Annex XXXVIII

**USA Comments**

CHAPTER X.X.

# INFECTION WITH PORCINE REPRODUCTIVE AND RESPIRATORY SYNDROME VIRUS

Article X.X.1.

**General provisions**

The pig is the only natural host for porcine reproductive and respiratory syndrome virus (PRRSV).

For the purposes of the *Terrestrial Code,* porcine reproductive and respiratory syndrome (PRRS) is defined as an *infection* of domestic and *captive wild* pigs with PRRSV together with clinical disease or outbreak characteristic of PRRS.

The following defines *infection* with PRRSV:

1) a strain of PRRSV has been isolated from samples from a domestic or *captive wild* pig that is epidemiologically linked to a confirmed or suspected case of PRRS, or giving cause for suspicion of previous association or contact with the PRRSV, with or without clinical signs consistent with PRRS;

**Rationale**: PRRSV nucleic acid may be detectable due to vaccination. The text regarding the expectation of the presence of nucleic acid with or without clinical signs is not clear. With vaccination PRRSV nucleic acid may be detected even though there are no clinical signs and no wild PRRSV infection.

OR

2) viral antigen has been identified, or viral ribonucleic acid specific to PRRSV has been demonstrated to be present, in samples from a domestic or *captive wild* pig epidemiologically linked to a confirmed or suspected *outbreak* of PRRS, or giving cause for suspicion of previous association or contact with PRRSV, with or without clinical signs consistent with PRRS;

OR

3) virus-specific antibodies against PRRSV that are not a consequence of *vaccination*, have been identified in samples from a domestic or *captive wild* pig in a *herd* showing clinical signs consistent with PRRS, or epidemiologically linked to a confirmed or suspected *outbreak* of PRRS, or giving cause for suspicion of previous association or contact with PRRSV;

OR

4) the detection of a vaccinal or vaccine-like virus in a non-vaccinated domestic or *captive wild* pig in a heard showing clinical sings consistent with PRRS, or epidemiologically linked to a confirmed or suspected outbreak of PRRS, or giving cause for suspicion of previous association or contact with PRRSV..

**Rationale:** Since PRRS is a disease syndrome, the definition includes the presence of the diseases syndrome in conjunction with the etiological agent (the PRRSV). Presence of vaccine strains or antibodies in the absence of clinical signs of disease is not the PRRS syndrome – this appears to fit the intent of the *Terrestrial Code*.

For the purposes of the *Terrestrial Code*, the *incubation period* for PRRS is 14 days. Pigs are usually infective between days 3 and 40 post-*infection*, but can remain so for several months.

A Member Country should not impose bans on the trade in *commodities* of domestic and *captive wild* pigs in response to information on the presence of *infection* with PRRSV in *wild* or *feral* pigs.

Standards for diagnostic tests and vaccines are described in the *Terrestrial Manual.*

Article X.X.2.

**Safe commodities**

When authorising import or transit of the following *commodities* and any products made from these *commodities* and containing no other tissues from pigs, *Veterinary Authorities* should not require any PRRS related conditions, regardless of the PRRS status of the *exporting country, zone* or *compartment*:

1) hides, skins and trophies;

2) bristles;

3) *meat products*;

4) *meat-and-bone meal*;

5) blood by-products;

6) casings.

Article X.X.3.

**Country, zone or compartment free from PRRS**

A country, *zone* or *compartment* may be considered free from PRRS when:

1) PRRS is a *notifiable disease* in the country;

2) an *early detection system* is in place;

3) *surveillance* in accordance with Articles X.X.15. to X.X.18. has been in place for at least 12 months, capable of detecting the presence of *infection* with PRRSV even in the absence of clinical signs;

4) no evidence of *infection* with PRRSV has been found in domestic and *captive wild* pigs during the past 12 months;

5) no *vaccination* against PRRS has been carried out during the past 12 months;

6) measures are in place to prevent the introduction of PRRSV;

7) imported pigs and pig *commodities* comply with the requirements in Articles X.X.5. to X.X.14.

