone* could not be recognized as free from *Brucella* in bovids for instance, if *B. suis* were to be cultured from a cow.

- ~~For the purpose of this chapter,~~ 'Animals' means domestic and *captive wild* animal populations of the following categories:
 - 1) ~~Bovidae bovids~~; this term means cattle (*Bos taurus*, *B. indicus*, *B. frontalis*, ~~and~~ *B. javanicus*), ~~yak (and~~ *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 bears~~ (*Sus scrofa*);
 - 4) ~~Camelidae camelids~~; this term means dromedary camel (*Camelus dromedarius*), Bactrian camel (*Camelus bactrianus*), llama (*Lama glama*), alpaca (*Lama pacos*), guanaco (*Lama guanicoe*) and vicuna (*Vicugna vicugna*);

- 5) Cervidae cervids means roe deer (*Capreolus capreolus*), red deer (*Cervus elaphus elaphus*), wapiti/elk (*C. elaphus canadensis*), sika (*C. nippon*), samba (*C. unicolor unicolor*), rusa (*C. timorensis*), fallow deer (*Dama dama dama*), white-tailed, black-tailed, mule deer (*Odocoileus spp.*) and reindeer (*Cervus elaphus elaphus*, *C. elaphus canadensis*, *C. nippon*, *C. unicolor unicolor*, *C. timorensis*, *Dama dama dama*, *Odocoileus virginianus borealis*, *O. docoileus homionus columbianus*, *O. docoileus homionus homionus* and *Rangifer tarandus*);
- 6) European hare (*Lepus europaeus*).

For the purpose of the *Terrestrial Code*, a case is an animal infected with *Brucella*.

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 a~~ diagnostic tests have been obtained which result in a reactor classification and or there is [an sufficient](#) epidemiological [link to a confirmed case](#) evidence of *Brucella infection* evidence of *Brucella infection*.

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

Rationale: Per current text in the *Terrestrial Manual* reads: “*No single serological test is appropriate in all epidemiological situations; all have limitations especially when it comes to screening individual animals (31, 64). Consideration should be given to all factors that impact on the relevance of the test method and test results to a specific diagnostic interpretation or application.*” Interpretation of “positive” results (i.e. other than negative results) for some serologic diagnostic tests for brucellosis includes a suspect and reactor classification. Opportunity must be provided to assess additional epidemiologic evidence when making a final classification of the diagnostic test results. An epidemiologic link to a confirmed case is not necessary as the case at hand may be the index case. For this disease, the determination of the presence of *Brucella* infection should consider both diagnostic test results and epidemiologic information. The two are not necessarily mutually exclusive.

The definition of brucellosis infection does not include animals held within a government (i.e. federally) approved brucellosis research facilities.

Rationale: Exclude research animals to facilitate research on brucellosis-exposed or infected animals in those facilities without adversely affecting that country’s or *zone*’s brucellosis status.

When authorising import or transit of *commodities* listed in this chapter, with the exception of those listed in Article 8.x.2., *Veterinary Authorities* should require the conditions prescribed in this chapter relevant to the *Brucella infection* status of the animal population of the *exporting country, zone, herd or flock*.

Article 8.X.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 infection* 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 8.X.3.

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

Note : The USA edits to this Article (and the same in the next Article) include the re-ordering of the qualifications to follow a more logical priority order.

~~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.~~

- 1) To qualify as free from *Brucella* infection **in bovids** without vaccination in bovids, a country or zone should satisfy for each relevant category of animals the following requirements:
 - 1-a) *Brucella* infection in animals is a notifiable disease in the country or zone;
 - b) ~~no case of abortion due to no *Brucella abortus* infection and no isolation of *Brucella*~~ has been recorded in animals bovids for at least the past three years;

Rationale: The USA recommends deleting “case of” to be consistent with the text change on page 1 reflecting the deletion of “a case of” in the sentence which reads, “*The following defines a case of Brucella infection:*”

