

GLOSSARY

COMPETENT AUTHORITY

means ~~the Veterinary Authority or other~~ a Governmental Authority of a Member Country ~~having the responsibility and that has competence for ensuring or supervising~~ **having responsibility in the whole or part of the territory for the implementation of animal health and welfare measures, international veterinary certification and other any certain standards and recommendations of in the Terrestrial Code and in the OIE Aquatic Animal Health Code in the whole territory, which are not under the competence of the Veterinary Authority.**

VETERINARY AUTHORITY

means the Governmental Authority of a Member Country, ~~comprising the OIE Delegate, veterinarians, other professionals and paraprofessionals, having the primary responsibility in the whole territory and competence for coordinating ensuring or supervising the implementation of animal health, and animal welfare and veterinary public health measures, international veterinary certification and other the standards and recommendations of in the Terrestrial Code in the whole territory.~~

VETERINARY SERVICES

means **the combination of the governmental and non-governmental individuals and organisations that perform activities to implement animal health, and animal welfare and veterinary public health measures and other the standards and recommendations of in the Terrestrial Code and the OIE Aquatic Animal Health Code in the territory. The Veterinary Services are under the overall control and direction of the Veterinary Authority. Private sector organisations, veterinarians, veterinary paraprofessionals or aquatic animal health professionals are normally accredited or approved by the Veterinary Authority to deliver the delegated functions.**

Edited definitions in clean text:

COMPETENT AUTHORITY

means a Governmental Authority of a Member Country having responsibility in the whole or part of the territory for the implementation of certain standards of the *Terrestrial Code*.

VETERINARY AUTHORITY

means the Governmental Authority of a Member Country having the primary responsibility in the whole territory for coordinating the implementation of the standards of the *Terrestrial Code*.

VETERINARY SERVICES

means the combination of governmental and non-governmental individuals and organisations that perform activities to implement the standards of the *Terrestrial Code*.

CHAPTER 8.14.
INFECTION WITH RABIES VIRUS

Article 8.14.6bis.

Recommendations for importation of dogs from countries or zones infected with rabies virus

Veterinary Authorities should require the presentation of an international veterinary certificate complying with the model of Chapter 5.11. attesting that the dogs:

- 1) showed no clinical sign of rabies the day prior to or on the day of shipment;
- 2) were permanently identified and their identification number stated in the certificate;
- 3) and either:
 - a) were vaccinated or revaccinated in accordance with the recommendations of the manufacturer, with a vaccine that was produced in accordance with the *Terrestrial Manual* and were subjected, not less than 30 days and not more than 12 months prior to shipment, to an antibody titration test as prescribed in the *Terrestrial Manual* with a positive result of at least 0.5 IU/ml;
 - or
 - b) were kept in a quarantine station for six months prior to shipment.

Article 8.14.7.

Recommendations for importation of ~~dogs~~, cats and ferrets from countries or zones infected with rabies virus

Veterinary Authorities should require the presentation of an international veterinary certificate complying with the model of Chapter 5.11. attesting that the animals:

- 1) showed no clinical sign of rabies the day prior to or on the day of shipment;
 - 2) were permanently identified and their identification number stated in the certificate;
 - 3) and either:
 - a) were vaccinated or revaccinated in accordance with the recommendations of the manufacturer, with a vaccine that was produced in accordance with the *Terrestrial Manual* and were subjected not less than 3 months and not more than 12 months prior to shipment to an antibody titration test as prescribed in the *Terrestrial Manual* with a positive result of at least 0.5 IU/ml;
 - or
 - b) were kept in a quarantine station for six months prior to shipment.
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CHAPTER 7.7.

DOG POPULATION MANAGEMENT

Article 7.7.1.

Introduction

Dog Population Management (DPM) refers to the holistic approach that aims to improve the welfare of dogs, reduce problems they may present and create harmonious co-existence with people and their environment. Dogs are present in every human society around the world and valued for the range of roles they fulfil. However, they can present public health and safety and animal health and *animal welfare* issues, especially when free to roam.

