２００５年４月

豚コレラに係るＯＩＥコード改正案のポイント

清浄国又は地域の要件として、新たに以下の事項が削除又は追加された案が提示されている。

（削除された項目）

・生産農場を離れる際に豚に識別を施し、生産農場へのトレースバックを確保すること

・残飯の給与が禁止されていること、又は豚コレラウイルスが死滅する条件での処理がなされていない残飯の給与が禁止されていること

・施設のある国又は地域への侵入リスクを最小化するため、特定の品目の移動制限に係る家畜衛生上の規則が少なくとも２年以上措置されていること

・ワクチン接種を併用したスタンピングアウト政策が選択された場合には、ワクチン非接種豚との識別が確保されない限り、全ての飼養豚に対するワクチン接種が当該国又は地域において少なくとも１年以上にわたって禁止されており、過去５年以内にワクチン接種が行われた場合には、６ヶ月齢から１２ヶ月齢の豚群における感染を否定するための血清学的モニタリングシステムが少なくとも６ヶ月継続されており、かつ、飼養されている豚において発生が少なくとも１２ヶ月以上確認されていないこと

（追加された項目）

・サーベイランスについては、新設された豚コレラのサーベイランスのガイドライン（別添）に従うこととされたこと

（別添）

豚コレラのサーベイランスのガイドライン［概要］

イントロダクション

- 本文書は、Appendix3.8.1（サーベイランスに関する一般的なガイドライン）に従い、豚コレラのサーベイランスの原則の定義とガイダンスを提供するもの。
- 豚コレラの影響と疫学は世界の地域ごとに大きく異なることから、全て状況に対し個別のガイドラインを提供することは不可能。
- 豚コレラのサーベイランスは、豚コレラウイルスの感染について国又は地域全体が清浄であるということを確立するためにデザインされた継続的なプログラムから構成されるべき。

一般的な条件及び方法

- Appendix3.8.1 に従うサーベイランスシステムは、家畜衛生当局の責任の下で行うべき。
- 豚コレラのサーベイランスプログラムは、生産、流通、加工に至るまでの疑う事例に関する早期警戒システムを含み、ハイリスク群又は豚コレラ汚染国又は地域に隣接した群に対する適切、定期的かつ頻回の臨床検査又は血清検査を導入すべき。

サーベイランスの戦略

- サーベイランスには、他の目的で収集されたサンプルの検査を含み得るが、より効率的で効果的な戦略は、リスク要因を同定し、狙いを定めたサーベイランス(targeted surveillance)。
- 各国は、Appendix3.8.1 に従い、豚コレラウイルス感染の存在及び疫学的な状況を検出するために適当なものとして選択されたサーベイランスの戦略を正当化すべき。
- また、各国は、Appendix3.8.1 に従い、サーベイランスの目的及び疫学的な状況に基づく浸潤度（有病率）のデザイン及び信頼度の選択について正当化する必要。
- 狙いを定めたサーベイランスという役割の他にも、豚コレラの臨床及びウイルス学的サーベイランスには、①清浄国又は地域へのウイルスの進入とその検出までの期間の短縮及び、②未報告の発生がないことの確認という２つの目的がある。
- 血清学的サーベイランスの目的は、豚コレラウイルスに対する抗体を検出することであるが、抗体陽性の原因には、①野外株による感染、②合法又は非合法のワクチン接種、③移行抗体、④他のペスチウイルスによる交差反応及び⑤非特異反応の５つが存在。
- 撲滅に向かっている国又は地域においては、血清サーベイランスは、疾病のステータス及び管理プログラムの効力に関する有益な情報を提供可能。また、若齢の個体に狙いを定めたサーベイランスは、移行抗体の存在も考慮する必要があるものの、新たに広まっているウイルスの存在の有無を示すこととなる。
- 無作為あるいは狙いを定めた血清サーベイは、豚コレラウイルスの感染が当該国又は地域に存在しないということの信頼できる証拠を提供する上で重要。それゆえ、サーベイを文書として継続的に保存しておくことが不可欠。

Appendix XIV

CHAPTER 2.6.7.