- c) ~~af) regular and periodic on-going and statistically valid surveillance testing of the bovid population of the country or zone testing of all herds or flocks has been in place for at least the past consecutive three years; and this testing has demonstrated~~ that *Brucella abortus* infection ~~was is~~ not present in at least 99.8% of the ~~herds or flocks~~ and representing at least 99.9% of animals bovids in the country or zone ~~three consecutive years;~~

Rationale: Statistically valid surveillance testing, as opposed to whole herd testing of all herds each year for three consecutive years, provides a sound means to demonstrate valid disease freedom in countries or zones with large bovid populations or when resources are limited and/or should be focused on high-risk areas. Whole herd testing of each herd annually for at least three consecutive years, if a country or zone chose to do so, would more than meet this requirement.

- 2-~~b~~ d) regulatory measures for the early detection ~~a programme should be in place to ensure effective reporting of all cases suggestive of *Brucella* infection in bovids, particularly abortions, and including the epidemiological investigation of all non-negative brucellosis test results to discern the presence of~~

infection in a herd. If areas in the country or *zone* are considered to be high risk for disease re-introduction or resurgence, appropriate targeted surveillance activities such as the regular submission of abortion material to diagnostic laboratories for investigation, testing animals prior to movement, etc, have been implemented;

Rationale: The recommended text provides clearer guidance on expected performance standards that allow a country or *zone* to determine if it is satisfying the qualification. It also provides a country or *zone* to implement specific activities that address and mitigate that country/*zone*'s specific risks.

3.c) ~~neither domestic nor captive wild animals~~ no bovids have been vaccinated against *Brucella infection* for at least the past three years, and no vaccinated bovids that are have been introduced in the country or zone have not been vaccinated during the past three years;

Rationale: The text as currently written provides for the continual introduction of vaccinated bovids that are at least 3 years older than when vaccinated. The suggested edits address the intent to create a total population of unvaccinated bovids.

4.d) ~~no case of abortion due to *Brucella infection* and no isolation of *Brucella* has been recorded in animals bovids~~ for at least the past three years;

5) except for pigs:

e f) bovids and their genetic materials introduced in the country or zone should comply with the recommendations in Articles 8.X.13., 8.X.15. to 8.X.17.;

af) ~~regular and periodic testing of all herds or flocks has been in place for the past three years; and this testing has demonstrated that *Brucella infection* was not present in at least 99.8% of the herds or flocks and representing at least 99.9% of animals bovids in the country or zone three consecutive years;~~

2) To maintain the status as free from *Brucella abortus infection* without vaccination in bovids, a country or zone should satisfy the following requirements:

a) the requirements in points 1a) to 1fe) above are met;

Rationale : The noted correction is made to reflect all 6 qualifications under Point 1) above.

b) ~~a surveillance programme based on regular and periodic testing of animals should be~~ bovids is in place in the country or *zone* to detect *Brucella infection* in accordance with Chapter 1.4.;

c) ~~if a the surveillance programme described in Points 2 and 5 a) and b) above has not detected *Brucella infection* for the past five~~ two three consecutive years, ~~surveillance should~~ may be maintained in accordance with Chapter 1.4.

Rationale: changed from two to three years to be consistent with 1) b.

6.3) ~~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 in bovids a specified animal category is not affected by the occurrence of *Brucella infection* in other animal categories or feral and or wild animals provided that effective measures have been implemented to prevent transmission of *Brucella infection* to the relevant animal population bovids belonging to the specified animal category free from *Brucella infection* is effectively separated from the potential source of infection.~~

Article 8.X.4.

