Annex 11

CHAPTER 11.5.

INFECTION WITH *MYCOPLASMA MYCOIDES* SUBSP. *MYCOIDES* ~~*SC*~~ (CONTAGIOUS BOVINE PLEUROPNEUMONIA)

Norway	**Category:** General **Proposed amended text:** not relevant **Rationale:** Norway thanks the WOAH for the work done on this chapter and would like to contribute with the comments below. **Supporting evidence:** not relevant

Article 11.5.1.

General provisions

~~1)~~ ~~For the purposes of this chapter, susceptible *animals* means domestic bovines (*Bos indicus*, *B. taurus*, *B. grunniens* and *Bubalus bubalis*).~~

1~~2~~1) For the purposes of the *Terrestrial Code*, ~~the *incubation period* for~~ contagious bovine pleuropneumonia (CBPP) ~~shall be six months.~~

~~For the purpose of this chapter,~~ is defined as an ~~*animal* *infection*~~ed ~~of susceptible animals~~ bovines (*Bos indicus*, *B. taurus*, *B. grunniens* and *Bubalus bubalis*) with *Mycoplasma mycoides* subspecies *mycoides* ~~SC~~ (*Mmm* ~~SC~~)~~.~~, ~~and freedom from CBPP means freedom from *Mmm* SC *infection*.~~

~~For the purpose of this chapter, susceptible *animals* include bovids (*Bos indicus*, *B. taurus* and *B. grunniens*) and water buffaloes (*Bubalus bubalis*)~~

2~~3~~) ~~For the purposes of *international trade*~~This chapter deals not only with the occurrence of clinical signs caused by *Mmm*~~SC~~, but also with the presence of *infection* with *Mmm*~~SC~~ in the absence of clinical signs.

3~~4~~) The following defines the occurrence of *infection* with *Mmm*~~SC~~ ~~*infection*~~:

~~1~~a) *Mmm*~~SC~~ has been isolated and identified as such in ~~from an *animal*, embryos, oocytes or semen~~ a sample from a ~~susceptible animal~~ bovine~~; or~~; or

~~2~~b) ~~*Mmm* deoxyribo~~nucleic acid specific to *Mmm* has been detected in a sample from a ~~susceptible animal~~ bovine showing pathological lesions consistent with an *infection* with *Mmm*~~SC~~, ~~and~~ or epidemiologically link~~s~~ed to a confirmed *case*~~.~~; or

c) antibodies specific to *Mmm*~~SC~~ ~~antigens,~~ which are not the consequence of *vaccination*~~,~~ have been detected in a sample from a ~~susceptible animal~~ bovine showing pathological lesions consistent with an *infection* with *Mmm*, ~~and~~ or epidemiologically link~~s~~ed to a confirmed *case*~~or *Mmm*SC deoxyribonucleic acid have been identified in one or more animals showing pathological lesions consistent with *infection* with *Mmm*SC with or without clinical signs, and epidemiological links to a confirmed *outbreak* of CBPP in susceptible *animals*~~.

Norway	**Category:** Addition **Proposed amended text:** Points b) and c) should include a link to suspected cases: “or epidemiologically linked to a confirmed or suspected case” **Rationale:** Provides with more flexibility for the Veterinary Authorities and allows to align with other case disease chapters in the Code.

~~4~~5) For ~~T~~the purposes of the *Terrestrial Code*, the *incubation period* shall be six months.

~~When authorising import or transit of the *commodities* listed in this chapter, with the exception of those listed in Article 11.5.2., *Veterinary Authorities* should require the conditions prescribed in this chapter relevant to the CBPP status of the domestic bovids and water buffalo population of the *exporting country*, *zone* or *compartment*.~~

~~5~~6) Standards for diagnosis ~~diagnostic tests~~ and vaccines, as well as information on the epidemiology, are described in the *Terrestrial Manual*.

Article 11.5.2.

Safe commodities

When authorising the importation or transit of the following *commodities*, *Veterinary Authorities* should not require any CBPP-related conditions, regardless of the ~~CBPP~~ *animal health status* of ~~the domestic bovids~~ bovine ~~and water buffalo population of~~ the *exporting country*, *zone* or *compartment*:

1) *milk* and *milk products*;

2) hides and skins;

3) *meat* and *meat products* (excluding lung);

4) *protein meal*;

5) rendered fat.

Article 11.5.3.