CLASSICAL SWINE FEVER

Article 2.6.7.1.

The pig is the only natural host for classical swine fever (CSF) virus. The definition of pigs includes all varieties of *Sus scrofa*, both domestic breeds and wild boar. A distinction is made between farmed and permanently captive pigs, and free-living pigs. Farmed and permanently captive pigs of any breed will hereafter be referred to as domestic pigs. Free-living pigs of any breed will hereafter be referred to as wild pigs. Extensively kept pigs may fall into either of these categories or may alternate between the two.

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 7-10 days, and are usually infective between post-infection days 5 and 14, but up to 3 months in cases of chronic infections.

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

Article 2.6.7.2.

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

1) a risk assessment has been conducted, identifying all potential factors for CSF occurrence and their historic perspective;

2) CSF should be notifiable in the whole country and all clinical signs suggestive of CSF should be subjected to field and/or laboratory investigations;

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

4) the *Veterinary Administration* should have current knowledge of, and authority over, all *establishments* containing pigs in the whole country;

5) the *Veterinary Administration* should have current knowledge about the population and habitat of wild pigs in the whole country.

Article 2.6.7.3.

For the purposes of the *Terrestrial Code*:

'CSF infected establishment' means a domestic pig holding in which the presence of the infection has been confirmed by field and/or laboratory investigations.

'Country, *zone* or *compartment* with CSF infection in domestic pigs' means a country, *zone* or *compartment* containing a CSF infected *establishment*.

The size and limits of a CSF domestic pig control area must be based on the control measures used and the presence of natural and administrative boundaries, as well as an assessment of the risks for disease spread.

Appendix XIV (contd)

Article 2.6.7.4.

Country or *zone* free of CSF in domestic and wild pigs

1) Historically free status

A country or zone may be considered free from the disease in domestic and wild pigs after conducting a risk assessment as referred to in Article 2.6.7.2. but without formally applying a specific surveillance programme (historical freedom) if the country or zone complies with the provisions of Article 3.8.1.2.

2) Free status as a result of an eradication programme

A country or zone which does not meet the conditions of point 1) above may be considered free from CSF in domestic and wild pigs after the conduct of a risk assessment as referred to in Article 2.6.7.2. and when:

a) it is a notifiable disease;

~~b) domestic pigs are properly identified when leaving their *establishment* of origin with an indelible mark giving the identification number of their herd of origin; a reliable tracing back procedure is in place for all pigs leaving their *establishment* of origin;~~

~~c) the feeding of swill is forbidden, unless the swill has been treated to destroy any CSF virus that may be present, in conformity with one of the procedures referred to in Article 3.6.4.1.;~~

~~d) animal health regulations to control the movement of *commodities* covered in this Chapter in order to minimise the risk of introduction of the infection into the *establishments* of the country or zone have been in place for at least 2 years;~~

AND EITHER

c) where a *stamping-out policy* without vaccination has been practised for CSF control, no *outbreak* has been observed in domestic pigs for at least 6 months; or

~~f) where a *stamping-out policy* combined with vaccination has been practised, vaccination against CSF should have been banned for all domestic pigs in the country or zone for at least one year, unless there are validated means of distinguishing between vaccinated and infected pigs; if vaccination has occurred in the past 5 years, a serological monitoring system should have been in place for at least 6 months to demonstrate absence of infection within the population of domestic pigs 6 months to one year old, and no *outbreak* has been observed in domestic pigs for at least 12 months; or~~

g) where a vaccination strategy has been adopted, with or without a *stamping-out policy*, vaccination against CSF ~~should have~~ has been banned ~~for~~ in all domestic pigs in the country or zone for at least one year, unless there are validated means of distinguishing between vaccinated and infected pigs; if vaccination has occurred in the past 5 years, ~~a serological monitoring system should have surveillance~~ in accordance with Appendix XXX has been in place for at least 6 months to demonstrate absence of infection within the population of domestic pigs 6 months to one year old, and no *outbreak* has been observed in domestic pigs for at least 12 months;

AND

h) CSF infection is not known to occur in the wild pig population and monitoring of wild pigs indicates that there is no residual infection.