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

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

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

4-a) *Brucella* infection in animals is a notifiable disease in the country or zone;

b) no ~~case of abortion due to *Brucella abortus* infection and no isolation of *Brucella*~~ has been recorded in animals bovinds for at least the past three years;

c) ~~regular and periodic on-going statistically valid surveillance testing of the bovid population of the country or zone all herds or flocks has been in place for the past three consecutive years; and this testing has demonstrates that *Brucella abortus* infection was is not present in at least 99.8% of the herds or flocks and representing at least 99.9% of animals bovinds in the country or zone. three consecutive years;~~

Rationale: Statistically valid surveillance testing, as opposed to whole herd testing of all herds each year for three consecutive years, provides a sound means to demonstrate valid disease freedom in countries or zones with large bovid populations or when resources are limited and/or should be focused on high-risk areas. Whole herd testing of each herd annually for at least three consecutive years, if a country or zone chose to do so, would more than meet this requirement.

2-bd) ~~regulatory measures for the early detection a programme should be in place to ensure effective reporting of all cases suggestive of *Brucella* infection in bovinds, particularly abortions, and including epidemiologic investigation of all non-negative brucellosis test results to discern the presence of infection in a herd. If areas for the country or zone are considered high risk for disease re-introduction or resurgence, appropriate targeted surveillance activities such as the regular submission of abortion material to diagnostic laboratories for investigation, testing animals prior to movement, etc. have been implemented;~~

Rationale: The recommended text provides clearer guidance on expected performance standards that allow a country or zone to determine if it is satisfying the qualification. It also provides a country or zone to implement specific activities that address and mitigate that country/zone's specific risks.

3-e e) vaccinated animals bovinds should be identified with a permanent mark or an official individual unique animal identification device that provides for documentation and verification of vaccination status;

Rationale: The USA recommended text provides for the use of RFID devices or other official animal identification devices approved for such use which facilitates efficient and effective movement of vaccinated bovinds in marketing channels.

4-d) ~~no case of abortion due to *Brucella* infection and no isolation of *Brucella* has been recorded in animals bovinds for at least the past three years;~~

5e f) bovinds and their genetic materials introduced in the country or zone comply with the recommendations in Articles 8.X.13., 8.X.15. to 8.X.17.;

f) ~~regular and periodic testing of all herds or flocks has been in place for the past three years; and this testing has demonstrated that *Brucella* infection was not present in at least 99.8% of the herds or flocks and representing at least 99.9% of animals bovinds in the country or zone. three consecutive years;~~

2) To maintain the status as free from *Brucella abortus* infection with vaccination in bovids, a country or zone should satisfy the following requirements:

a) the requirements in points 1a) to 1e-f) above are met;

6-b) a surveillance programme based on regular and periodic testing of ~~animals should be~~ bovids is in place in the country or zone to detect *Brucella* infection in accordance with Chapter 1.4.;

- c) if a the surveillance programme described in Points 2 and 5 a) and b) above has not detected *Brucella* infection for ~~the past five~~ two three consecutive years, ~~surveillance should~~ may be maintained in accordance with Chapter 1.4.

Rationale: changed from two to three years to be consistent with 1) b.

7-8. ~~animals and genetic materials introduced should comply with the recommendations in Articles 11.3.8. to 11.3.12.~~

- 3) ~~The free status with vaccination of the country or zone for bovids a specified animal category is not affected by the occurrence of *Brucella abortus* infection in other animal categories or feral and or wild animals provided that effective measures have been implemented to prevent transmission of *Brucella abortus* infection to the relevant animal population bovids belonging to the specified animal category free from *Brucella* infection is effectively separated from the potential source of infection.~~
- 4) In addition, if a country or zone free from *Brucella abortus* infection with vaccination in bovids wishes to change its status to country or zone free from *Brucella abortus* infection without vaccination, the status of this country or zone remains unchanged for a period of at least three years after vaccination has ceased, provided that the requirements in point 1c) of Article 8.X.3. are met during that period and no vaccinated bovids have been introduced in the country or zone during that same period of at least three years.

Rationale: The United States recommends the added text to reduce the possibility of having vaccinated bovids be continually introduced into the herd. The text addresses the intent to establish a total population of unvaccinated bovids.

Article 8.X.5.

