Annex XXXVI

CHAPTER 15.3.

CLASSICAL SWINE FEVER

EU position

The EU supports the adoption of the modified chapter.

Article 15.3.1.

General provisions

For the purposes of *international trade*, classical swine fever (CSF) is defined as an *infection* of domestic pigs.

Domestic pig is defined as 'all domesticated pigs, permanently captive or farmed free range, used for the production of *meat* for consumption, for the production of other commercial products or for breeding these categories of pigs.

The pig is the only natural host for classical swine fever (CSF) virus. The definition of pig includes all varieties of *Sus scrofa*, both domestic and wild. For the purposes of this chapter, a distinction is made between domestic pig and wild pig (including feral pigs) populations.

Pigs exposed to CSF virus prenatally may be persistently infected throughout life and may have an *incubation period* of several months before showing signs of *disease*. Pigs exposed postnatally have an *incubation period* of 2-14 days, and are usually infective between post-infection days 5 and 14, but up to 3 months in cases of chronic *infections*.

For the purposes of *international trade*, a Member should not impose trade bans in response to a notification of *infection* with classical swine fever virus in wild pigs according to Article 1.2.3. of the *Terrestrial Code* after the Member confirms that Article 15.3.2. is appropriately implemented.

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

Article 15.3.2.

Determination of the CSF status of a country, zone or compartment

The CSF status of a country, *zone* or *compartment* can only be determined after considering the following criteria in domestic and wild pigs, as applicable:

1. CSF should be notifiable in the whole territory, and all clinical signs suggestive of CSF should be subjected to appropriate field and/or *laboratory* investigations;

2. an on-going awareness programme should be in place to encourage reporting of all *cases* suggestive of CSF;

3. the *Veterinary Authority* should have current knowledge of, and authority over, all domestic pigs in the country, *zone* or *compartment*;

4. the *Veterinary Authority* should have current knowledge about the population and habitat of wild pigs in the country or *zone*;

5. for domestic pigs, appropriate *surveillance*, capable of detecting the presence of *infection* even in the

absence of clinical signs, and the risk posed by wild pigs, is in place; this may be achieved through a *surveillance* programme in accordance with Articles 15.3.23. to 15.3.28.

6. for wild pigs, if present in the country or *zone*, a *surveillance* programme is in place according to Article 15.3.28., taking into account the presence of natural and artificial boundaries, the ecology of the wild pig population, and an assessment of the risks of disease spread.

7. Based on the assessed risk of spread within the wild pig population, and according to Article 15.3.26., the domestic pig population should be separated from the wild pig population by appropriate biosecurity measures to prevent transmission of CSF from wild to domestic pigs.

Article 15.3.3.

CSF free country, zone or compartment

A country, *zone* or *compartment* may be considered free from CSF when *surveillance* in accordance with Articles 15.3.23. to 15.3.28. has been in place for at least 12 months, and when:

1. there has been no *outbreak* of CSF in domestic pigs during the past 12 months;

2. no evidence of CSFV infection has been found in domestic pigs during the past 12 months;

3. no vaccination against CSF has been carried out in domestic pigs during the past 12 months unless there are means, validated to OIE standards (Chapter 2.8.3. of the *Terrestrial Manual*), of distinguishing between vaccinated and infected pigs;

4. imported domestic pigs comply with the requirements in Article 15.3.5. or Article 15.3.6.

Article 15.3.4.

Recovery of free status

Should a CSF *outbreak* occur in a free country, *zone* or *compartment*, the free status may be restored where *surveillance* in accordance with Articles 15.3.23. to 15.3.28. has been carried out with negative results either:

1. 3 months after the last *case* where a *stamping-out policy* without vaccination is practised;

OR

2. where a *stamping-out policy* with emergency vaccination is practised:

   a) 3 months after the last *case* and the *slaughter* of all vaccinated animals, or

   b) 3 months after the last *case* without the *slaughter* of vaccinated animals where there are means, validated to OIE standards (Chapter 2.8.3. of the *Terrestrial Manual*), of distinguishing between vaccinated and infected pigs;

OR

3. where a *stamping-out policy* is not practised, the provisions of Article 15.3.3. should be followed.

