

## NOTE:

The rationale for this new chapter is contained in the February 2014 and September 2015 Scientific Commission meeting reports. (<http://www.oie.int/en/international-standard-setting/specialists-commissions-groups/scientific-commission-reports/meetings-reports/>)

## USA Comments notes in blue font

### CHAPTER 15.X.

## INFECTION WITH PORCINE REPRODUCTIVE AND RESPIRATORY SYNDROME VIRUS

#### Article 15.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.

#### Rationale:

The United States believes that differentiating captive wild pigs from domestic pigs is prudent and does not support the inclusion of “captive wild pigs” in the same category as domestic pigs in this nor any other swine disease Chapter. In the United States, and other Member countries, **the population of “captive wild pigs” does not comingle with domestic swine. Captive wild pigs present a higher risk than domestic pigs.** The inclusion of “captive wild pigs” in the same category as domestic pigs could support a Member Country imposing bans on the trade of commodities of domestic pigs in response to a notification of infection with PRRSV in captive wild pigs. Therefore, we urge the Commission to reconsider placing “captive wild pigs” in the same category as domestic production pigs. We have noted this recommended change throughout the chapter.

The following defines *infection* with PRRSV:

1) a strain of PRRSV has been isolated from samples from a domestic ~~or captive wild~~ pig;

OR

2) ~~viral antigen has been identified, or viral ribonucleic acid specific to PRRSV, which is not a consequence of vaccination, has been demonstrated to be present detected~~ 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) antigen or ribonucleic acid specific to a PRRSV vaccine strain has been detected in samples from a domestic ~~or captive wild~~ pig that is unvaccinated, or has been vaccinated with an inactivated vaccine, or with a different vaccine strain;

OR

3) ~~virus-specific antibodies specific against to 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.~~

For the purposes of the *Terrestrial Code*, the *incubation period* for PRRS is shall be 14 days. Pigs are usually infective between days 3 three and 40 days 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. Commodities of domestic or captive wild pigs can be traded safely according to the relevant articles of this chapter, even if exporting countries inform the OIE of the presence of infection with PRRSV in wild, captive wild or feral pigs.~~

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

#### Article 15.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) fresh meat & meat products;
- 4) *meat-and-bone meal*;
- 5) ~~blood by-products~~ blood by products;
- 6) casings;
- 6) gelatine.

##### Rationale:

Fresh meat belongs to the list of safe commodities. In addition, blood by-products which had been on the list, should be reinstated to the list. The OIE ad hoc group on PRRSV, as well as the Scientific Commission for Animal Diseases (SCAD) and the European Food Safety Authority, had made the same determination. In its 23-25 June 2015 report, the ad hoc group on PRRSV notes that "The experts agreed that based on their experience and on current scientific literature, there was no evidence to suggest that meat, as defined in the *Terrestrial Code*, poses a risk for transmission of PRRS virus.", and should be considered as safe provided that they have been derived from pigs that have passed ante- and post-mortem inspections in accordance with Chapter 6.2. It was also noted that blood by-products were included in the definition of meat. Considering the epidemiology of the disease, the Group concluded that these commodities as defined in the *Terrestrial Code*, pose no additional risk for transmission of PRRS virus".

Further, data from PRRSV free countries demonstrate the lack of additional risk through the legal importation of pork and pork products from PRRSV positive countries. Since the late 1980's when PRRSV was first observed in the EU, countries such as Sweden, Norway, Finland, and Switzerland have remained PRRSV-free. Prior to 2002, the feeding of swill to pigs was legal in all four countries. Indeed, during the 13 year period between 1990, when PRRSV became established in the EU, and 2002, when the ban on swill feeding was implemented, the total amount of pork imported into Sweden, Norway, Finland and Switzerland from PRRSV-positive countries was more than 500,000 tons without a single PRRS outbreak linked to imported pork products. The historical data supports the fact that the risk of introducing PRRSV through the legal importation of fresh/chilled/frozen pork is virtually non-existent. Between 1990 and 2001, New Zealand remained PRRSV free while importing more than 59,000 tons of pork from PRRSV-positive countries, including between 1998 and 2001, a period in which there were no restrictions on swill feeding and over 40,000 tons of pork were imported from PRRSV-endemic countries, accounting for approximately 80% of total pork imports (Murray, Noel, and Howard Pharo. 2006. "Import risk analysis: Porcine reproductive and respiratory syndrome (PRRS) virus in pig meat." In *Biosecurity New Zealand Ministry of Agriculture and Forestry*. Wellington, New Zealand). This additional evidence shows that these commodities present no risk.

## Article 15.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 15.X.4513. to 15.X.4816. 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 with inactivated vaccines has been carried out during the past 12 months;
- 6) no vaccination against PRRS with modified live vaccines has been carried out during the past 24 months;
- 7) measures are in place to prevent the introduction of PRRSV;
- 8) imported pigs and pig *commodities* comply with the requirements in Articles 15.X.5. to 15.X.4412.

## Article 15.X.4.

**Recovery of free status**

Should a PRRS *outbreak* occur in a previously free country, zone or compartment, the free status may be restored three months after the disposal or slaughter of the last case, provided that:

- = by means of a stamping-out policy or the slaughter of all susceptible animals in the infected herds, followed by cleaning and disinfection of the farm establishments, has been implemented, 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 has been carried out in accordance with Articles 15.X.4513. to 15.X.4816. with negative results.