NOTE: The United States has no control or eradication program against *Brucella* in sheep, goats, camelids and cervids. Therefore, the United States is not specifically providing comments to Articles 8.X.5 through 8.X.8. However, as mentioned in our comment/note at the beginning of this chapter, the United States strongly insists that :

1. The *Brucella* species should be specific to the host species ; and
2. The USA recommended changes noted in Articles 8.X.3 and 8.X.4 would be applicable to those same parallel Points and Sub-points in Articles 8.X.5 through 8.X.8.

Country or zone free from *Brucella* infection without vaccination in sheep and goats

- 1) To qualify as free from *Brucella* infection without vaccination in sheep and goats, a country or zone should satisfy the following requirements:
- a) *Brucella* infection in animals is a notifiable disease in the country or zone;
 - b) regulatory measures for the early detection of *Brucella* infection in sheep and goats, including the regular submission of abortion material to diagnostic laboratories for investigation, have been implemented;

- c) no sheep and goats have been vaccinated against *Brucella infection* for at least the past three years and sheep and goats that are introduced in the country or zone, have not been vaccinated during the past three years;
- d) no case of *Brucella infection* has been recorded in sheep and goats for at least the past three years;
- e) sheep and goats and their genetic materials introduced in the country or zone comply with the recommendations in Articles 8.X.13., 8.X.15. to 8.X.17.;
- f) regular and periodic testing of all flocks has been in place for the past three years; and this testing has demonstrated that *Brucella infection* was not present in at least 99.8% of the flocks representing at least 99.9% of sheep and goats in the country or zone.
- 2) To maintain the status as free from *Brucella infection* without vaccination in sheep and goats, a country or zone should satisfy the following requirements:
- a) the requirements in points 1a) to 1e) above are met;
- b) a surveillance programme based on regular and periodic testing of sheep and goats is in place in the country or zone to detect *Brucella infection* in accordance with Chapter 1.4.;
- c) if the surveillance programme described in b) above has not detected *Brucella infection* for two consecutive years, surveillance may be maintained in accordance with Chapter 1.4.

- 3) The free status without vaccination of the country or zone in sheep and goats is not affected by the occurrence of *Brucella infection* in other animal categories or feral or wild animals provided that effective measures have been implemented to prevent transmission of *Brucella infection* to sheep and goats.

Article 8.X.6.

Country or zone free from *Brucella infection* with vaccination in sheep and goats

- 1) To qualify as free from *Brucella infection* with vaccination in sheep and goats, a country or zone should satisfy the following requirements:
- a) *Brucella infection* in animals is a notifiable disease in the country or zone;
 - b) regulatory measures for the early detection of *Brucella infection* in sheep and goats, including the regular submission of abortion material to diagnostic laboratories for investigation, have been implemented;
 - c) vaccinated sheep and goats should be identified with a permanent mark;
 - d) no case of *Brucella infection* has been recorded in sheep and goats for at least the past three years;
 - e) sheep and goats and their genetic materials introduced in the country or zone comply with the recommendations in Articles 8.X.13., 8.X.15. to 8.X.17.;
 - f) regular and periodic testing of all flocks have been in place for the past three years; and this testing has demonstrated that *Brucella infection* was not present in at least 99.8% of the flocks representing at least 99.9% of sheep and goats in the country or zone.
- 2) To maintain the status as free from *Brucella infection* with vaccination in sheep and goats, a country or zone should satisfy the following requirements:
- a) the requirements in points 1a) to 1e) above are met;
 - b) a surveillance programme based on regular and periodic testing of sheep and goats is in place in the country or zone to detect *Brucella infection* in accordance with Chapter 1.4.;
 - c) if the surveillance programme described in b) above has not detected *Brucella infection* for two consecutive years, surveillance may be maintained in accordance with Chapter 1.4.
- 3) The free status with vaccination of the country or zone in sheep and goats is not affected by the occurrence of *Brucella infection* in other animal categories or feral or wild animals provided that effective measures have been implemented to prevent transmission of *Brucella infection* to sheep and goats.
- 4) In addition, if a country or zone free from *Brucella infection* with vaccination in sheep and goats wishes to change its status to country or zone free from *Brucella infection* without vaccination, the status of this country or zone remains unchanged for a period of at least three years after vaccination has ceased, provided that the requirements in point 1c) of Article 8.X.5. are met during that period.