Article 15.3.5.

Recommendations for importation from countries, zones or compartments free of CSF

for domestic pigs

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

1. showed no clinical sign of CSF on the day of shipment;

2. were kept in a country, *zone* or *compartment* free of CSF since birth or for at least the past 3 months;

3. have not been vaccinated against CSF, nor are they the progeny of vaccinated sows, unless there are means, validated to OIE standards (Chapter 2.8.3. of the *Terrestrial Manual*), of distinguishing between vaccinated and infected pigs.

Article 15.3.6.

Recommendations for importation from CSF infected countries or zones

for domestic pigs

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

1. showed no clinical sign of CSF on the day of shipment;

2. were kept since birth or for the past 3 months in a CSF free *compartment*;

3. have not been vaccinated against CSF nor are they the progeny of vaccinated sows, unless there are means, validated to OIE standards (Chapter 2.8.3. of the *Terrestrial Manual*), of distinguishing between vaccinated and infected pigs.

Article 15.3.7.

Recommendations for the importation of wild pigs

Regardless of the CSF 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 CSF on the day of shipment;

2. were kept in a *quarantine station* for 40 days prior to shipment, and were subjected to a virological test and a serological test performed at least 21 days after entry into the *quarantine station*, with negative results;

3. have not been vaccinated against CSF, unless there are means, validated to OIE standards (Chapter 2.8.3. of the *Terrestrial Manual*), of distinguishing between vaccinated and infected pigs.

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Article 15.3.8.

Recommendations for importation from countries, zones or compartments free of CSF

for semen of domestic 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 of CSF since birth or for at least 3 months prior to collection;

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

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

Article 15.3.9.

Recommendations for importation from CSF infected countries or zones

for semen of domestic pigs

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

1. the donor animals:

    a) were kept in a *compartment* free of CSF since birth or for at least 3 months prior to collection;

    b) showed no clinical sign of CSF on the day of collection of the semen and for the following 40 days;

    c) met one of the following conditions:

        i) have not been vaccinated against CSF and were subjected to a serological test performed at least 21 days after collection, with negative results; or

        ii) have been vaccinated against CSF and were subjected to a serological test in accordance with the *Terrestrial Manual* performed at least 21 days after collection and it has been conclusively demonstrated that any antibody is due to the vaccine; or

        iii) have been vaccinated against CSF and were subjected to a virological test performed in accordance with the *Terrestrial Manual* on a sample taken on the day of collection and it has been conclusively demonstrated that the boar is negative for virus genome;

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

Article 15.3.10.

Recommendations for importation from countries, zones or compartments free of CSF

for *in vivo* derived embryos of domestic pigs

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

1. the donor females showed no clinical sign of CSF on the day of collection of the embryos;

2. the embryos were collected, processed and stored in conformity with the provisions of Chapter 4.7. or Chapter 4.9., as relevant.

Article 15.3.11.

Recommendations for importation from CSF infected countries or zones

for *in vivo* derived embryos of domestic pigs

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

1. the donor females:

   a) were kept in a *compartment* free of CSF since birth or for at least 3 months prior to collection;

   b) showed no clinical sign of CSF on the day of collection of the embryos and for the following 40 days;

   c) and either:

      i) have not been vaccinated against CSF and were subjected, with negative results, to a serological test performed at least 21 days after collection; or

      ii) have been vaccinated against CSF and were subjected to a serological test performed at least 21 days after collection and it has been conclusively demonstrated by means, validated to OIE standards (Chapter 2.8.3. of the *Terrestrial Manual*), that any antibody is due to the vaccine;

2. the embryos were collected, processed and stored in conformity with the provisions of Chapter 4.7. or Chapter 4.9., as relevant.

Article 15.3.12.

Recommendations for importation from countries, zones or compartments free of CSF

for fresh meat of domestic pigs

Veterinary Authorities should require the presentation of an *international veterinary certificate* attesting that the entire consignment of *meat* comes from animals which:

1. have been kept in a country, *zone* or *compartment* free of CSF ~~since birth or for at least the past 3 months~~, or which have been imported in accordance with Article 15.3.5. or Article 15.3.6.;

2. have been slaughtered in an approved *abattoir*, have been subjected to ante-mortem and post-mortem inspections in accordance to Chapter 6.2. and have been found free of any sign suggestive of CSF.