Country or zone free from CBPP ~~free country or zone~~

A country or *zone* may be considered free from CBPP when the relevant provisions in point 2 of Article 1.4.6. have been complied with, and when within the proposed free country or *zone* for at least the past 24 months:

1) there has been no *case* of *infection* with *Mmm*;

2) the *Veterinary Authority* has current knowledge of, and authority over, all *herds* of ~~susceptible animals~~ bovines;

3) appropriate *surveillance* has been implemented in accordance with:

   a) Article 1.4.6. where historical freedom can be demonstrated; or

   b) Articles 11.5.13. and 11.5.14. where historical freedom cannot be demonstrated;

4) measures to prevent the introduction of the *infection* have been in place; in particular, the importations or movements of bovine *commodities* into the country or *zone* have been carried out in accordance with this chapter and other relevant chapters of the *Terrestrial Code*;

5) no *vaccination* or treatment against CBPP has been carried out;

6) no animal vaccinated or treated against CBPP ~~have~~ has been introduced ~~since the cessation of *vaccination*~~.

~~To qualify for inclusion in the existing list of CBPP free countries and *zones*, a Member Country should:~~

~~1) have a record of regular and prompt animal disease reporting;~~

~~2) send a declaration to WOAH stating that:~~

~~a) there has been no *outbreak* of CBPP during the past 24 months;~~

~~b) no evidence of CBPP *infection* has been found during the past 24 months;~~

~~c) no *vaccination* against CBPP has been carried out during the past 24 months,and supply documented evidence that *surveillance* for CBPP in accordance with this chapter is in operation and that regulatory measures for the prevention and control of CBPP have been implemented;~~

~~3) not have imported since the cessation of *vaccination* any animals vaccinated against CBPP.~~

The country or *zone* will be included in the list of countries or *zones* free from CBPP in accordance with Chapter 1.6. ~~only after the submitted evidence has been accepted by WOAH~~.

Retention on the list requires annual reconfirmation of compliance with all points above and the ~~relevant~~ provisions under point 4 of Article 1.4.6. ~~that the information in points 2 *a)*, 2 *b)*, 2 *c)* and 3 above be re-submitted annually and~~ Documented evidence should be resubmitted annually for points 1 to 4 above. Any changes in the epidemiological situation or other significant events should be ~~reported~~ notified to WOAH in accordance with ~~the requirements in~~ Chapter 1.1.

Norway	**Category:** Deleted **Proposed amended text:** The following text should be deleted: **"**~~Documented evidence should be resubmitted annually for points 1 to 4 above.~~**"** **Rationale:** The annual reconfirmation process needs to be simplified to reduce the administrative burden on Member Countries. Such changes could also be required in other relevant disease-specific chapters and/or in chapter 1.6 on procedures for official recognition of animal health status, endorsement of an official control program, and publication of a self-declaration of animal health status, by WOAH.

Article 11.5.4~~6~~.

Compartment free from CBPP ~~free compartment~~

~~The bilateral recognition of a CBPP free *compartment* should follow the principles laid down in this chapter and in Chapters 4.3. and 4.4.~~

A *compartment* free from CBPP can be established in any country or *zone*. In defining such a *compartment* the principles of Chapters 4.4. and 4.5. should be followed. ~~Susceptible animals~~ Bovines in the *compartment* should be separated from any other ~~susceptible animals~~ bovines by the effective application of a *biosecurity plan*.

A Member Country wishing to establish a *compartment* free from CBPP should:

1) have a record of regular and prompt animal disease reporting and, if not free, have an *official control programme* and a *surveillance* system for CBPP in place in accordance with Articles 11.5.13. and 11.5.14. that allows knowledge of the prevalence, distribution and characteristics of CBPP in the country or *zone*;

2) declare for the free *compartment* that:

~~a) there has been no case of CBPP during the past 24 months;~~

~~b~~a) no *infection* with *Mmm* has ~~been detected~~ occurred during the past 24 months;

~~c~~b) *vaccination* against CBPP is prohibited;

~~d~~c) no animal vaccinated or treated against CBPP within the past 24 months is in the *compartment*;

~~e~~d) animals, semen and embryos may only enter the *compartment* in accordance with relevant articles in this chapter;

~~f~~e) documented evidence shows that *surveillance* in accordance with Articles 11.5.13. and 11.5.14. is in operation;

~~g~~f) an *animal identification* and *traceability* system in accordance with Chapters 4.1. and 4.2. is in place;

3) describe in detail:

a) the animal *subpopulation* in the *compartment*;

b) the *biosecurity plan* to mitigate the risks identified by the *surveillance* carried out in accordance with point 1 notably to prevent the aerosol transmission of CBPP.

The *compartment* should be approved by the *Veterinary Authority*.

Article 11.5.5.

Country ~~of~~ or zone infected with *Mmm* ~~CBPP infected country or zone~~

A country or *zone* shall be considered as infected with *Mmm* ~~W~~when the requirements for acceptance as a ~~CBPP free~~ country or *zone* free from CBPP are not fulfilled~~, a country or *zone* shall be considered as infected~~.