DPM is an integral part of effective and sustainable rabies control programmes and control of other zoonoses. Recognising that mass culling is ineffective and may be counterproductive, reducing dog population size is not an effective means of reducing rabies *prevalence* [WHO, 2018]. However, DPM can contribute to rabies control by reducing population turnover, therefore supporting maintenance of herd immunity within a vaccinated dog population. The components of turnover most relevant for rabies are the reduction in the birth of unwanted puppies that would be at risk of remaining unvaccinated, and improving welfare and life expectancy of vaccinated dogs.

Reproduction control as part of DPM also reduces breeding behaviours which may increase the *risk* of rabies transmission due to increased contact rates between dogs.

Promotion of *responsible dog ownership* as part of DPM can strengthen owner motivation, knowledge and therefore behaviour in caring for their dogs, including timely rabies *vaccination* of *owned dogs* to maintain immunity.

The OIE recognises the importance of managing dog populations without causing unnecessary animal suffering.

Article 7.7.2.

Scope

The scope of this chapter is to provide recommendations for the management of dog (*Canis lupus familiaris*) populations to improve human health and safety, animal health and *animal welfare* and to minimise their potential negative socio-economic and environmental impacts. The recommendations will also assist Members in the implementation of zoonotic disease control programmes such as *infection* with rabies virus in accordance with Chapter 8.14.

Article 7.7.3.

Guiding principles

Building upon the guiding principles described in Chapter 7.1., the following apply:

- DPM has direct benefits to public health and safety, and animal health and welfare.
- Dogs are domesticated species and therefore dependent on human communities, thus there is an ethical responsibility to ensure their health and welfare even in the absence of ownership.
- Recognising diversity of stakeholders in the management of dog populations, it is crucial to clarify roles and responsibilities.
- Dog ecology is linked with human activities. Therefore, effective management of dog populations should be accompanied by changes in human behaviour, including promotion of *responsible dog ownership*.
- Acknowledging that the *owned dog* population is a common source of free-roaming dogs, DPM programmes should consider all dogs.

Annex 17 (contd)

- Understanding local dog population dynamics and community attitudes is a key element to determine whether and how DPM programmes might contribute to rabies control and which tools would be most successful.
- Considering that sources and drivers of free-roaming dogs and management goals differ across communities, DPM should be individually tailored at local and national level.
- DPM programmes should be designed to be sustainable, evaluated and refined.

Article 7.7.4.

Definitions for the purpose of this chapter

DPM programme means a combination of DPM measures that enhance the care of dogs and influence dog population dynamics to sustainably improve dog health and welfare, public health and safety, environment and related economic benefit and costs.

Rabies means dog-mediated rabies.

Free roaming dog means any *owned dog* or unowned dog that is without direct human supervision or control.

Article 7.7.5.

DPM programme objectives

DPM programmes may include the following objectives:

- promote and establish *responsible dog ownership*;
- improve health and welfare of dog populations;
- reduce number of *free-roaming dogs* to a manageable level;
- stabilise the dog population by reducing turnover;
- reduce *risks* to public health and safety including dog bites, zoonotic *diseases* including rabies and traffic accidents;
- contribute towards eradicating dog-mediated human rabies by 2030;
- reduce nuisance free roaming dogs may cause (e.g., environmental impact, negative publicity directed at governments, tourism disincentives);
- prevent harm to livestock and other animals;
- prevent dog illegal trade and trafficking.

Article 7.7.6.

Roles and responsibilities

As a cross-sectoral subject, DPM requires a high level of engagement and collaboration between *Competent Authorities* responsible for animal health and welfare, food safety and public health, in line with the One Health approach.

DPM activities performed by *Veterinary Services* or other *Competent Authorities* should be integrated to the greatest extent possible with the activities of all other responsible agencies.

Articles 7.7.7. and 7.7.8. describe the roles and responsibilities that different organisations may play in the planning and implementation of DPM programmes, at the national and local level.

Article 7.7.7.