Article 15.3.13.

Recommendations for the importation of fresh meat of wild pigs

Regardless of the CSF status of the country of origin, *Veterinary Authorities* should require the presentation of an *international veterinary certificate* attesting the entire consignment of *meat* comes from animals:

1. which have been subjected to a post-mortem inspection in accordance with Chapter 6.2. in an approved examination centre, and have been found free of any sign suggestive of CSF;

2. from each of which a sample has been collected and has been subjected to a virological test and a serological test for CSF, with negative results.

Article 15.3.14.

Recommendations for the importation of meat and meat products of pigs, or for products of animal origin (from fresh meat of pigs) intended for use in animal feeding, for agricultural or industrial use, or for pharmaceutical or surgical use

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

1. have been prepared:

    a) exclusively from *fresh meat* meeting the conditions laid down in Article 15.3.12.;

    b) in a processing establishment:

        i) approved by the *Veterinary Authority* for export purposes;

        ii) processing only *meat* meeting the conditions laid down in Article 15.3.12.;

OR

2. have been processed in an establishment approved by the *Veterinary Authority* for export purposes so as to ensure the destruction of the CSF virus in conformity with one of the procedures referred to in Article 15.3.21. and that the necessary precautions were taken after processing to avoid contact of the product with any source of CSF virus

Article 15.3.15.

Recommendations for the importation of products of animal origin (from pigs, but not derived from fresh meat) intended for use in animal feeding

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

1. originated from domestic pigs in a CSF free country, *zone* or *compartment* and have been prepared in a processing establishment approved by the *Veterinary Authority* for export purposes; or

2. have been processed in an establishment approved by the *Veterinary Authority* for export purposes so as to ensure the destruction of the CSF virus in accordance with Article 15.3.20. and that the necessary precautions were taken after processing to avoid contact of the product with any source of CSF virus.

Article 15.3.16.

Recommendations for the importation of products of animal origin (from pigs, but not derived from fresh meat) intended for agricultural or industrial use

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

1. originated from domestic pigs in a CSF free country, *zone* or *compartment* and have been prepared in a processing establishment approved by the *Veterinary Authority* for export purposes; or

2. have been processed in an establishment approved by the *Veterinary Authority* for export purposes so as to ensure the destruction of the CSF virus (under study) and that the necessary precautions were taken after processing to avoid contact of the product with any source of CSF virus.

Article 15.3.17.

Recommendations for the importation of bristles

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

1. originated from domestic pigs in a CSF free country, *zone* or *compartment* and have been prepared in a processing establishment approved by the *Veterinary Authority* for export purposes; or

2. have been processed in an establishment approved by the *Veterinary Authority* for export purposes so as to ensure the destruction of the CSF virus (under study) and that the necessary precautions were taken after processing to avoid contact of the product with any source of CSF virus.

Article 15.3.18.

Recommendations for the importation of litter and manure

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

1. originated from domestic pigs in a CSF free country, *zone* or *compartment* and have been prepared in a processing establishment approved by the *Veterinary Authority* for export purposes; or

2. have been processed in an establishment approved by the *Veterinary Authority* for export purposes so as to ensure the destruction of the CSF virus (under study) and that the necessary precautions were taken after processing to avoid contact of the product with any source of CSF virus.

Article 15.3.19.

Recommendations for the importation of skins and trophies derived from wild pigs

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

1. originated from domestic pigs in a CSF free country, *zone* or *compartment* and have been prepared in a processing establishment approved by the *Veterinary Authority* for export purposes; or

2. have been processed in an establishment approved by the *Veterinary Authority* for export purposes so as to ensure the destruction of the CSF virus in conformity with one of the procedures referred to in Article 15.3.22. and that the necessary precautions were taken after processing to avoid contact of the product with any source of CSF virus.

Article 15.3.20.