Article 2.6.7.5.

Country or zone free of CSF in domestic pigs but with infection in the wild pig population

Requirements in point 2) of Article 2.6.7.4., as relevant, are complied with, but CSF infection is known to occur in wild pigs. Additional conditions for the free status are that in the country or zone:

1) a programme for the management of CSF in wild pigs is in place, and CSF wild pig control areas are delineated around every CSF *case* reported in wild pigs, taking into account the measures in place to manage the disease in the wild pig population, the presence of natural boundaries, the ecology of the wild pig population, and an assessment of the risk of disease spread;

2) biosecurity measures are applied to prevent transmission from wild pigs to domestic pigs;

3) ~~clinical and laboratory monitoring (under study)~~ surveillance in accordance with Appendix XXX is carried out in the domestic pig population, with negative results.

Article 2.6.7.6.

Recovery of free status

Should a CSF *outbreak* occur in an *establishment* of a free country or zone (free in domestic and wild pigs, or free in domestic pigs only), the status of the country or zone may be restored at least 30 days after completion of a *stamping-out policy* which should include the following measures:

1) a CSF domestic pig control area (including an inner protection area of at least 3-kilometre radius and an outer surveillance area of at least 10-kilometre radius) should be delineated around the *outbreak*, taking into account the control measures applied, the presence of natural and administrative boundaries, and an assessment of the risk of disease spread;

2) all the pigs have been killed and their carcasses destroyed, and *disinfection* has been applied within the *establishment*;

3) in the protection area around a CSF *outbreak*:

   a) a risk assessment should be carried out to determine the likelihood of CSF infection in neighbouring *establishments*; when a significant risk is indicated, a *stamping-out policy* of all domestic pigs within a radius of at least 0.5 kilometre may be applied;

   b) an immediate clinical examination of all pigs in all pig *establishments* situated within the protection area has been carried out;

4) in the surveillance area around a CSF *outbreak*, all sick pigs should be subjected to laboratory tests for CSF;

5) ~~an epidemiological examination including clinical examination, and/or serological and/or virological testing~~ surveillance in accordance with Appendix XXX has been carried out in all pig *establishments* that have been directly or indirectly in contact with the infected *establishment* and in all pig *establishments* located within the CSF domestic pig control area, demonstrating that these *establishments* are not infected;

6) measures aimed at preventing any virus spread by live pigs, pig semen and pig embryos, contaminated material, *vehicles*, etc. have been implemented.

Appendix XIV (contd)

If emergency vaccination has been practised within the CSF domestic pig control area, recovery of the free status can not occur before all the vaccinated pigs have been slaughtered, unless there are validated means of distinguishing between vaccinated and infected pigs.

Article 2.6.7.7.

Country or zone free of CSF in wild pigs

A country or zone may be considered free from CSF in wild pigs when:

1) the domestic pig population in the country or zone is free from CSF infection;

2) ~~a monitoring system (under study)~~ surveillance in accordance with Appendix XXX has been in place to determine the CSF status of the wild pig population in the country, and in the country or zone:

   a) there has been no clinical, nor virological evidence of CSF in wild pigs during the ~~last~~ past 12 months;

   b) no seropositive wild pigs have been detected in the age class 6-12 months during the ~~last~~ past 12 months;

3) there has been no vaccination in wild pigs for ~~at least~~ the past 12 months;

4) the feeding of swill to wild pigs is forbidden, unless the swill has been treated to destroy any CSF virus that may be present in conformity with one of the procedures referred to in Article 3.6.4.1.;

5) imported wild pigs comply with the relevant requirements set forth in the present chapter.