Competent Authority for dog population management

The development and implementation of DPM occur at the local level through specific DPM programmes, whose success requires a supportive and enabling environment created by the *Competent Authority* at the national level. As DPM is relevant to several governmental agencies and various stakeholders, a multi-sectorial group should establish governance and coordinate actions across governmental agencies and programmes, including those focusing on zoonotic diseases where dogs play a role, such as rabies.

1. Governance

DPM should be identified as the responsibility of a *Competent Authority*, which may be the *Veterinary Authority*. National level action plans provide the details of actions which support the implementation of DPM programmes and coordinate with other action plans, such as those focused on dog-related zoonoses. These plans are led by this *Competent Authority* and developed in collaboration with the multi-sectorial group.

2. Legislation

Implementation of DPM programmes requires the support of a suitable regulatory framework (see Article 7.7.9.). Further secondary regulations provide adaptations to suit local requirements.

3. Enforcement

The *Competent Authority* can support enforcement of legislation through guidelines on enforcement procedures/practices, training, and funding of enforcement agencies, and defining penalties.

4. Funding

To establish sustainable DPM with long-lasting impacts, the *Competent Authority* and multi-sectorial group should establish a policy and legislative basis for sufficient funding of national action plans and DPM Programmes. The One Health concept provides strength to the argument for increasing the priority of DPM across the animal health, environmental, and public health sectors.

5. Training and support

Training of professionals including *veterinarians* and providing accessibility to appropriate drugs at local, national or regional level led by the *Competent Authority* would support achievement of minimum standards across DPM Programmes. The *Competent Authority* should support DPM through national level communication and education initiatives.

Article 7.7.8.

Other organisations involved in dog population management

The following may have a role in the development of DPM programmes [Paolini *et al.*, 2020]:

1. Veterinary Authority

The *Veterinary Authority* plays a lead role in preventing zoonotic diseases and ensuring *animal welfare* and should be involved in DPM, coordinating its activities with other relevant *Competent Authorities*.

2. Veterinary Services

Veterinary Services should play an active role and coordinate their activities with relevant *Competent Authorities* and may be responsible for the organisation, implementation, and supervision of DPM Programmes.

Annex 17 (contd)3. Other governmental agencies

The responsibilities of governmental agencies will depend on the *risk* being managed and the objective or nature of the DPM measures implemented.

a) Public health

The ministry or other governmental agencies responsible for public health, would normally play a leadership role and may have legislative authority in dealing with zoonotic diseases and regarding other human health *risks* (e.g., free-roaming dogs on roads; dog bites).

b) Environmental protection

Environmental protection governmental agencies may take responsibility for problems associated with free-roaming dogs when they present a *hazard* to the environment (e.g., control of *feral* dogs in national parks; prevention of predation to *wildlife* or transmission of diseases to *wildlife*) or where a lack of environmental controls encourage dogs to roam.

c) Education

The Ministry of Education can play a key role in promoting *responsible dog ownership* and dog bite prevention programmes at school level.

d) Local authorities

In many countries, local authorities are responsible for the implementation of DPM programmes and the enforcement of legislation relating to dog ownership (e.g., *registration* and *identification*, *vaccination*, leash laws, animal abandonment). This should be done with the support and enabling environment created by the *Competent Authority*.

4. Civil Society

The responsibilities of civil society stakeholders will depend on their involvement with the DPM measures implemented.

a) Dog owners

When a person takes on the ownership of a dog, there should be an immediate acceptance of responsibility for that dog, and for any offspring it may produce, for the duration of its life or until a subsequent owner is found. The owner responsibilities should include providing for the health and welfare of the dog and mitigating negative impacts on public health and the environment, in accordance with Article 7.7.17.

b) Dog breeders and sellers

Dog breeders and sellers have the same responsibilities as dog owners and in addition should comply with the recommendations in accordance with Article 7.7.15.

5. Advisory group

The development of a DPM programme should also benefit from the support of an advisory group, which should include *veterinarians*, experts in dog ecology, dog behaviour and zoonotic diseases, and representatives of relevant stakeholders (local authorities, human health services or authorities, environmental control services or authorities, non-governmental organisations and the public).

Article 7.7.9.