Procedures for the inactivation of the CSF virus in swill

For the inactivation of classical swine fever (CSF) viruses likely to be present in swill, one of the following procedures should be used:

1. the swill should be maintained at a temperature of at least 90°C for at least 60 minutes, with continuous stirring; or

2. the swill should be maintained at a temperature of at least 121°C for at least 10 minutes at an absolute pressure of 3 bar.

Article 15.3.21.

Procedures for the inactivation of the CSF virus in meat

For the inactivation of viruses present in *meat*, one of the following procedures should be used:

1. Heat treatment

   Meat shall be subjected to one of the following treatments:

   a) heat treatment in a hermetically sealed container with a Fo value of 3.00 or more;

   b) heat treatment at a minimum temperature of 70°C, which ~~must~~ should be reached throughout the *meat*.

2. Natural fermentation and maturation

   The *meat* should be subjected to a treatment consisting of natural fermentation and maturation having the following characteristics:

   a) an aw value of not more than 0.93, or

   b) a pH value of not more than 6.0.

   Hams should be subjected to a natural fermentation and maturation process for at least 190 days and loins for 140 days.

3. Dry cured pork meat

   a) Italian style hams with bone-in should be cured with salt and dried for a minimum of 313 days.

   b) Spanish style pork *meat* with bone-in should be cured with salt and dried for a minimum of 252 days for Iberian hams, 140 days for Iberian shoulders, 126 days for Iberian loin, and 140 days for Serrano hams.

Article 15.3.22.

Procedures for the inactivation of the CSF virus in trophies

For the inactivation of CSF viruses likely to be present in trophies, one of the following procedures should be used:

1. boiling in water for an appropriate time so as to ensure that any matter other than bone, tusks or teeth is removed;

2. gamma irradiation at a dose of at least 20 kiloGray at room temperature (20°C or higher);

3. soaking, with agitation, in a 4% (w/v) solution of washing soda (sodium carbonate - Na_2CO_3) maintained at pH 11.5 or above for at least 48 hours;

4. soaking, with agitation, in a formic acid solution (100 kg salt [NaCl] and 12 kg formic acid per 1,000 litres water) maintained at below pH 3.0 for at least 48 hours; wetting and dressing agents may be added;

5. in the case of raw hides, salting for at least 28 days with sea salt containing 2% washing soda (sodium carbonate - Na_2CO_3).

Article 15.3.23.

Surveillance: introduction

Articles 15.3.23. to 15.3.28. define the principles and provide a guide on the *surveillance* for CSF, complementary to Chapter 1.4., applicable to Members seeking to determine their CSF status. This may be for the entire country or a *zone*. Guidance for Members seeking free status following an *outbreak* and for the maintenance of CSF status is also provided.

The impact and epidemiology of CSF differ widely in different regions of the world, and it is, therefore, impossible to provide specific recommendations for all situations. The *surveillance* strategies employed for demonstrating freedom from CSF at an acceptable level of confidence will need to be adapted to the local situation. For example, the approach ~~must~~ should be tailored in order to prove freedom from CSF for a country or *zone* where wild pigs provide a potential reservoir of *infection*, or where CSF is present in adjacent countries. The method ~~must~~ should examine the epidemiology of CSF in the region concerned and adapt to the specific risk factors encountered. This should include provision of scientifically based supporting data. There is, therefore, latitude available to Members to provide a well-reasoned argument to prove that absence of classical swine fever virus (CSFV) infection is assured at an acceptable level of confidence.

Surveillance for CSF should be in the form of a continuing programme designed to establish that a population in a country, *zone* or *compartment* is free from CSFV infection or to detect the introduction of CSFV into a population already recognized as free. Consideration should be given to the specific characteristics of CSF epidemiology which include: the role of swill feeding and the impact of different production systems on *disease* spread, the role of semen in transmission of the virus, the lack of pathognomonic gross lesions and clinical signs, the frequency of clinically inapparent *infections*, the occurrence of persistent and chronic *infections*, and the genotypic, antigenic, and virulence variability exhibited by different strains of CSFV. Serological cross-reactivity with other pestiviruses has to be taken into consideration when interpreting data from serological surveys. A common route by which ruminant pestiviruses can infect pigs is the use of vaccines contaminated with bovine viral diarrhoea virus (BVDV).