Article 11.5.5bis.

Establishment of a containment zone within a country or zone previously free from CBPP

In the event of *outbreaks* of ~~CBPP~~ *infection* with *Mmm* within a country or *zone* previously free from CBPP, including within a *protection zone*, a *containment zone*, which includes all epidemiologically linked *outbreaks*, ~~can~~ may be established, in accordance with Article 4.4.7., to minimise the impact on the rest of the country or *zone*.

Norway	**Category:** Addition **Proposed amended text:** The following should be added at the beginning of the paragraph above: **"**Without prejudice to other possible disease control measures including other types of zoning, in the event of *outbreaks* ...**"** **Rationale:** This is to clarify that a country may also establish other types of zones to control and eradicate an outbreak, in line with Chapter 4.4. This is not only relevant for countries that do not have an officially recognised disease status. Such changes are required in other relevant disease-specific chapters as well.

For this to be achieved and for the Member Country to take full advantage of this process, the *Veterinary Authority* should submit as soon as possible to WOAH, in addition to the requirements of Article 4.4.7., ~~in support of the application,~~ documented evidence that:

1) on suspicion, a ~~strict~~ standstill has been imposed on the suspected *establishments*, and ~~in the country or *zone* animal movement control has been imposed and~~ effective controls on the movement of animals and other relevant *commodities* are in place in the country or *zone*;

2) the *infection* has been confirmed and notified in accordance with Chapter 1.1.;

3~~2~~) on confirmation, ~~an~~ the ~~additional~~ standstill and movement ~~of susceptible animals has been imposed~~ controls described in point 1 have been reinforced ~~in the entire *containment zone* and the movement controls described in point 1 have been reinforced~~;

4~~3~~) epidemiological investigations into the likely source of the *outbreaks* have been carried out;

5~~4~~) a *slaughter* policy, with or without the use of emergency *vaccination*, has been applied;

6~~5~~) *surveillance* in accordance with Articles 11.5.13. and 11.5.14. is in place in the *containment zone* and in the rest of the country or *zone*;

7~~6~~) measures that prevent the spread of CBPP to the rest of the country or *zone*, taking into consideration physical and geographical barriers, are in place.

The free status of the areas outside the *containment zone* is suspended while the *containment zone* is being established. The free status of these areas ~~outside the *containment zone*~~ may be reinstated irrespective of the provisions of Article 11.5.4., once the *containment zone* has been approved by WOAH as complying with Article 4.4.7. and points 1 to ~~6~~ 7 above.

In the event of recurrence of *infection* with *Mmm* in the *containment zone*, established in accordance with point 4 a) of Article 4.4.7., the approval of the *containment zone* is withdrawn and the ~~CBPP~~ free status of the whole country or *zone* is suspended until the relevant requirements of Article 11.5.46. are fulfilled.

In the event of occurrence of *infection* with *Mmm* in the outer zone of a *containment zone* established in accordance with point 4 b) of Article 4.4.7., the approval of the *containment zone* is withdrawn and the free status of the whole country or *zone* is suspended until the relevant requirements of Article 11.5.46. are fulfilled.

The recovery of the ~~CBPP~~ free status of the *containment zone* should follow the provisions of Article 11.5.46.

Article 11.5.6~~4~~.

Recovery of free status

Should an *outbreak* of CBPP occur in a previously free country or *zone*, its status may be recovered when *surveillance* in accordance with Articles 11.5.13. and 11.5.14. has been carried out with negative results, and 12 months after:

1) the *disinfection* of the last affected *establishment*, provided that a *slaughter* policy without *vaccination* has been implemented; or

2) the *disinfection* of the last affected *establishment* and the *slaughter* of all vaccinated animals, provided that a *slaughter* policy with emergency *vaccination* and *slaughter* of vaccinated animals has been implemented.

~~When a CBPP *outbreak* occurs in a CBPP free country or *zone*, one of the following waiting periods is required to regain the status of CBPP free country or *zone*:~~

~~1) 12 months after the last case where a *stamping-out* policy and serological *surveillance* and strict movement control are applied in accordance with this chapter;~~

~~2) if *vaccination* was used, 12 months after the *slaughter* of the last vaccinated *animal*.~~

~~1) 12 months after the *slaughter* of the last *case* where a *slaughter* policy, without emergency *vaccination*, and *surveillance* are applied in accordance with Articles 11.5.13. and 11.5.14.; or~~

~~2) 12 months after the *slaughter* of the last *case* and of all vaccinated animals, whichever occurred last, where a *slaughter* policy, emergency *vaccination* and *surveillance* in accordance with Articles 11.5.13. and 11.5.14. are applied.~~

The country or *zone* will regain the status of CBPP free country or *zone* only after the submitted evidence, based on the provisions of Chapter 1.10., has been accepted by WOAH.