Article X.X.4.

**Recovery of free status**

Should a PRRS *outbreak* occur in a free country, *zone* or *compartment* the free status may be restored by means of a *stamping-out policy* or a *modified stamping-out policy* with or without emergency *vaccination.* Free status can be regained three months after the culling of the last *case* or vaccinated pig provided *surveillance* is carried out, in accordance with Articles X.X.15. to X.X.18., with negative results.

Where a *stamping-out policy* or *modified stamping-out policy* is not practised, the provisions of Article X.X.3. apply.

Article X.X.5.

**Recommendations for importation from countries, zones or compartments free from PRRS**

For domestic and captive wild pigs

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

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

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

Article X.X.6.

**Recommendations for importation from countries or zones not free from PRRS**

For domestic and captive wild pigs for breeding or rearing

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

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

2) have not been vaccinated against PRRS nor are they the progeny of vaccinated sows;

3) were isolated and subjected to a serological test for PRRS, with negative results, on two occasions, at an interval of not less than 21 days, the second test being performed within 15 days prior to shipment.

Article X.X.7.

**Recommendations for importation from countries or zones not free from PRRS**

For domestic and captive wild pigs for *slaughter*

*Veterinary Authorities* should require the presentation of an *international veterinary certificate* attesting that the *animals* showed no clinical sign of PRRS on the day of shipment.

The pigs should be transported directly from the *place of shipment* to the *slaughterhouse/abattoir* for immediate *slaughter*.

**Comment:** What does "immediate" mean? Within 48 hours? Within 2 weeks of importation? May need to define this term.

Article X.X.8.

**Recommendations for importation of wild and feral pigs**

Regardless of the PRRS status of the country of origin, *Veterinary Authorities* should require the presentation of an *international veterinary certificate* attesting that the *animals:*

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

2) were isolated in a *quarantine station*, and were subjected to a serological test for PRRS, with negative results, on two occasions, at an interval of not less than 21 days, the second test being performed within 15 days prior to shipment;

3) have not been vaccinated against PRRS.

Article X.X.9.

**Recommendations for importation from countries, zones or compartments free from PRRS**

For semen of domestic and captive wild pigs

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

1) the donor *animals*:

   a) were kept in a country, *zone* or *compartment* free from PRRS since birth or for at least three months prior to collection;

   b) showed no clinical sign of PRRS on the day of collection of the semen;

2) the semen was collected, processed and stored in conformity with the provisions of Chapters 4.5. and 4.6.

Article X.X.10.

**Recommendations for importation from countries or zones not free from PRRS**

For semen of domestic and captive wild pigs

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

1) the donor *animals* have not been vaccinated against PRRS;

   a) and either:

      i) were kept, since birth or for at least three months prior to entry into the pre-entry isolation facility in an *establishment* without any evidence of PRRS ;

      ii) showed no clinical sign of PRRS and were serologically tested with negative results on the day of entry into the pre-entry isolation facility;

      iii) were kept in the pre-entry isolation facility for at least 28 days and were subjected to a serological test with negative results at least 21 days after entry;

      iv) have been kept in an *artificial insemination centre* where all boars are subjected, at least every month, to a serological test for PRRS with negative results;

   b) or

      i) have been kept in an *artificial insemination centre* where all boars were seronegative for PRRS on the day of collection;

      ii) a sample of semen from each collection for export has been tested for PRRSV nucleic acid with negative results;

2) the semen was collected, processed and stored in conformity with the provisions of the relevant Articles in Chapters 4.5. and 4.6.

Article X.X.11.

**Recommendations for importation of *in vivo* derived embryos of domestic and captive wild pigs**

Regardless of the PRRS status of the country of origin, *Veterinary Authorities* should require the presentation of an *international veterinary certificate* attesting that:

1) the donor females showed no clinical sign of PRRS on the day of collection of the embryos;

and

2) tested negative using the PCR test; and

**Rationale:** for donor females, adult, non-late gestation, females are particularly resistant to clinical signs. See: W T Christianson, C S Choi, J E Collins, T W Molitor, R B Morrison, and H S Joo. 1993. Pathogenesis of porcine reproductive and respiratory syndrome virus infection in mid-gestation sows and fetuses.Can J Vet Res. Oct 1993; 57(4): 262–268. PMCID: PMC1263638

3) the embryos were collected, processed and stored in conformity with the relevant provisions of Chapters 4.7. and 4.9.