For the purposes of this chapter, virus *infection* means presence of CSFV as demonstrated directly by virus isolation, the detection of virus antigen or virus nucleic acid, or indirectly by seroconversion which is not the result of vaccination.

Article 15.3.24.

Surveillance: general conditions and methods

1. A *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 to an accredited *laboratory* as described in the *Terrestrial Manual*.

2. The CSF *surveillance* programme should:

   a) include an early warning system throughout the production, marketing and processing chain for reporting suspicious *cases*. Farmers and workers, who have day-to-day contact with livestock, as well as diagnosticians, should report promptly any suspicion of CSF to the *Veterinary Authority*. They should be supported directly or indirectly (e.g. through private *veterinarians* or *veterinary para-professionals*) by government information programmes and the *Veterinary Authority*. Since many strains of CSFV do not induce pathognomonic gross lesions or clinical signs, cases in which CSF cannot be ruled out should be immediately investigated employing clinical, pathological, and *laboratory* diagnosis. This requires that sampling kits and other equipment are available to those responsible for *surveillance*. Personnel responsible for *surveillance* should be able to call for assistance from a team with expertise in CSF diagnosis, epidemiological evaluation, and control;

   b) implement, when relevant, regular and frequent clinical inspections and serological testing of high-risk groups of animals (for example, where swill feeding is practised), or those adjacent to a CSF infected country or *zone* (for example, bordering areas where infected wild pigs are present).

   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 CSFV. The rate at which such suspicious *cases* are likely to occur will differ between epidemiological situations and cannot, therefore, be reliably predicted. Recognitions for freedom from CSFV infection should, as a 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 standstill orders, etc.).

Article 15.3.25.

Surveillance strategies

1. Introduction

There are two basic strategies that can be employed for CSF *surveillance* depending on the purpose of the Member for seeking recognition of freedom from CSF. In countries free of CSF, *surveillance* programmes should be designed to detect the introduction of CSFV into domestic or wild swine. The optimal strategy to meet this objective is most often targeted *surveillance.*

The population covered by *surveillance* aimed at detecting *disease* and *infection* should include domestic and wild pig populations within the country or *zone* to be recognised as free from CSFV infection. Such *surveillance* may involve opportunistic testing of samples submitted for other purposes, but a more efficient and effective strategy is one which includes targeted *surveillance.*

Surveillance is targeted to the pig population which presents the highest risk of *infection* (for example, swill fed farms, pigs reared outdoors or farms in proximity to infected wild pigs). Each Member will need to identify its individual risk factors. These may include: temporal and spatial distribution of past *outbreaks*, pig movements and demographics, etc.

For reasons of cost, the longevity of antibody levels, as well as the existence of clinically inapparent *infections* and difficulties associated with differential diagnosis of other *diseases*, serology is often the most effective and efficient *surveillance* methodology. In some circumstances, which will be discussed later, clinical and virological *surveillance* may also have value.

The Member should justify the *surveillance* strategy chosen as adequate to detect the presence of CSFV infection in accordance with Chapter 1.4. and the epidemiological situation. Cumulative survey results in combination with the results of passive *surveillance*, over time, will increase the level of confidence in the *surveillance* strategy. If a Member wishes to apply for recognition by other Members of a specific *zone* within the country as being free from CSFV infection, the design of the *surveillance* strategy and the basis for any sampling process would need to be aimed at the population within the *zone*.

For random surveys, the design of the sampling strategy will need to incorporate epidemiologically appropriate design prevalence. The sample size selected for testing will need to 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 Member ~~must~~ 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 clearly needs to be based on the prevailing or historical epidemiological situation.

Irrespective of the survey design selected, the sensitivity and specificity of the diagnostic tests employed are 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 for the vaccination/*infection* history and production class of animals in the target population.

Irrespective of the testing system employed, the *surveillance* system design should anticipate the occurrence of false positive reactions. This is especially true of the serological diagnosis of CSF because of the recognized cross-reactivity with ruminant pestiviruses. There needs to be an effective procedure for following up positives to ultimately determine with a high level of confidence, whether or not they are indicative of CSFV infection. This should involve confirmatory and differential tests for pestiviruses, as well as further investigations concerning the original sampling unit as well as animals which may be epidemiologically linked.