Regulatory framework

DPM legislation is a key element for the sustainability and efficiency of DPM Programmes. It can ensure that DPM is carried out with respect to *animal welfare* guiding principles (see Chapter 7.1.).

Regulations related to the following areas, may support successful DPM Programmes; these may be found in a DPM regulatory framework or other regulatory frameworks:

- Owners' obligations regarding the principles of *responsible dog ownership*, including *animal welfare*;
- *animal welfare* obligations of authorities;
- *registration* and *identification* of dogs in a centralised database;
- authorisation and licensing of dog breeders and sellers;
- authorisation and licensing of dog shelters, rehoming centres and holding facilities;
- licensing practice of veterinary medicine, including surgery;
- licensing preparation, use and sales of *veterinary products*;
- preventive and medical measures against rabies and other zoonotic diseases;
- dog movements and trade at international and national level;
- waste management.

This regulatory framework must be designed with both incentive measures for compliance and penalties for non-compliance.

Article 7.7.10.

Assessment, monitoring and evaluation

DPM programmes should be regularly evaluated and adapted to improve effectiveness and to respond to changes in wider context that influence dog population dynamics. This requires an evidence base from data collected through initial assessment and continued *monitoring* using objective methods.

Recognising the different needs of communities and the multi-sectorial roles in DPM, this should be conducted with involvement of advisory groups and relevant authorities.

Competent Authorities should support assessment, monitoring and evaluation by:

- Developing training and tools to help with implementing assessment and *monitoring*;
- Providing the budget of DPM programmes including the costs for *monitoring* activities;
- Establishing standardised indicators with feasible and repeatable methods of measurement that can be used across locations and over time, to support subsequent evaluations and compare performance between different DPM programmes. It should be expected that DPM programmes will also use and benefit from their own context-specific indicators and methods of measurement;
- Encourage the use of *monitoring* data for evaluation, learning and subsequent adaptation of DPM programmes.

Annex 17 (contd)

Article 7.7.11.

DPM programme development

Developing a DPM programme requires an evidence-based approach. Areas for assessment that provide this evidence should include:

- 1) Review of the current regulatory framework and evaluation of the efficiency and effectiveness of DPM control measures used historically and currently.
- 2) Identification of the priority issues related to dogs from the perspective of all relevant stakeholders. The resolution of these issues will form the objectives of DPM programmes. Establishing baselines and *monitoring* methods for indicators reflecting each objective allows for later evaluation of efficiency and effectiveness. Identifying which dogs are associated with priority issues may include *owned dogs*.
- 3) Exploration of dog population dynamics in the whole dog population (not limited to the current free-roaming dog population) to identify the sources of free-roaming dogs:
 - *owned dogs* that roam freely;
 - dogs that have been lost or abandoned, including puppies resulting from uncontrolled breeding of *owned dogs*;
 - unowned dogs that reproduce.
- 4) Identify peoples' knowledge, attitudes and practices of dog care and responsibility over *owned dogs* and unowned dogs. Further, citizens' attitudes towards potential control measures should be explored. This information can be used to ensure the DPM programme acceptability to local communities and effectiveness at changing human behaviours.
- 5) Estimating dog population size and demography

Dog population size estimates can help with planning DPM programmes. Accuracy of estimates is typically improved with more time-consuming methods. Where resources are limited, a rough estimate may be sufficient at the outset. This estimate may be refined by *monitoring* population coverage achieved by the implementation of measures and comparing this to the number of dogs receiving these measures (e.g., rabies *vaccination* and sterilisation in "Catch, Neuter and Return").

For evaluation of DPM programme effectiveness, *monitoring* changes in population trends (e.g., changes in the density of free-roaming dogs on public streets, proportion of lactating females and presence of puppies) may be sufficient rather than investing in repeated estimates of population size.

Methods to estimate population size may also measure demographic factors such as age, sex, sterilisation and reproductive status (lactation and pregnancy in females) to allow for refinement of estimates to sub-populations of relevance.