Article X.X.12.

**Recommendations for importation of fresh meat of domestic and captive wild pigs**

Regardless of the PRRS status of the country of origin, *Veterinary Authorities* should require the presentation of an *international veterinary certificate* attesting that the entire consignment of *fresh meat*;

1) does not contain lymphoid tissues of the head and neck, and thoracic and abdominal viscera; and

2) comes from *animals* which:

   a) showed no clinical signs suggestive of PRRS within 24 hours before *slaughter*;

   b) have been slaughtered in a *slaughterhouse/abattoir* and have been subjected to ante- and post-mortem inspections in accordance with Chapter 6.2.

Article X.X.13.

**Recommendations for importation of fresh meat of wild and feral pigs**

Regardless of the PRRS status of the country of origin, *Veterinary Authorities* should require the presentation of an *international veterinary certificate* attesting that the entire consignment of *fresh meat*;

1) does not contain lymphoid tissues of the head and neck, and thoracic and abdominal viscera; and

2) comes from *animals* which:

   a) have been subjected to a post-mortem inspection in accordance with Chapter 6.2. in an approved examination centre;

   b) have been found free from any sign suggestive of PRRS.

~~Article X.X.14.~~

~~**Recommendations for importation of offal**~~

~~*Veterinary Authorities* should require the presentation of an *international veterinary certificate* attesting that the entire consignment of offal or products containing offal comes from pigs coming from *establishments* located in a PRRS-free country, *zone* or *compartment*.~~

**Rationale:** The United States recommends deleting this Article. According to this Article, offal can only be imported into a PRRS-free country from a PRRS-free country. There is no scientific published data on the risk of offal to PRRSV introduction. Recommendations should be based on the availability of good science, not on the absence of any science.

Article X.X.15.

**Introduction to surveillance**

The following defines the principles and provides a guide to the *surveillance* for PRRS, complementary to Chapter 1.4. This may be for the entire country, a *zone* or a *compartment*. Guidance is also provided for Member Countries seeking recovery of PRRS status for the entire country, for a *zone* or for a *compartment*, following an *outbreak* and for the maintenance of PRRS status.

*Surveillance* for PRRS should be in the form of a continuing programme designed to establish that domestic and *captive wild* pig populations in a country, *zone* or *compartment* are free from *infection* with PRRSV or to detect the introduction of PRRSV into a population already defined as free. Consideration should be given to the specific characteristics of PRRS epidemiology which include:

– the role of semen in transmission of the virus;

– the role of pig-to-pig contact

**Rationale**: pig-to-pig contact is the primary route of PRRSV transmission. This should be explicitly stated.

– the ~~existence~~ possibility of aerosol transmission ~~over short distances~~;

**Rationale:** Although aerosol transmission of PRRSV over short distances has been demonstrated, the relative risk of PRRSV transmission via aerosol still remains under scientific study. The research on aerosol transmission is equivocal (a summary of such results with references is attached).

Including the qualifier "over short distances" leaves the impression that aerosol transmission is scientifically verified for other distances as well; hence the United States recommends deleting this part of the text.

– the existence of two distinct genotypes of PRRSV, also with antigenic and virulence variability among strains of both genotypes;

– the frequency of clinically inapparent *infections*, particularly in older *animals*;

– the occurrence of long-term virus-shedding even in the presence of antibodies;

– the lack of a differentiating test for vaccinal antibodies and the inherent risks associated with the use of modified live vaccines for PRRS.

*Veterinary Authorities* may have information on the genotype prevailing in the country but the absence of the other genotype should not be assumed. Therefore, molecular and serological tests used for *surveillance* should be able to detect both genotypes and antibodies to both genotypes with similar sensitivity.