Where a ~~*stamping-out*~~ *slaughter* policy is not practised, the above waiting periods do not apply but Article 11.5.3. applies.

Article 11.5.7.

Recommendations for importation of ~~susceptible animals~~ bovines from ~~CBPP free~~ countries, ~~or~~ zones, or compartments free from CBPP ~~free compartments~~

~~For domestic bovids and water buffaloes~~

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

1) showed no clinical sign of CBPP on the day of shipment;

2) were kept in a CBPP free country, *zone* or *compartment* since birth or for at least the past six months.

Article 11.5.8.

Recommendations for importation of ~~susceptible animals~~ bovines from ~~CBPP infected~~ countries or zones infected with *Mmm* for immediate slaughter

~~For domestic bovids and water buffaloes for slaughter~~

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

1) showed no clinical sign of CBPP on the day of shipment;

2) originate from an *establishment* in which *surveillance* in accordance with Articles 11.5.13. and 11.5.14. demonstrates that ~~where~~ no *case* of CBPP ~~had~~ has occurred ~~was officially reported for~~ during the past six months; and

3) are transported ~~directly~~ under the supervision of the *Veterinary Authority* in a *vehicle/vessel*, which was subjected to *disinfection* before loading, directly from the *establishment* of origin to the ~~*slaughterhouse/abattoir*~~ *place of shipment*~~in sealed *vehicles*~~ without coming into contact with other ~~susceptible animals~~ bovines.

Article 11.5.9.

Recommendations for importation of bovine semen from ~~CBPP free~~ countries, ~~or~~ zones, or compartments free from CBPP ~~free compartments~~

~~For bovine semen~~

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

1) the donor animals:

a) showed no clinical sign of CBPP on the day of collection of the semen;

b) were kept in a CBPP free country, *zone* or *compartment* since birth or for at least the past six months;

2) the semen was collected, processed and stored in accordance with Chapters 4.6. and 4.7.

Article 11.5.10.

Recommendations for importation of bovine semen from ~~CBPP infected~~ countries or zones infected with *Mmm*

~~For bovine semen~~

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

1) the donor animals:

a) were kept since birth, or for the past six months, in an *establishment* in which *surveillance* in accordance with Articles 11.5.13. and 11.5.14. demonstrates that no *case* of *infection* with *Mmm* has occurred during that period;

~~a~~b) showed no clinical sign of CBPP on the day of collection of the semen;

~~b~~c) were subjected to ~~the complement fixation~~ a serological test for CBPP with negative results, on two occasions, with an interval of not less than 21 days and not more than 30 days between ~~each~~ samplings~~tests~~, the second sampling~~test~~ being performed within 14 days prior to collection;

~~c~~d) were isolated from other ~~domestic bovids and water buffaloes~~ ~~susceptible animals~~ bovines that did not meet the same health requirements from the day of the first ~~the complement fixation~~ serological test until collection;

~~d) were kept since birth, or for the past six months, in an *establishment* in which *surveillance* in accordance with Articles 11.5.13. and 11.5.14. demonstrates that where no case of CBPP was reported had occurred during that period, , and that the *establishment* was not situated in a CBPP infected *zone*;~~

e) AND EITHER:

i) have not been vaccinated against CBPP;

OR

ii) were vaccinated ~~using a vaccine complying with the standards described in the *Terrestrial Manual*~~ not more than four months prior to collection; in this case, the condition laid down in point (~~b~~c) above is not required;

2) the semen:

a) was collected, processed and stored in accordance with Chapters 4.~~5~~6. and 4.~~6~~7.;

b) was subjected to a test for the ~~identification~~ detection of the agent.

Article 11.5.11.

Recommendations for importation of *in vivo* derived or *in vitro* produced oocytes or embryos of ~~susceptible animals~~ bovines from ~~CBPP free~~ countries, ~~or~~ zones, or compartments free from CBPP ~~free compartments~~

~~For *in vivo* derived or *in vitro* produced oocytes or embryos of domestic bovids and water buffaloes~~

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

1) the donor animals:

   a) showed no clinical sign of CBPP on the day of collection of the oocytes or embryos;

   b) were kept in a ~~CBPP free~~ country, *zone* or *compartment* free from CBPP since birth or for at least the past six months;

2) the oocytes were fertilised with semen meeting the conditions of Article~~s~~ 11.5.9. or 11.5.10.;

3) the oocytes or embryos were collected, processed and stored in accordance with Chapters 4.8., 4.9. and 4.10., as relevant.

Article 11.5.12.