Article 8.X.7.

Country or zone free from *Brucella infection* in camelids

- 1) To qualify as free from *Brucella infection* in camelids, a country or zone should satisfy the following requirements:
- a) *Brucella infection* in animals is a notifiable disease in the country or zone;

- b) regulatory measures for the early detection of *Brucella infection* in camelids, including the regular submission of abortion material to diagnostic laboratories for investigation, have been implemented;
 - c) no camelids have been vaccinated against *Brucella infection*;
 - d) no case of *Brucella infection* has been recorded in camelids for at least the past three years;
 - e) camelids and their genetic materials introduced in the country or zone comply with the recommendations in Articles 8.X.13., 8.X.15. to 8.X.17.;
 - f) regular and periodic testing of all herds has been in place for the past three years; and this testing has demonstrated that *Brucella infection* was not present in at least 99.8% of the herds representing at least 99.9% of camelids in the country or zone.
- 2) To maintain the status as free from *Brucella infection* in camelids, a country or zone should satisfy the following requirements:
- a) the requirements in points 1a) to 1e) above are met;
 - b) a surveillance programme based on regular and periodic testing of camelids is in place in the country or zone to detect *Brucella infection* in accordance with Chapter 1.4.;
 - c) if the surveillance programme described in b) above has not detected *Brucella infection* for two consecutive years, surveillance may be maintained in accordance with Chapter 1.4.
- 3) The free status of the country or zone in camelids is not affected by the occurrence of *Brucella infection* in other animal categories or feral or wild animals provided that effective measures have been implemented to prevent transmission of *Brucella infection* to camelids.

Article 8.X.8.

Country or zone free from *Brucella infection* in cervids

- 1) To qualify as free from *Brucella infection* in cervids, a country or zone should satisfy the following requirements:
- a) *Brucella infection* in animals is a notifiable disease in the country or zone;
 - b) regulatory measures for the early detection of *Brucella infection* in cervids, including the regular submission of abortion material to diagnostic laboratories for investigation, have been implemented;
 - c) no cervids have been vaccinated against *Brucella infection*;
 - d) no case of *Brucella infection* has been recorded in cervids for at least the past three years;
 - e) cervids and their genetic materials introduced in the country or zone comply with the recommendations in Articles 8.X.13., 8.X.15. to 8.X.17.;
 - f) regular and periodic testing of all herds has been in place for the past three years; and this testing has demonstrated that *Brucella infection* was not present in at least 99.8% of the herds representing at least 99.9% of cervids in the country or zone;
- 2) To maintain the status as free from *Brucella infection* in cervids, a country or zone should satisfy the following requirements:

- a) the requirements in Points 1.a) to 1.e) above are met;
 - b) a surveillance programme based on regular and periodic testing of cervids is in place in the country or zone to detect *Brucella* infection in accordance with Chapter 1.4.;
 - c) if the surveillance programme described in b) above has not detected *Brucella* infection for two consecutive years, surveillance may be maintained in accordance with Chapter 1.4.;
- 3) The free status of the country or zone in cervids is not affected by the occurrence of *Brucella* infection in other animal categories or feral or wild animals provided that effective measures have been implemented to prevent transmission of *Brucella* infection to cervids.

Article 8.X.9.

Herd or flock free from *Brucella* infection without vaccination in bovids, sheep and goats, camelids or cervids

- 1) To qualify as free from *Brucella* infection without vaccination, a herd or flock of ~~the relevant animal category~~ bovids, sheep and goats, camelids or cervids 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 **and no vaccinated animals have been added to the herd or flock;**

Rationale : The United States recommends the added text to reduce the possibility of having vaccinated animals be continually introduced into the herd. The text addresses the intent to establish a herd free of vaccinated animals.