Available methods for population size estimates include the following:

- *Owned dogs*: Dog *registration* databases, household questionnaires (to estimate proportion of dog owning households and mean number of dogs per dog owning household), post-*vaccination* campaign coverage and animal ownership surveys as part of human census.
- Free-roaming *owned dogs*: Household questionnaires including questions or visible inspection of whether *owned dogs* are confined or allowed to roam unsupervised.

- All free-roaming dogs, including both owned roaming and unowned:

Direct observation of free-roaming dogs during surveys along routes through public streets at peak roaming time; capturing of these data can provide the mean free roaming dogs per km of street surveyed. This can be extrapolated by the estimated total street length within the defined area to estimate the total number of free-roaming dogs on the street at the time of survey; some free roaming dogs will not have been visible during the survey and so this is an underestimate of the total free roaming dog population.

Mark-resight is a method that aims to estimate population size considering that not all animals are visible to direct observation on a survey. This is achieved by first marking dogs with temporary marks such as paint, or photographs for individual recognition, or using marks applied as part of control measures, such as collars or paint applied during *vaccination* and ear notches or tags applied during neutering in Catch, Neuter and Return programmes. Then noting the proportion of marked and unmarked dogs during subsequent surveys. Mark-resight methods rely on assumptions that may not hold true in dog populations, such as equal resighting probability in marked and unmarked dogs, lack of immigration/emigration and no or measurable mark loss.

Mark-resight is a relatively resource intensive method as compared to direct observation which may limit the extent of the area that can be feasibly surveyed.

Mark-resight and direct observation may be done concurrently in a sample of areas to estimate the proportion of free roaming dogs visible during direct observation. This proportion can be used to correct the data regarding those dogs missed during direct observation over a larger geographical area.

Article 7.7.12.

Monitoring and evaluation

Monitoring aims to check the progress of DPM programme measures against targets and support performance management. It should allow for regular adjustments of implementation of measures and collect data on indicators of objectives. It should also include *monitoring* of costs associated with measures and costs or savings relating to objectives to support cost-benefit analysis.

Evaluation is a periodic assessment of progress using data collected through *monitoring*, usually carried out at milestones to assess whether the DPM programme is achieving the desired objectives and to adapt the DPM programme to improve effectiveness and efficiency. Where methods of *monitoring* are equivalent, evaluation can compare effectiveness and efficiency across DPM programmes.

Indicators are the measurable signs of objectives. Indicators of DPM objectives may include:

- *Owned dog* population size, demographics and whether they are receiving *responsible dog ownership* (can include their *vaccination* status, sterilisation, *registration*, identification, level and method of confinement and how they were acquired).
- Free-roaming dog population density, demography (age, sex, sterilisation, lactating females, and puppies) and welfare (e.g., body condition score and presence of a skin problem) recorded by direct observation of free-roaming dog on surveys along standardised routes.
- *Prevalence* of zoonotic diseases in both the animal and human population; for example, Chapter 8.14. and Chapter 8.5.
- Knowledge, attitudes and practices of communities relating to the free-roaming dog population, and dog owner knowledge, attitudes and practices of *responsible dog ownership*.
- Adoption or reuniting facility performance including intake, adoption rates, welfare state of dogs in their care, mortality and *euthanasia* rate.
- Dog bites reported to health centres or number of rabies post-exposure prophylaxis provided to the exposed individuals or the cost incurred by the public health authorities for provision of post-exposure prophylaxis.
- Number and nature of complaints about dogs to local government authorities.
- Compensation costs relating to dog-related damages to people, livestock, or property.

Annex 17 (contd)

Article 7.7.13.

Recommendations for DPM measures

The recommendations for DPM measures in Articles 7.7.14. to 7.7.24. should be implemented in accordance with the national context and local circumstances. A combination of the following measures should be used for a successful DPM programme.

- *Registration and identification of dogs*
- Commercial dog breeding and sale
- Control of national and international (export and import) dog movements
- Promoting *responsible dog ownership*
- Reproductive control
- “Catch, Neuter and Return”
- Reuniting and adoption
- Access to veterinary care
- Environmental controls
- Education in safe dog-human interaction.