Recommendations for importation of *in vivo* derived or *in vitro* produced oocytes or embryos of ~~susceptible animals~~ bovines from ~~CBPP infected~~ countries or zones infected with *Mmm*

~~For *in vivo* derived or *in vitro* produced oocytes or embryos of domestic bovids and water buffaloes~~

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

1) the donor animals:

   a) were kept since birth, or for the past six months, in an *establishment* in which *surveillance* in accordance with Articles 11.5.13. and 11.5.14. demonstrates that no *case* of *infection* with *Mmm* has occurred during that period;

   ~~a~~b) showed no clinical sign of CBPP on the day of collection of the embryos or oocytes;

   ~~b~~c) were subjected to ~~the complement fixation~~ a serological test for CBPP with negative results, on two occasions, with an interval of not less than 21 days and not more than 30 days between ~~each~~ samplings~~tests~~, the second sampling~~test~~ being performed within 14 days prior to collection;

   ~~c~~d) were isolated from other ~~domestic bovids and water buffaloes~~ bovines that did not meet the same health requirements from the day of the first ~~the complement fixation~~ serological test until collection;

   ~~d) were kept since birth, or for the past six months, in an *establishment* in which *surveillance* in accordance with Articles 11.5.13. and 11.5.14. demonstrates that where no *case* of CBPP was reported had occurred during that period, and that the *establishment* was not situated in a CBPP infected *zone*;~~

   e) AND EITHER:

      i) have not been vaccinated against CBPP;

      OR

      ii) were vaccinated ~~using a vaccine complying with the standards described in the *Terrestrial Manual*~~ not more than four months prior to collection; in this case, the condition laid down in point (~~b~~c) above is not required;

2) the oocytes were fertilised with semen meeting the conditions of Articles 11.5.9. ~~and~~ or 11.5.10.;

3) the oocytes or embryos were collected, processed and stored in accordance with Chapters 4.8., 4.9. and 4.10., as relevant.

Article 11.5.13.

~~Introduction to surveillance~~ General principles of surveillance

Surveillance aims at identifying *infection* in bovines. Articles 11.5.13. ~~to~~ and 11.5.~~17~~14. define the principles and provide a guide for the *surveillance* of CBPP in accordance with Chapter 1.4. notably point ~~2(h)~~ 3 of Article 1.4.3. concerning quality assurance. They are applicable to Member Countries seeking establishment ~~of freedom from CBPP. Guidance is provided for Member Countries seeking reestablishment~~, maintenance or recovery of freedom from CBPP ~~for~~ at the ~~entire~~ country, ~~or for a *zone*, following an *outbreak*~~ or *compartment* level or seeking endorsement by WOAH of their *official control programme* for CBPP, in accordance with Article 11.5.13. ~~*Surveillance* aims at identifying *infection* in bovines susceptible species as indicated in Article 11.5.1.~~

1. Early detection

A *surveillance* system for early detection should be in place in accordance with Chapter 1.4. under the responsibility of the *Veterinary Authority*.

2. Demonstration of freedom

The impact and epidemiology of CBPP differ widely in different regions of the world and therefore it is impossible to provide specific recommendations for all situations. *Surveillance* strategies employed for demonstrating freedom from CBPP at an acceptable level of confidence should be adapted to the local situation. It is incumbent upon the applicant Member Country to submit a dossier to WOAH in support of its application that not only explains the epidemiology of CBPP in the region concerned but also demonstrates how all the risk factors are managed. This should include provision of science ~~scientifically~~ based supporting data. Therefore, ~~T~~there is ~~therefore~~ considerable latitude available to Member Countries to provide a well-reasoned argument to prove that the absence of ~~CBPP~~ *infection* with *Mmm* is assured at an acceptable level of confidence.

Surveillance for CBPP should be in the form of a continuing programme designed to establish that the whole territory or part of it is free from CBPP ~~*infection*~~.

A Member Country wishing to substantiate freedom from CBPP should demonstrate absence of *infection* with *Mmm* in bovines.

~~Article 11.5.14.~~

~~General conditions and methods for surveillance~~

3. WOAH endorsed official control programme

Surveillance strategies employed in support of a WOAH endorsed *official control programme* should demonstrate evidence of the effectiveness of any control strategy used and of the ability to rapidly detect all *outbreaks* of *infection* with *Mmm* ~~CBPP~~.

Considerable latitude exists for Member Countries to design and implement *surveillance* to establish that the whole country or a *zone* is free from CBPP and to understand the epidemiology of CBPP as part of the *official control programme*.

The Member Country should submit an application ~~dossier~~ to WOAH ~~in~~ supported by a dossier ~~of its application~~ that explains the epidemiology of CBPP in the region concerned and demonstrates how all the risk factors are identified and managed. This should include provision of ~~scientifically~~ science-based supporting data.