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 relevant category of the herd or flock has been vaccinated during the past three years **and no vaccinated animals have been added to the herd or flock;**
 - iii) ~~no case of *Brucella* infection has been detected in the herd or flock has not shown evidence of *Brucella* infection~~ for at least the ~~past nine~~ past 12 months;
 - iv) ~~animals showing clinical signs consistent with *Brucella* infection all suspect cases (such as animals which have aborted abortions) have been subjected to the necessary clinical and laboratory investigations diagnostic tests with negative results;~~
 - v) for at least the past 12 months, there has been no evidence of *Brucella* infection in other susceptible animals of the same epidemiological unit, or measures have been implemented to prevent any transmission of the *Brucella* infection from other susceptible animals;
 - vi) all sexually mature animals of the relevant category, except castrated males were subjected to a prescribed serological test for *Brucella* infection 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.

Note : As we understand Point 1) c) vi) in Article 8.X.9, basically three consecutive negative herd tests would be necessary because the second test would likely include animals that may be too young to be included in the first test ; however, these younger animals would still need another test.

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

- a) the requirements in points 1a) or 1b) or 1c) i) to vi) above are met;
- ab) regular prescribed tests, at a frequency depending on the prevalence of *herd or flock infection* in the country or zone, in accordance with Chapter xxx Article xxx demonstrate the continuing absence of *Brucella infection*;

Rationale : Performance standards need to be clear and consistent.

- bc) animals of the relevant category introduced into the *herd or flock* ~~are~~ 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 of the relevant category have not been vaccinated during the past three years;
- OR
- iii) a *herd or flock* free from *Brucella infection* with or without vaccination, and provided that the animals have not been vaccinated in the past 3 years and were subjected ~~negative results were shown~~ to a prescribed test for *Brucella infection* during within the 30 days prior to shipment with negative results; in the ~~case case~~ of post-parturient females ~~which have given birth during the past 30 days~~, the test ~~is~~ should be carried out at least 30 days after giving ~~the~~ birth. This test is not required for sexually immature *animals* or vaccinated *animals* less than 18 months of age.

Observation/problem: The text, as currently written under Article 8.X.9 Point 2) c) iii), provides for the continual introduction of vaccinated animals that are at least 3 years older than when vaccinated. This text also provides for the introduction into the herd or flock of vaccinated but untested animals less than 18 months of age. The United States is unclear if this is what was truly intended given that the title of this Article indicates “**Herd or flock free from *Brucella infection* without vaccination in bovids, sheep and goats, camelids or cervids**”.

- e) ~~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.~~

Rationale : The United States recommends ‘undeleting’ the text since there should be no evidence of infection in any species on the same premises that could serve as a source of exposure.

Article 8.X.10.

Herd or flock free from *Brucella* infection with vaccination in bovinds, sheep and goats

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

1) To qualify as free from *Brucella* infection with vaccination, a herd of bovids or flock of sheep and goats ~~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 ~~of the relevant categories should be~~ are permanently identified with an official individual unique animal identification device that provides for documentation and verification of vaccination status ;

Rationale: The USA recommended text provides for the use of RFID devices or other official animal identification devices approved for such use which facilitates efficient and effective movement of vaccinated bovinds in marketing channels.

iii) no case of *Brucella* infection has been detected in the herd or flock ~~has not shown evidence of *Brucella* infection~~ for at least the past ~~nine~~ 12 months;

- iv) any animals of the relevant category on the premises showing clinical signs consistent with *Brucella infection* ~~all suspect cases (such as animals which have aborted abortions)~~ have been subjected to the necessary clinical and laboratory investigations diagnostic tests with negative results;
- v) for at least the past 12 months, there has been no evidence of *Brucella infection* in any other susceptible animals on the premises of the same epidemiological unit, or measures have been implemented to prevent any transmission of the *Brucella infection* from other susceptible animals;

Rationale : Herds or flocks certified free from the disease should also abide by the management factors to mitigate risk of exposure to the disease.