2. Clinical and virological surveillance

Beyond their role in targeted *surveillance*, clinical and virological *surveillance* for CSF has two aims: a) to shorten the period between introduction of CSF virus into a *disease* free country or *zone* and its detection, and b) to confirm that no unnoticed *outbreaks* have occurred.

In the past, clinical identification of *cases* was the cornerstone of early detection of CSF. However, emergence of low virulence strains of CSF, as well as new *diseases* - such as post-weaning multisystemic wasting syndrome and porcine dermatitis and nephropathy syndrome - have made such reliance less effective, and, in countries where such *diseases* are common, can add significant risk of masking the presence of CSF.

The spectrum of *disease* signs and gross pathology seen in CSF infections, along with the plethora of other agents that can mimic CSF, renders the value of clinical examination alone somewhat inefficient as a *surveillance* tool. These factors, along with the compounding effects of concurrent *infections* and *diseases* caused by ruminant pestiviruses, dictate the need for *laboratory* testing in order to clarify the status of CSF suspects detected by clinical monitoring.

Nevertheless, clinical presentation should not be ignored as a tool for early detection; in particular, any cases where clinical signs or lesions consistent with CSF are accompanied by high morbidity and/or mortality should be investigated without delay. In CSFV infections involving low virulence strains, high mortality may only be seen in young animals. Otherwise close physical examination of susceptible animals is useful as a selection criteria for CSF *surveillance*, particularly in diagnostic *laboratories* or *slaughter* establishments or when applied to high risk populations such as swill feeding operations.

The difficulties in detecting chronic *disease* manifested by non-specific clinical signs and delayed seroconversion and seronegativity, in persistently infected piglets, both of which may be clinically normal, makes virological investigation essential. As part of a *herd* investigation, such animals are likely to be in a minority and would not confound a diagnosis based on serology. Individually or as part of recently mixed batches, such animals may, however, escape detection by this method. A holistic approach to investigation, taking note of *herd* history, pig, personnel and *vehicle* movements and disease status in neighbouring *zones* or countries, can also assist in targeting *surveillance* in order to increase efficiency and enhance the likelihood of early detection.

The labour-intensive nature of clinical, pathological and virological investigations, along with the smaller 'window of opportunity' inherent in virus, rather than antibody detection, has, in the past, resulted in greater emphasis being placed on mass serological screening as the best method for *surveillance*. However, *surveillance* based on clinical and pathological inspection and virological testing should not be underrated. If targeted at high risk groups in particular, it provides an opportunity for early detection that can considerably reduce the subsequent spread of *disease*. *Herds* predominated by adult animals, such as nucleus *herds* and artificial insemination studs, are particularly useful groups to monitor, since *infection* by low virulence viruses in such groups may be clinically inapparent, yet the degree of spread may be high.

Clinical and virological monitoring may also provide a high level of confidence of rapid detection of *disease* if a sufficiently large number of clinically susceptible animals is examined. In particular, molecular detection methods are increasingly able to offer the possibility of such large-scale screening for the presence of virus, at reasonable cost.

Wild pigs and, in particular, those with a wholly free-living existence, rarely present the opportunity for clinical observation, but should form part of any *surveillance* scheme and should, ideally, be monitored for virus as well as antibody.

Vaccine design and diagnostic methodologies, and in particular methods of virus detection, are increasingly reliant on up-to-date knowledge of the molecular, antigenic and other biological characteristics of viruses currently circulating and causing *disease*. Furthermore, epidemiological understanding of the pathways of spread of CSFV can be greatly enhanced by molecular analyses of viruses in endemic areas and those involved in *outbreaks* in disease free areas. It is therefore essential that CSFV isolates are sent regularly to the regional OIE Reference Laboratory for genetic and antigenic characterisation.