The entire investigative process should be documented within the *surveillance* programme. All the epidemiological information should be substantiated, and the results should be collated in the final report.

~~The entire investigative process should be documented within the *surveillance* system in accordance with Chapter 1.4. should be under the responsibility of the Veterinary Authority. A procedure should be in place for the rapid collection and transport of samples from suspect cases of CBPP to a laboratory for CBPP diagnoses.~~

~~2) The CBPP *surveillance* programme should:~~

~~a) include an early warning system throughout the production, marketing and processing chain for reporting suspicious cases. Farmers and workers (such as community animal health workers) who have day-to-day~~

~~contact with livestock, *meat* inspectors as well as *laboratory* diagnosticians, should report promptly any suspicion of CBPP. They should be integrated directly or indirectly (e.g. through private *veterinarians* or *veterinary para-professionals*) into the *surveillance* system. All suspect cases of CBPP should be investigated immediately. Where suspicion cannot be resolved by the epidemiological and clinical investigation, samples should be taken and submitted to a *laboratory*. This requires that sampling kits information should be substantiated, and other equipment are available for those responsible for *surveillance*. Personnel responsible for *surveillance* should be able to call for assistance from a team with expertise in CBPP diagnosis and control;~~

~~b) implement, when relevant, regular and frequent clinical inspection and testing of high-risk groups of *animals*, such as those adjacent to a CBPP infected country or *zone* (for example, areas of transhumant production systems);~~

~~c) take into consideration additional factors such as animal movement, different production systems, geographical and socio-economic factors that may influence the risk of *disease* occurrence.~~

~~An effective *surveillance* system will periodically identify suspicious cases that require follow-up and investigation to confirm or exclude that the cause of the condition is CBPP. The rate at which such suspicious cases are likely to occur will differ between epidemiological situations and cannot therefore be predicted reliably. Applications for freedom from CBPP *infection* should, in consequence, provide details of the occurrence of suspicious cases and how they were investigated and dealt with. This should include the results of *laboratory* testing and the control measures to which the *animals* concerned were subjected during the investigation (quarantine, movement stand-still orders, etc.). should be collated in the final report.~~

~~Article 11.5.15.~~

4. Surveillance strategies

~~1. Introduction~~

~~The target population for *surveillance* aimed at identifying *disease* and *infection* should cover all the susceptible species (*Bos taurus*, *B. indicus*, *B. grunniens* and *Bubalusbubalis*) within the country or *zone*.~~

~~Given the limitations of the diagnostic tools available,~~ tThe interpretation of serological *surveillance* results should be at the *herd* level rather than at the individual animal level.

Randomised *surveillance* may not be the preferred approach given the epidemiology of the disease (usually uneven distribution and potential for occult foci of *infection* in small populations) and the limited sensitivity and specificity of currently available tests. ~~Targeted~~ Risk-based *surveillance* (e.g. based on the increased likelihood of *infection* in particular localities or species, focusing on *slaughter* findings, and active clinical *surveillance*) may be the most appropriate strategy. The applicant Member Country should justify the *surveillance* strategy chosen as adequate to detect the presence of ~~CBPP~~ *infection* with *Mmm* in accordance with Chapter 1.4. ~~and the epidemiological situation.~~

~~Targeted~~ Risk-based *surveillance* may involve testing of the entire target subpopulation or a sample from it. In the latter case the sampling strategy should incorporate an epidemiologically appropriate design prevalence. The sample size selected for testing should be large enough to detect *infection* if it were to occur at a predetermined minimum rate. The sample size and expected disease prevalence determine the level of confidence in the results of the survey. The applicant Member Country should justify the choice of design prevalence and confidence level based on the objectives of *surveillance* and the epidemiological situation, in accordance with Chapter 1.4. Selection of the design prevalence in particular should be clearly based on the prevailing or historical epidemiological situation.

Regular and frequent clinical inspection and testing of high-risk groups of *animals*, such as those adjacent to a country or *zone* infected with *Mmm* (for example, areas of transhumant production systems), should be implemented when relevant.

Additional factors such as animal movement, different production systems, geographical and socio-economic factors that may influence the risk of disease introduction and occurrence should be taken into consideration.

Irrespective of the survey design selected, the sensitivity and specificity of the diagnostic tests employed are key factors in the design, sample size determination and interpretation of the results obtained. ~~Ideally, the sensitivity and specificity of the tests used should be validated.~~

5. Follow-up of suspected cases and interpretation of results

An effective *surveillance* system will identify suspected *cases* that require immediate follow-up and investigation to confirm or exclude that the cause of the condition is an *infection* with *Mmm*. Samples should be taken and submitted for diagnostic testing, unless the suspected *case* can be confirmed or ruled out by epidemiological and clinical investigation. Details of the occurrence of suspected *cases* and how they were investigated and dealt with should be documented. This should include the results of diagnostic testing and the measures applied to the animals concerned during the investigation.