- vi) all sexually mature animals of the relevant category except castrated males were subjected to a prescribed serological test for *Brucella infection* 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.

Note : As we understand Point 1) b) vi) in Article 8.X.10, basically three consecutive negative herd tests would be necessary because the second test would likely include animals that may be too young to be included in the first test ; however, these younger animals would still need another test.

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

- a) the requirements in points 1 a) or 1b) i) to v) above are met;
- ab) regular prescribed tests, at a frequency depending on the prevalence of *herd or flock infection* in the country or zone, in accordance with Chapter xxx, Article xxx demonstrate the continuing absence of *Brucella infection*;

Rationale : Performance standards need to be clear and consistent.

- bc) animals of the relevant category 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, and provided that the animals have not been vaccinated in the past 3 years and were subjected to a prescribed test for *Brucella infection* within during the 30 days prior to shipment with negative results; in the case case of post-parturient females which have given birth during the past 30 days, the test is should be carried out at least 30 days after giving the birth. This test is not required for sexually immature *animals* or vaccinated *animals* less than 18 months of age.
- e) 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.

Rationale : The United States recommends 'undeleting' the text since there should be no evidence of infection in any species on the same premises that could serve as a source of exposure.

Article 8.X.11.

Herd free from *Brucella* infection in pigs

- 1) To qualify as free from *Brucella* infection, a herd of pigs should satisfy the following requirements:
- a) *Brucella* infection in animals is a notifiable disease in the country;
 - b) no pigs of the herd have been vaccinated;
 - c) no case of *Brucella* infection has been detected in the herd for at least the past three years;
 - d) animals showing clinical signs consistent with *Brucella* infection (such as abortions or orchitis) have been subjected to the necessary diagnostic tests;
 - e) for at least the past three years, there has been no evidence of *Brucella* infection in other susceptible animals of the same epidemiological unit, or measures have been implemented to prevent any transmission of the *Brucella* infection from other susceptible animals.

- 2) To maintain the free status, the following conditions should be met:
- a) the requirements in point 1) above are met;
 - b) animals introduced into the herd are accompanied by a certificate from an Official Veterinarian attesting that:
 - i) they come from a herd free from Brucella infection;

OR

 - ii) they come from a herd in which a statistically valid sample of the breeding pigs, selected in accordance with the provisions of Chapter 1.4., was subjected to a prescribed test within 30 days prior to shipment, demonstrating the absence of Brucella infection;

OR

 - iii) they were subjected to a prescribed test within 30 days prior to shipment with negative results.

Article 8.X.12.

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 as described in Articles 8.X.3. to 8.X.8., the status is suspended the free status and may not be recovered until once the following requirements are met:

- 1) all infected animals of the relevant category were are slaughtered or destroyed as soon as Brucella infection is confirmed the result of the diagnostic test was known;
- 2) an epidemiological investigation is performed within 60 days of Brucella infection confirmation in the herd or flock, aiming at identifying the likely source and the distribution of the infection, and shows that Brucella infection has spread to less than 0.2% of herds or flocks;
- 3) in the herds or flocks identified by the epidemiological investigation:
 - a) depopulation is practised; or

Clarity is needed. Does this refer to whole herd/flock depopulation (all infected and exposed animals) or just depopulation of the infected animals? This is an important consideration given the text in 3c) below.

 - 2.b) depopulation is not practised in animal categories other than pigs, and all remaining sexually mature animals in the herd or flocks except castrated males have been subjected to a serological prescribed test, with negative results, on three occasions, at an interval of not less than two months, then a further fourth test six months later and a final fifth test a year later;
 - c) no animals are moved from the herds or flocks except for direct slaughter until the processes in point a) or b) above are completed;

If only the infected animals are removed from the herd or flock, the remaining exposed animals need to be tested with negative results before any animals are moved from that herd or flock. The rationale for this is as a risk mitigation measure to prevent further potential spread of disease.