A zoning approach can only be adopted if there is a wild pig population that is isolated from other wild pigs.

Article 2.6.7.8.

When importing from countries or zones free of CSF in domestic and wild pigs, *Veterinary Administrations* should require:

for domestic pigs

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 or zone free of CSF in domestic and wild pigs 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 validated means of distinguishing between vaccinated and infected pigs.

Article 2.6.7.9.

When importing from countries or zones free of CSF in domestic pigs but with infection in the wild pig population, *Veterinary Administrations* should require:

for domestic pigs

the presentation of an *international veterinary certificate* attesting that the animals:

1) were kept in a country or zone free of CSF in domestic pigs since birth or for at least the past 3 months;

2) have not been vaccinated against CSF, nor are they the progeny of vaccinated sows, unless there are validated means of distinguishing between vaccinated and infected pigs;

3) come from an *establishment* which is not located in a CSF wild pig control area as defined in Article 2.6.7.5., and has been regularly monitored to verify absence of CSF in accordance with Appendix XXX;

4) have had no contact with pigs introduced into the *establishment* during the past 40 days;

5) showed no clinical sign of CSF on the day of shipment.

Article 2.6.7.10.

When importing from countries or zones with CSF infection in domestic pigs, *Veterinary Administrations* should require:

for domestic pigs

the presentation of an *international veterinary certificate* attesting that the animals:

1) have not been vaccinated against CSF nor are they the progeny of vaccinated sows, unless there are validated means of distinguishing between vaccinated and infected pigs;

2) were kept since birth, or for the past 3 months, in an *establishment* not situated in a CSF domestic or wild pig control area as defined in Article 2.6.7.5. and in Article 2.6.7.6.;

3) were isolated in a *quarantine station* for at least 40 days;

4) were subjected during that period of quarantine to a virological test, and a serological test performed at least 21 days after entry into the *quarantine station*, with negative results;

5) showed no clinical sign of CSF on the day of shipment.

Article 2.6.7.11.

When importing from countries or zones free of CSF in domestic and wild pigs, *Veterinary Administrations* should require:

for wild pigs

the presentation of an *international veterinary certificate* attesting that the animals:

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

2) have been captured in a country or zone free from CSF in domestic and wild pigs;

Appendix XIV (contd)

3) have not been vaccinated against CSF, unless there are validated means of distinguishing between vaccinated and infected pigs;

and, if the zone where the animal has been captured is adjacent to a zone with infection in wild pigs:

4) 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.

Article 2.6.7.12.

When importing from countries or zones free of CSF in domestic and wild pigs, *Veterinary Administrations* should require:

for semen of domestic pigs

the presentation of an *international veterinary certificate* attesting that:

1) the donor animals:

   a) were kept in a country or zone free of CSF in domestic and wild pigs since birth or for at least the past 3 months;

   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 Appendix 3.2.3.

Article 2.6.7.13.

When importing from countries or zones free of CSF in domestic pigs but with infection in the wild pig population, *Veterinary Administrations* should require:

for semen of domestic pigs

the presentation of an *international veterinary certificate* attesting that:

1) the donor animals:

   a) have been kept in an *artificial insemination centre* which is not located in a CSF wild pig control area and is regularly monitored to verify absence of CSF;

   b) were isolated in the *artificial insemination centre* for at least 40 days prior to collection;

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

2) the semen was collected, processed and stored in conformity with the provisions of Appendix 3.2.3.

Article 2.6.7.14.

When importing from countries or zones considered infected with CSF in domestic pigs, *Veterinary Administrations* should require:

for semen of domestic pigs

the presentation of an *international veterinary certificate* attesting that:

1) the donor animals:

   a) showed no clinical sign of CSF on the day of collection of the semen and for the following 3 months;

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

2) the semen was collected, processed and stored in conformity with the provisions of Appendix 3.2.3.

Article 2.6.7.15.