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

Laboratory results should be examined in the context of the epidemiological situation.

Article 11.5.14.

Methods of surveillance

1. Clinical surveillance

Clinical *surveillance* aims at detecting clinical signs of CBPP in a *herd* by ~~close~~ a thorough physical examination of ~~susceptible *animals*~~ bovines. Clinical inspection is an important component of CBPP *surveillance* contributing to reaching the desired level of confidence of detection of disease if a sufficiently large number of ~~clinically susceptible *animals*~~ bovines ~~is~~ are examined.

~~Clinical *surveillance* and *laboratory* testing should always be applied in series to clarify the status of CBPP suspects detected by either of these complementary diagnostic approaches. *Laboratory* testing and post-mortem examination may contribute to confirm clinical suspicion, while clinical *surveillance* may contribute to confirmation of positive serology. Any sampling unit within which suspicious *animals* are detected should be classified as infected until contrary evidence is produced.~~

~~3~~2. Pathological surveillance

Systematic pathological *surveillance* for CBPP is the most effective approach and should be conducted at ~~*slaughterhouses/abattoirs* and other~~ *slaughter* ~~facilities~~. Suspect pathological findings should be confirmed by agent identification. Training courses for *slaughter* personnel and *meat* inspectors are highly recommended.

~~4.~~ ~~Serological~~ 3. Laboratory testing

Serological *surveillance* is not the preferred strategy for CBPP. However, in the framework of epidemiological investigations, serological testing may be used.

The limitations of available serological tests for CBPP make the interpretation of results difficult and useful only at the *herd* level. Positive findings should be followed up by clinical and pathological investigations and agent identification.

Clustering of seropositive reactions should be expected in CBPP ~~*infections*~~ and is usually accompanied by clinical signs. As clustering may signal field strain *infection*, the investigation of all instances should be incorporated into the *surveillance* strategy.

Following the identification of a CBPP infected *herd*, contact *herds* should be tested serologically. Repeated testing may be necessary to reach an acceptable level of confidence in *herd* classification.

~~5.~~ ~~Agent surveillance~~

Agent *surveillance* should be conducted to ~~follow up and~~ confirm or exclude *infection* with *Mmm*. ~~suspect *cases*. Isolates should be typed to confirm *Mmm*SC.~~

~~Article 11.5.16.~~

~~**Countries or zones applying for recognition of freedom from CBPP**~~

~~In addition to the general conditions described in this chapter, a Member Country applying for recognition of CBPP freedom for the country or a *zone* should provide evidence for the existence of an effective *surveillance* programme. The strategy and design of the *surveillance* programme depend on the prevailing epidemiological circumstances and should be planned and implemented in accordance with general conditions and methods in this chapter, to demonstrate absence of CBPP *infection*, during the preceding 24 months in susceptible populations. This requires the support of a national or other *laboratory* able to undertake identification of CBPP *infection*.~~

~~Article 11.5.17.~~

~~**Countries or zones re-applying for recognition of freedom from CBPP following an outbreak**~~

~~In addition to the general conditions described in this chapter, a Member Country re-applying for recognition of country or *zone* freedom from CBPP should show evidence of an active *surveillance* programme for CBPP, following the recommendations of this chapter.~~

~~Two strategies are recognised by WOAH in a programme to eradicate CBPP *infection* following an *outbreak*:~~

~~1) *slaughter* of all clinically affected and in-contact susceptible animals;~~

~~2) *vaccination* used without subsequent *slaughter* of vaccinated animals.~~

~~The time periods before which an application can be made for re-instatement of freedom from CBPP depends on which of these alternatives is followed. The time periods are prescribed in Article 11.5.4.~~

Article 11.5.15~~18~~.

WOAH endorsed official control programme for CBPP

~~The overall objective of a WOAH endorsed *official control programme* for CBPP is for Member Countries to progressively improve their situation and eventually attain CBPP free status. The *official control programme* should be applicable to the entire country even if certain measures are directed towards defined subpopulations.~~

A Member Country~~ies~~ may, on a voluntary basis, apply for endorsement of ~~their~~ its *official control programme* for CBPP in accordance with Chapter 1.6., when ~~they have~~ it has implemented measures in accordance with this article.