3.4) in pig herds, where cases of *Brucella infection* have occurred, all pigs were slaughtered or destroyed cleansing and disinfection procedures have been applied at the end of the slaughter process and before new animals are introduced.

When these requirements are **not** met, Articles 8.X.3. to 8.X.8. apply as relevant.

Rationale : Recommendations in Articles 8.X.3 to 8.X.8 address freedom of diseases, therefore, the above requirements would need to be met to recover free status as reflected in the title of Article 8.X.12.

Article 8.X.13.

Recommendations for the importation of animals bovids, sheep and goats, camelids or cervids for breeding or rearing

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

1) showed no clinical signs of *Brucella infection* on the day of shipment;

2) originate from:

a) a country or zone free from *Brucella infection* as relevant;

OR

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

This test is not required for:

- pigs;
- young bovines before the age of 12 months;
- young ovidae and capridae before the age of 6 months;
- young *Camelidae* and *Corvidae* 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 12 months prior to shipment;
- ii) the animals were isolated for 30 days prior to shipment and subjected during within that period to a prescribed serological test for *Brucella infection* with negative results; ~~in the case case of post-parturient females which have given birth during the past 30 days, the test is should be carried out at least 30 days after giving the birth. This test is not required for sexually immature animals or vaccinated animals less than 18 months of age.~~

Article 8.X.14.

Recommendations for the importation of pigs for breeding or rearing

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

1) showed no clinical signs of *Brucella infection* on the day of shipment;

2) either:

a) originate from a herd free from *Brucella* infection;

OR

b) originate from a herd in which a statistically valid sample of the breeding pigs, selected in accordance with the provisions of Chapter 1.4., was subjected to a prescribed test within 30 days prior to shipment, demonstrating the absence of *Brucella* infection;

OR

c) were subjected to a prescribed test for *Brucella* infection within 30 days prior to shipment with negative results.

Article 8.X.15.

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, herd or flock free from *Brucella infection* with or without vaccination;
- OR
- 3) are not being eliminated as part of an eradication programme against *Brucella infection* and in the case of sexually mature bovids, sheep and goats, camelids or cervids, were subjected to a prescribed test for *Brucella infection* with negative results during within 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.~~

Article 8.X.16.

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 showed no clinical signs of *Brucella infection* on the day of collection of the semen;
- 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 for *Brucella infection* with negative results, and the semen was collected, processed and stored in conformity with the provisions of Articles 4.5.3. to 4.5.5. and Articles 4.6.5. to 4.6.7.
- 3) ~~the semen was collected, processed and stored in conformity with the provisions of Chapter 4.5. and Chapter 4.6.~~

Article 8.X.17.

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 showed no clinical signs of *Brucella infection* on the day of collection;

- 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*, as relevant;

OR

 - b) were kept in a *herd* or *flock* free from *Brucella infection* and ~~are~~ subjected every six months to a prescribed test for *Brucella infection* 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 8.X.18.

Recommendations for the importation of fresh meat and meat products other than mentioned in Article 8.X.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 country or zone free from *Brucella infection*, as relevant;

OR

 - ab) originate from a *herd* or *flock* free from *Brucella infection*;

OR

 - bc) have not been eliminated as part of an eradication programme against *Brucella infection* have not tested positive to a prescribed test for *Brucella infection*.

Article 8.X.19.

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* in a country, zone, herd or flock free of a ~~herd or flock~~ free from *Brucella infection*;
- OR
- 2) were subjected to pasteurisation 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 8.X.20.

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~~ eliminated as part of an eradication programme against *Brucella* infection;

OR

- 2) have been processed to ensure the destruction of the *Brucella*.

Article 8.X.21.**Procedures for the inactivation of *Brucella* in casings of bovids, sheep and goats, and pigs**

For the inactivation of *Brucella* in casings of bovids, sheep and goats, and pigs, the following procedures should be used: salting for at least 30 days either with dry salt (NaCl) or with saturated brine ($A_w < 0.80$), and kept at a temperature of greater than 20°C during this entire period.