When importing from countries or zones free of CSF in domestic and wild pigs, *Veterinary Administrations* should require:

for *in vivo* derived embryos of pigs

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 Appendix 3.3.1.

Article 2.6.7.16.

When importing from countries or zones free of CSF in domestic pigs but with infection in the wild pig population, *Veterinary Administrations* should require:

for *in vivo* derived embryos of pigs

the presentation of an *international veterinary certificate* attesting that:

1) the donor females:

   a) were kept for at least 40 days prior to collection in an *establishment* which is not located in a CSF domestic or wild pig control area and is regularly monitored to verify absence of CSF;

   b) 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 Appendix 3.3.1.

Article 2.6.7.17.

When importing from countries considered infected with CSF in domestic pigs, *Veterinary Administrations* should require:

Appendix XIV (contd)

for *in vivo* derived embryos of pigs

the presentation of an *international veterinary certificate* attesting that:

1) the donor females:

   a) were kept for at least 40 days prior to collection in an *establishment* which is not located in a CSF domestic or wild pig control area and is regularly monitored to verify absence of CSF in accordance with Appendix XXX;

   b) showed no clinical sign of CSF on the day of collection of the embryos and for the following 21 days;

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

2) the embryos were collected, processed and stored in conformity with the provisions of Appendix 3.3.1.

Article 2.6.7.18.

When importing from countries or zones free of CSF in domestic and wild pigs, *Veterinary Administrations* should require:

for *fresh meat* of domestic pigs

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 or zone free of CSF in domestic and wild pigs since birth or for at least the past 3 months;

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

Article 2.6.7.19.

When importing from countries or zones free of CSF in domestic pigs but with infection in the wild pig population, *Veterinary Administrations* should require:

for *fresh meat* of domestic pigs

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

1) were kept in a country or zone free of CSF in domestic pigs since birth or for at least the past 3 months;

2) were kept in an *establishment* which was not located in a CSF wild pig control area and had been regularly monitored to verify absence of CSF in accordance with Appendix XXX;

3) have been slaughtered in an *approved abattoir* not located in a CSF control area, have been subjected to ante-mortem and post-mortem inspections and have been found free of any sign suggestive of CSF.

Article 2.6.7.20.

When importing from countries or zones free of CSF in domestic and wild pigs, *Veterinary Administrations* should require:

for *fresh meat* of wild pigs

the presentation of an *international veterinary certificate* attesting that:

1) the entire consignment of meat comes from animals which:

   a) have been killed in a country or zone free of CSF in domestic and wild pigs;

   b) have been subjected to post-mortem inspection in an approved examination centre, and have been found free of any sign suggestive of CSF;

and, if the zone where the animal has been killed is adjacent to a zone with infection in wild pigs:

2) a sample has been collected from every animal shot, and has been subjected to a virological test and a serological test for CSF, with negative results.

Article 2.6.7.21.

Veterinary Administrations of *importing countries* should require:

for *meat products* of pigs (either domestic or wild), 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, or for trophies derived from wild pigs

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 Articles 2.6.7.18., 2.6.7.19. or 2.6.7.20., as relevant;

   b) in a processing establishment:

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

      ii) regularly inspected by the *Veterinary Authority*;

      iii) not situated in a CSF control area;

      iv) processing only meat meeting the conditions laid down in Articles 2.6.7.18., 2.6.7.19. or 2.6.7.20., as relevant;

OR

2) have been processed in an establishment approved by the *Veterinary Administration* for export purposes and regularly inspected by the *Veterinary Authority* so as to ensure the destruction of the CSF virus in conformity with one of the procedures referred to in Article 3.6.4.2.

Appendix XIV (contd)

Article 2.6.7.22.