3. Serological surveillance

Serological *surveillance* aims at detecting antibodies against CSFV. Positive CSFV antibody test results can have five possible causes:

a) natural *infection* with CSFV;

b) legal or illegal vaccination against CSF;

c) maternal antibodies derived from an immune sow (maternal antibodies) are usually found only up to 4.5 months of age, but, in some individuals, maternal antibodies can be detected for considerably longer periods;

d) cross-reactions with other pestiviruses;

e) non-specific reactors.

The *infection* of pigs with other pestiviruses may complicate a *surveillance* strategy based on serology. Antibodies to bovine viral diarrhoea virus (BVDV) and Border disease virus (BDV) can give positive results in serological tests for CSF, due to common antigens. Such samples will require differential tests to confirm their identity. Although persistently infected immunotolerant pigs are themselves seronegative, they continuously shed virus, so the prevalence of antibodies at the *herd* level will be high. Chronically infected pigs may have undetectable or fluctuating antibody levels.

It may be possible to use sera collected for other survey purposes for CSF *surveillance*. However, the principles of survey design described in this chapter and the requirement for statistical validity should not be compromised.

The discovery of clustering of seropositive reactions should be foreseen. It may reflect any of a series of events, including but not limited to the demographics of the population sampled, vaccinal exposure or the presence of *infection* by field strains or other pestiviruses. Because clustering may signal field strain *infection*, the investigation of all instances ~~must~~ should be incorporated in the survey design. Clustering of positive animals is always epidemiologically significant and therefore should be investigated.

In countries or *zones* that are moving towards freedom, serosurveillance can provide valuable information on the disease status and efficacy of any control programme. Targeted serosurveillance of young stock will indicate whether newly circulating virus is present, although the presence of maternal antibody will also need to be considered. If conventional attenuated vaccine is currently being used or has been used in the recent past, serology aimed at detecting the presence of field virus will likewise need to be targeted at unvaccinated animals and after the disappearance of maternal antibody. General usage in such situations may also be used to assess levels of vaccine coverage.

Vaccines also exist which, when used in conjunction with dedicated serological tests, may allow discrimination between vaccinal antibody and that induced by field *infection*. Such tools, described in the *Terrestrial Manual*, will need to be fully validated. They do not confer the same degree of protection as that provided by conventional vaccines, particularly with respect to preventing transplacental *infections*. Furthermore, serosurveillance using such differentiation requires cautious interpretation on a *herd* basis.

The results of random or targeted serological surveys are important in providing reliable evidence that no CSFV infection is present in a country or *zone*. It is therefore essential that the survey be thoroughly documented.

The free status should be reviewed whenever evidence emerges to indicate that changes which may alter the underlying assumption of continuing historical freedom, has occurred. Such changes include but are not limited to:

f) an emergence or an increase in the prevalence of CSF in countries or *zones* from which live pigs or products are imported;

g) an increase in the volume of imports or a change in their country or *zone* of origin;

h) an increase in the prevalence of CSF in the domestic or wild pigs of adjacent countries or *zones*;

i) an increased entry from, or exposure to, infected wild pig populations of adjacent countries or *zones*.

Article 15.3.26.

Countries, zones or compartments declaring freedom from CSF: additional surveillance procedures

1. Country or zone free of CSF

In addition to the general conditions described above, a Member seeking recognition of CSF freedom for the country or a *zone*, whether or not vaccination had been practised, should provide evidence for the existence of an effective *surveillance* programme. The strategy and design of the *surveillance* programme will depend on the prevailing epidemiological circumstances in and around the country or *zone* and will be planned and implemented according to the general conditions and methods described in this chapter, to demonstrate the absence of CSFV infection in domestic and wild pig populations. This requires the support of a national or other *laboratory* able to undertake identification of CSFV infection through virus detection and serological tests described in the *Terrestrial Manual*.

2. Compartment free of CSF

The objective of *surveillance* is to demonstrate the absence of CSFV infection in the *compartment*. The provisions of Chapter 4.3. should be followed. The effective separation of the two subpopulations should be demonstrated. To this end, a *biosecurity plan* that includes but is not limited to the following provisions should be implemented:

a) proper containment of domestic pigs;

b) control of movement of *vehicles* with cleaning and *disinfection* as appropriate;

c) control of personnel entering into the *establishments* and awareness of risk of fomite spread;

d) prohibition of introduction to the *establishments* of wild caught animals and their products;

e) record of animal movements into and out of *establishments*;

f) information and training programmes for farmers, processors, *veterinarians*, etc.