For an *official control programme* for CBPP to be endorsed by WOAH, the Member Country should provide a detailed *official control programme* for the control and eventual eradication of CBPP in the country or *zone*. This document should address and provide documented evidence on the following:

1) epidemiology:

   a) the detailed epidemiological situation of CBPP in the country, highlighting the current knowledge and gaps;

   b) the main production systems and movement patterns of ~~susceptible animals~~ bovines and their products within and into the country and, where applicable, the specific *zone*;

2) surveillance and diagnostic capabilities:

a) CBPP *surveillance* in place, in accordance with Chapter 1.4. and Articles 11.5.13. and 11.5.14.;

b) diagnostic capability and procedures, including regular submission of samples to a laboratory that performs diagnostic testing and further characterisation of strains in accordance with the *Terrestrial Manual* including procedures to isolate and identify *Mmm*;

3) vaccination (if practised as part of the *official control programme* for CBPP):

a) *vaccination* is in accordance with Chapter 4.18. and compulsory in the target *population*;

b) detailed information on *vaccination* campaigns, in particular:

i) the strategy that is adopted for the *vaccination* campaign;

ii) target *populations* for *vaccination*;

iii) target geographical area for *vaccination*;

iv) monitoring of *vaccination* coverage, including serological monitoring of population immunity;

v) the strategy to identify vaccinated animals;

vi) technical specification of the vaccines used and description of the vaccine licensing procedures in place;

vii) use of vaccines fully compliant with the standards and methods described in the *Terrestrial Manual*;

viii) the proposed strategy and work plan including the timeline for transition to the cessation of *vaccination*;

4) the measures implemented to prevent the introduction of the pathogenic agent and to ensure the rapid detection of all CBPP *outbreaks*;

5) an emergency preparedness plan and an emergency response plan to be implemented in case of CBPP *outbreaks*;

6) work plan and timelines of the *official control programme*;

7) performance indicators for assessing the effectiveness of the control measures to be implemented;

8) monitoring, evaluation and review of the *official control programme* to demonstrate the effectiveness of the strategies.

~~1) have a record of regular and prompt animal disease reporting in accordance with the requirements in Chapter 1.1.;~~

~~2) submit documented evidence of the capacity of *Veterinary Services* to control CBPP; this evidence can be provided by countries following the WOAH PVS Pathway;~~

~~3) submit a detailed plan of the programme to control and eventually eradicate CBPP in the country or *zone* including:~~

~~a) the timeline;~~

~~b) the performance indicators for assessing the efficacy of the control measures to be implemented;~~

~~c) submit documentation indicating that the *official control programme* for CBPP has been implemented and is applicable to the entire territory;~~

4) submit a dossier on the epidemiology of CBPP in the country describing the following:

   a) the general epidemiology in the country highlighting the current knowledge and gaps;

   b) the measures to prevent introduction of *infection*, the rapid detection of, and response to, all CBPP *outbreaks* in order to reduce the incidence of CBPP *outbreaks* and to eliminate CBPP in at least one *zone* in the country;

   c) the main livestock production systems and movement patterns of CBPP susceptible animals and their products within and into the country;

5) submit evidence that CBPP *surveillance* is in place,

   a) taking into account provisions in Chapter 1.4. and the provisions on *surveillance* of this chapter;

   b) have diagnostic capability and procedures, including regular submission of samples to a *laboratory* that carries out diagnosis and further characterisation of strains in accordance with the *Terrestrial Manual* including procedures to isolate and identify *M. mycoides* subsp. *mycoides* SC as opposed to *M. mycoides* subsp. *mycoides* LC;

6) where *vaccination* is practised as a part of the *official control programme* for CBPP, provide:

   a) evidence (such as copies of legislation) that *vaccination* of selected populations is compulsory;

   b) detailed information on *vaccination* campaigns, in particular on:

      i) target populations for *vaccination*;

      ii) monitoring of *vaccination* coverage;

      iii) technical specification of the vaccines used and description of the licensing procedures in place;

      iv) the proposed timeline and strategy for the cessation of *vaccination*;

7) provide an emergency preparedness and contingency response plan to be implemented in case of CBPP *outbreaks*.

The Member Country's *official control programme* for CBPP will be included in the list of programmes endorsed by WOAH only after the submitted evidence has been accepted by WOAH.

The country will be included in the list of countries having a WOAH endorsed *official control programme* for CBPP in accordance with Chapter 1.6.

Retention on the list requires an annual update on the progress of the *official control programme* and information on significant changes concerning the points above. Changes in the epidemiological situation and other significant events should be reported to WOAH in accordance with the requirements in Chapter 1.1.

WOAH may withdraw the endorsement of the *official control programme* if there is evidence of:

– non-compliance with the timelines or performance indicators of the programme; or

– significant problems with the performance of the *Veterinary Services*; or

– an increase in the incidence of CBPP that cannot be addressed by the programme.