Veterinary Administrations of *importing countries* should require:

for products of animal origin (from pigs, but not derived from *fresh meat*) intended for use in animal feeding and for agricultural or industrial use

the presentation of an *international veterinary certificate* attesting that the products:

1) have been prepared:

   a) exclusively from products meeting the conditions laid down for *fresh meat* in Articles 2.6.7.18., 2.6.7.19. or 2.6.7.20., as relevant;

   b) in a processing establishment:

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

      ii) regularly inspected by the *Veterinary Authority*;

      iii) not situated in a CSF control area;

      iv) processing only products meeting the conditions laid down in point a) above;

OR

2) have been processed in an establishment approved by the *Veterinary Administration* for export purposes and regularly inspected by the *Veterinary Authority* so as to ensure the destruction of the CSF virus in conformity with one of the procedures referred to in Article 3.6.4.2..

Article 2.6.7.23.

Veterinary Administrations of *importing countries* should require:

for bristles (from pigs)

the presentation of an *international veterinary certificate* attesting that the products:

1) come from a country or zone free of CSF in domestic and wild pigs; or

2) have been processed in an establishment approved by the *Veterinary Administration* for export purposes and regularly inspected by the *Veterinary Authority* so as to ensure the destruction of the CSF virus.

Article 2.6.7.24.

Veterinary Administrations of *importing countries* should require:

for litter and manure (from pigs)

the presentation of an *international veterinary certificate* attesting that the products:

1) come from a country or zone free of CSF in domestic and wild pigs; or

2) come from *establishments* situated in a country or zone free of CSF in domestic pigs but with infection in wild pigs, but not located in a CSF control area; or

3) have been processed in an establishment approved by the *Veterinary Administration* for export purposes and regularly inspected by the *Veterinary Authority* so as to ensure the destruction of the CSF virus.

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APPENDIX X.X.X

GUIDELINES FOR THE SURVEILLANCE OF CLASSICAL SWINE FEVER

Article X.X.X.1.

Introduction

This document defines the principles and provides a guide for the surveillance of classical swine fever (CSF) in accordance with Appendix 3.8.1., applicable to countries seeking recognition of freedom from CSF. This may be for the entire country or a zone within the country. Guidance for countries seeking reestablishment of freedom from CSF for the whole country or a zone, following an *outbreak*, as well as guidelines for demonstrating the maintenance of CSF free status are also provided. This Appendix complements Chapter 2.6.7.

The impact and epidemiology of CSF differ widely in different regions of the world and therefore it is impossible to provide specific guidelines for all situations. It is axiomatic that 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 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 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 Member Countries to provide a well-reasoned argument to prove that absence of 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 the whole country or zone is free from CSFV infection. 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 purpose of this Appendix 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 X.X.X.2.

General conditions and methods

1) A surveillance system in accordance with Appendix 3.8.1. should be under the responsibility of the *Veterinary Administration*. 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 Administration*. 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 stand-still orders, etc.).

Article X.X.X.3.

Surveillance strategies

The target population for surveillance aimed at identification of *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.

Depending on the local epidemiological situation, targeted surveillance could be considered as more effective than a randomized surveillance strategy. Surveillance is targeted to the pig population which presents the highest risk of *infection* (for example, swill fed farms, pigs reared outdoors, farms in proximity to infected wild pigs). Each country 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 country should justify the surveillance strategy chosen as adequate to detect the presence of CSFV infection in accordance with Appendix 3.8.1. 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 Country wishes to apply for recognition by other Member Countries 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 country must justify the choice of design prevalence and confidence level based on the objectives of surveillance and the epidemiological situation, in accordance with Appendix 3.8.1. 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 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 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.

1) Clinical and virological surveillance

Beyond their role in targeted surveillance, clinical and virological surveillance for CSF have 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.

One element of clinical surveillance involves the detection of clinical signs of CSF by close physical examination of susceptible animals. 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. 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.

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 - in particular 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. In zones or countries where such diseases exist, careful clinical and virological surveillance of such cases should be applied.