Article X.X.16.

**General conditions and methods for surveillance**

1) A *surveillance* system in accordance with Chapter 1.4. and under the responsibility of the *Veterinary Authority* should be in place including the following aspects:

   a) formal and on-going system for detecting and investigating *outbreaks* of PRRS;

   b) a system for recording, managing and analysing diagnostic and *surveillance* data.

2) The PRRS *surveillance* programme should:

   a) include a system for reporting suspected *cases*. Diagnosticians and those with regular contact with pigs should report promptly any suspicion of PRRS to the *Veterinary Authority*;

   b) implement, when relevant, regular and frequent clinical inspections and *laboratory* testing of populations at high risk of contracting or spreading *disease*, such as *artificial insemination centres* and nucleus *herds*, establishments in high pig density areas or with low biosecurity measures.

Article X.X.17.

**Surveillance strategies**

1. Introduction

   The objective of *surveillance* is to demonstrate freedom from *infection* or to detect introduction of PRRSV as soon as possible.

   Serology in unvaccinated populations is often the most effective and efficient *surveillance* methodology. In some *animals*, antibodies against PRRSV can disappear after approximately three to six months in the absence of further exposure and this should be considered when interpreting serological *surveillance* results.

In some circumstances such as clinical *disease* investigations and in high risk populations, virological *surveillance* may provide advantage through earlier detection.

   The *surveillance* strategy chosen should be justified as adequate to detect the presence of *infection* with PRRSV in accordance with Chapter 1.4. and the epidemiological situation. Cumulative results of targeted and general *surveillance* will increase the level of confidence in the *surveillance* strategy.

2. Clinical surveillance

   Clinical signs and pathological findings are useful for early detection. Episodes of high morbidity or mortality in young piglets and reproductive disorders in sows should also be investigated. Highly pathogenic strains may affect pigs of all ages and can include severe respiratory signs. In PRRSV *infections* involving low virulence strains, clinical signs may not be present or are seen only in young *animals*. Therefore, clinical *surveillance* should be supplemented by serological and virological *surveillance*.

3. Virological surveillance

   Virological *surveillance* should be conducted to investigate clinically suspect cases. Molecular detection methods are most commonly used for virological *surveillance* and can be also applied to large-scale screening. If targeted at high-risk populations, they provide an opportunity for early detection that can considerably reduce the subsequent spread of *disease*. Molecular analysis can

provide valuable information on genotype circulating in the country and enhance epidemiological understanding of the pathways of spread in endemic areas and those involved in *outbreaks* in *disease* free areas.

4. Serological surveillance

Maternal antibodies are generally detectable until four to eight weeks of age. The collection of samples should therefore take account of the type of *herd* and the age structure of the pigs, with an emphasis on older *animals*. However, in countries or *zones* where *vaccination* has been recently discontinued, targeted serological *surveillance* of young unvaccinated *animals* can indicate the presence of *infection*.

**Comment:** Serological surveillance of young, unvaccinated animals in herds where vaccination was recently discontinued is of uncertain value. Positive results might be due to maternal antibodies or to presence of infection. The United States recommends the OIE re-evaluate this statement.

Article X.X.18.

**Additional surveillance requirements for recovery of free status**

In addition to the general conditions described in this chapter, a Member Country declaring the recovery of country, *zone* or *compartment* PRRS free status should provide evidence of an active *surveillance* programme to demonstrate absence of *infection* with PRRSV.

This *surveillance* programme should cover:

1) *establishments* in the proximity of the *outbreaks*;

2) *establishments* epidemiologically linked to the *outbreaks*;

3) *animals* moved from or used to re-populate affected *establishments*.

The pig *herds* should undergo regular clinical, pathological, virological and serological examinations, planned and implemented according to the general conditions and methods described in these recommendations. To regain PRRS free status, the *surveillance* approach should provide at least the same level of confidence as within the original declaration of freedom.

---

- - - - - - - - - - - - - -

— Text deleted.