The *biosecurity plan* implemented also requires internal and external monitoring by the *Veterinary Authority*. This monitoring should include:

g) periodic clinical and serological monitoring of *herds* in the country or *zone*, and adjacent wild pig populations following these recommendations;

h) *herd* registration;

i) official accreditation of *biosecurity plans*;

j) periodic monitoring and review.

Monitoring the CSF status of wild and domestic pig populations outside the *compartment* will be of value in assessing the degree of risk they pose to the CSF free *compartment*. The design of a monitoring system is dependent on several factors such as the size and distribution of the population, the organisation of the *Veterinary Services* and resources available. The occurrence of CSF in wild and domestic pigs may vary considerably among countries. *Surveillance* design should be epidemiologically based, and the Member should justify its choice of design prevalence and level of confidence based on Chapter 1.4.

The geographic distribution and approximate size of wild pig populations need to be assessed as a prerequisite for designing a monitoring system. Sources of information may include government wildlife authorities, wildlife conservation organisations, hunter associations and other available sources. The objective of a *surveillance* programme when the *disease* is already known to exist should be to determine the geographic distribution and the extent of the *infection*.

Article 15.3.27.

Recovery of free status: additional surveillance procedures

In addition to the general conditions described in the above-mentioned articles, a Member seeking reestablishment of country or *zone* freedom from CSF should show evidence of an active *surveillance* programme to demonstrate absence of CSFV infection.

Populations under this *surveillance* programme should include:

a) *establishments* in the proximity of the *outbreak*;

b) *establishments* epidemiologically linked to the *outbreak*;

c) animals used to re-populate affected *establishments* and any *establishments* where contiguous culling is carried out;

d) wild pig populations in the area of the *outbreak*.

In all circumstances, a Member seeking reestablishment of country or *zone* freedom from CSF with vaccination or without vaccination should report the results of an active and a passive *surveillance* programme in which the pig population undergoes regular clinical, pathological, virological, and/or serological examination, planned and implemented according to the general conditions and methods described in these recommendations. The *surveillance* should be based on a statistically representative sample of the populations at risk.

Article 15.3.28.

Surveillance for CSF in wild pigs

While the same principles apply, *surveillance* in wild pigs presents challenges beyond those encountered in domestic populations in each of the following areas:

a) determination of the distribution, size and movement patterns associated with the wild pig population;

b) assessment of the possible presence of CSF within the population;

c) determination of the practicability of establishing a *zone*.

The design of a monitoring system for wild pigs is dependent on several factors such as the organisation of the *Veterinary Services* and resources available. The geographic distribution and approximate size of wild pig populations need to be assessed as a prerequisite for designing a monitoring system. Sources of information may include wildlife conservation organisations, hunter associations and other available sources. The objective of a *surveillance* programme is to determine if a given *disease* is present, and if so, at what prevalence.

Estimates of wild pig populations can be made using advanced methods (e.g. radio tracking, linear transect method, capture/recapture) or traditional methods based on the number of animals that can be hunted to allow for natural restocking (hunting bags).

For implementation of the monitoring programme, it will be necessary to define the limits of the territory over which wild pigs range in order to delineate the *epidemiological units* within the monitoring programme. It is often difficult to define *epidemiological units* for wild animals. The most practical approach is based on natural and artificial barriers.

The monitoring programme should also include animals found dead, road kills, animals showing abnormal behaviour or exhibiting gross lesions during dressing.

There may be situations where a more targeted *surveillance* programme can provide additional assurance. The criteria to define high risk areas for targeted *surveillance* include:

a) areas with past history of CSF;

b) sub-regions with large populations of wild pigs;

c) border regions with CSF affected countries or *zones*;

d) interface between wild and domestic pig populations;

e) picnic and camping areas;

f) farms with free-ranging pigs;

g) garbage dumps;

h) other risk areas determined by the *Veterinary Authority*.

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