Clinical signs and pathology of CSF infection will also vary considerably, depending on the strain of virus as well as host factors, such as age, nutrition and health status. These factors, along with the compounding effects of concurrent infections and disease caused by ruminant pestiviruses, dictate the need for laboratory testing in order to clarify the status of CSF suspects detected by clinical monitoring. 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. However, individually, or as part of recently mixed batches, such animals may 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.

Appendix XV (contd)

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.

2) Serological surveillance

Serological surveillance aims at the detection of 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 Appendix 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 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.

Article X.X.X.4.

Country or zone free of CSF in domestic and wild pigs

1) Historically free status

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:

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

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

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

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

Appendix XV (contd)

2) Free status as a result of an eradication programme

In addition to the general conditions described in Chapter 2.6.7., a Member Country 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 and will be planned and implemented according to general conditions and methods in this Appendix, 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.*

Article X.X.X.5.

Country or zone free of CSF in domestic pigs but with infection in the wild pig population

1) In addition to the general conditions described in Chapter 2.6.7., a Member Country 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 and will be planned and implemented according to general conditions and methods in this Appendix, 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) The objective of surveillance in this instance is to demonstrate that the two subpopulations are effectively separated by measures that ensure the biosecurity of domestic pigs. To this end, a biosecurity programme which includes but is not limited to the following provisions should be implemented:

   a) a programme for the management of CSF in wild pigs;
   b) delineation of CSF wild pig control areas around every CSF case reported in wild pigs;
   c) assessment of the presence and mitigative role of natural boundaries;
   d) documentation of the ecology of the wild pig population;
   e) proper containment of domestic pigs;
   f) control of movement of *vehicles* with cleaning and *disinfection* as appropriate;
   g) control of personnel entering into the *establishments* and awareness of risk of fomite spread;
   h) prohibition of introduction to the *establishments* of hunted animals and products;
   i) registry of animal movements into and out of *establishments*;
   j) information and training programmes for farmers, hunters, processors, veterinarians, etc. .

3) The biosecurity programme implemented would also require internal and external monitoring by the *Veterinary Authorities.* These elements should include but are not limited to:

   a) periodic clinical and serological monitoring of herds in the country or zone, and adjacent wild pig populations following these guidelines;
   b) herd registration;
   c) official accreditation of biosecurity programme;
   d) periodic monitoring and review.

4) Monitoring the CSF status of wild populations will be of value in assessing the degree of risk they pose to the CSF free domestic population. The design of a monitoring system for wild pigs is dependent on several factors such as the organization of the *Veterinary Services* and resources available. The occurrence of CSF in wild pigs may vary considerably among countries. Surveillance design should be scientifically based and the Member Country must justify its choice of design prevalence and level of confidence based on Appendix 3.8.1.

5) 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 organizations, 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 X.X.X.6.

Recovery of free status

1) Countries or zones re-seeking freedom from CSF following an outbreak

In addition to the general conditions described in Chapter 2.6.7. of the *Terrestrial Code*, a country re-seeking country or zone freedom from CSF should show evidence of an active surveillance programme for CSF as well as absence of CSFV infection.

Populations under this surveillance programme should include, but not be limited to:

a) *establishments* in the area 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 Country re-seeking country or zone freedom from CSF with vaccination or without vaccination should report the results of an active and passive surveillance programme in which the pig population undergoes regular clinical, pathological, virological, and/or serological examination, planned and implemented according to general conditions and methods in these guidelines. The surveillance should be based on a statistically representative sample of the populations at risk.

2) Country or zone free of 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 zones.

Appendix XV (contd)

The design of a monitoring system for wild pigs is dependent on several factors such as the organization 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 the geographic distribution and estimation of target population.

Estimates of wild pig population can be made using advanced methods (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 can be:

- areas with past history of CSF;
- sub-regions with high wild pig density;
- border regions with CSF affected countries or zones;
- areas of contact between sub-populations;
- picnic and camping areas;
- around farms with free-ranging pigs;
- special risk areas determined by local *Veterinary Authorities*.
- garbage dumps.