Where a stamping-out policy or depopulation by means of slaughter modified stamping-out policy is are not practised, the provisions of Article 15.X.3. applies.

## Article 15.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 15.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 pigs:~~

- 1) were kept, since birth or for at least three months prior to isolation in an establishment, in which no infection with PRRSV was detected within that period;
- 2) showed no clinical sign of PRRS on the day of shipment;
- 3) have not been vaccinated against PRRS nor are they the progeny of vaccinated sows;

- 34) were isolated by application of biosecurity and subjected to a serological test for infection with PRRSV, 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 15.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 with appropriate biosecurity from the *place of shipment* to the *slaughterhouse/abattoir* for immediate *slaughter*.

~~Article 15.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 15.X.9~~8~~.

**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* males:
  - 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 15.X.10~~9~~.

**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* males have not been vaccinated against PRRS and either:
  - 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, in which no infection with PRRSV was detected within that period without any evidence of PRRS;
    - ii) showed no clinical sign of PRRS and were ~~serologically tested~~ subjected to a serological test 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~~ no less than 21 days after entry;

- iv) have been kept in an *artificial insemination centre* where a statistically representative sample of all donor males is subjected ~~are all boars are subjected~~, at least every month, to a serological test for *infection with PRRSV* with negative results, at least every month. Donor males should be tested every 12 months and at least once during their stay;

or

- b) ~~or have been kept in an *artificial insemination centre* where all pigs~~
- i) ~~have been kept in an *artificial insemination centre* where all boars were~~ subjected to serological and virological examinations for *infection with PRRSV*, on serum samples taken ~~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 or~~
- 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 15.X.110.

**Recommendations for importation of *in vivo* derived embryos of domestic ~~and captive wild~~ pigs from countries, zones or compartments free from PRRS**

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 were kept in a country, zone or compartment free from PRRS since birth or for at least three months prior to collection;
- 2) the donor females showed no clinical sign of PRRS on the day of collection of the embryos;
- 3) the embryos were collected, processed and stored in conformity with the relevant provisions of in accordance with Chapters 4.7. and or 4.9., as relevant;
- 4) the semen used for the production of embryos complied with the provisions of Article 15.X.98. or 15.X.109.

Article 15.X.111.

**Recommendations for importation of *in vivo* derived embryos of domestic ~~and captive wild~~ pigs from countries or zones not free from PRRS**

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

- 1) the donor females:
  - a) showed no clinical sign of PRRS on the day of collection of the embryos;
  - b) were subjected to a serological test for *infection with PRRSV*, 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 embryo collection;
- 2) the embryos were collected, processed and stored in accordance with Chapters 4.7. or 4.9., as relevant;
- 3) the semen used for the production of embryos complied with the provisions of Article 15.X.98. or 15.X.109.

~~Article 15.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) ~~either:~~
    - a) ~~comes from pigs that were kept in a country, zone or compartment free from PRRS since birth or for at least the past three months;~~
- ~~or~~
- b) ~~does not contain:~~
    - ~~— tonsils;~~

~~== thymus;~~

~~== lymph nodes of the head, neck, or thoracic or abdominal viscera;~~

### Rationale:

As noted in the rationale under Article 15.X.2 (Safe Commodities), there is no strong evidence that clearly indicates that these commodities listed in 15.X.12. should have any restrictions. Indeed, the Code recommendations are all risk based, and not based on “zero” risk. This was a determination also made by the expert ad hoc Group on PRRS.

12) comes from pigs that have been slaughtered in a slaughterhouse/abattoir and have been subjected to ante- and post-mortem inspections in accordance with Chapter 6.2. with favourable results.

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 15.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 15.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.~~

~~Article 15.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 that include:

== the role of pig-to-pig contact;

– the role of semen in transmission of the virus;

- the ~~existence~~ occurrence of aerosol transmission ~~over short distances~~;
- 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~~ pigs;
- 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 it should not be assumed that the absence of the other genotype should not be assumed is absent. Therefore, molecular virological and serological tests used for *surveillance* should be able to detect both genotypes and antibodies to both genotypes with similar sensitivity.

Article 15.X.1614.

#### 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 and including include the following aspects elements:
  - 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~~ Any PRRS *surveillance* programme should:
  - a) ~~include a system for the~~ reporting and investigation of 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 lax~~ biosecurity measures.

Article 15.X.1715.

#### Surveillance strategies

##### 1. Introduction

The objective of the *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~~ pigs, 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 the absence of a test differentiating infected from vaccinated animals (DIVA), serology in vaccinated populations is less useful.

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;

- a) to monitor at risk populations;
- b) to investigate clinically suspected cases;

c) to follow up positive serological results.

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 pigs. However, in countries or *zones* where *vaccination* has been recently discontinued, targeted serological *surveillance* of young unvaccinated ~~animals~~ pigs older than eight weeks can indicate the presence of *infection*.

Article 15.X.1016.

**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~~ pigs moved from or used to repopulate 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.~~

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— Text deleted.