Article 7.7.14.

Registration and identification of dogs

Outcomes of *registration* and identification of dogs include the following:

- supports enforcement of legislation through proof of ownership;
- improves success rate in reuniting lost dogs to their owners;
- enables traceability in commercial breeding and sale;
- encourages responsible ownership behaviours;
- support for an animal health programme, e.g., mandatory rabies *vaccination* and traceability.

These outcomes require widespread adoption of *registration* and *identification*.

Competent Authorities should ensure that a centralised database is established for dog *registration* to allow for reuniting of identified dogs with registered owners across the territory. *Competent Authorities* should ensure there is an enforcement system in place with the capacity to deliver appropriate methods of identification to all dogs (such as microchipping or Quick Response tags [QR tags]), read identification when a dog is found (using scanners or other devices) and access the *registration* database to retrieve owner details.

Owners need to be informed and able to access identification services and the *registration* system both initially to enter each dog, to update contact information, when there is a change of ownership or the dog dies.

Article 7.7.15.

Commercial dog breeding and sale

Outcomes of regulating commercial breeding and sale include:

- protection of dog health and welfare,
- avoidance of abandonment,
- transparency in dog breeding and sales.

Competent Authorities should require mandatory *registration* of all breeders and sellers. For commercial breeders and sellers, where the number of litters produced per year exceeds a threshold set by regulations, a further requirement for licensing can be imposed, including the requirement for inspection before trade can begin.

Advertisements for dog sales should be required to carry the *registration* or licence number of the breeder and seller.

To ensure dogs traceability, the breeder should be established through identification and *registration* as the first owner.

The seller should ensure *registration* details of the dog are updated with those of the first buyer following transfer of ownership.

Regulations of breeding practices should include limits on number of litters, minimum breeding age to protect the health and welfare of dam, good health of both parents and avoidance of selective breeding that leads to inherited diseases and extreme conformations. Regulations of both breeders and sellers should also outline specific requirements for accommodation, veterinary care, husbandry, puppy socialisation and habituation to their environment, minimum puppy age before leaving the dam and training of staff. Sales of puppies or adult dogs should be limited to adults and sales from exhibitions or from the street should be banned.

Article 7.7.16.

Control of national and international (export or import) dog movements

International movements of dog (import and export) should comply with trade measures, import or export procedures and veterinary certification according to Chapters 5.11., 7.2., 7.3., 7.4. and 8.14.

Movement of dogs within a country should be under the responsibility of the owner with the following outcomes:

- reducing the *risk* of contagious diseases spread,
- protecting public health and safety,
- protecting *wildlife* and livestock.

Article 7.7.17.

Promoting responsible dog ownership

- 1) Owning a dog is a choice and should result in a mutually beneficial relationship. The benefits of dog ownership come with responsibilities. Promoting *responsible dog ownership* through education and enforcement of national and local regulations is a core component of a DPM programme to achieve the following outcomes:
 - improve the health and welfare of dogs;
 - support the human-animal bond;
 - minimise the *risk* that dogs pose to the community;
 - reduce the number of dogs allowed to roam.

Annex 17 (contd)

- 2) Education on *responsible dog ownership* (for the currently *owned dog* and any offspring it produces for its lifetime or until the responsibility is passed to the next owner) should address the following elements:
- providing appropriate care to ensure the welfare of the dog and any offspring according to the dog's five welfare needs (suitable environment, suitable diet, housed with or apart from other animals, ability to exhibit normal behaviour and protected from pain, suffering, injury, and disease) in order to meet the internationally recognised "five freedoms" (see point 2 of Article 7.1.2.);
 - encouraging appropriate behaviours, reducing unwanted behaviours (including dog bites) and supporting the dog's ability to cope with its environment through attention to socialisation and training;
 - *registration* and identification of dogs (see Article 7.7.14.);
 - access to veterinary care (see Article 7.7.21.);
 - preventing negative impacts of dogs on the community, via pollution (e.g., faeces and noise), *risks* to human health through bites or traffic accidents and *risks* to other dogs, *wildlife*, livestock and another companion animal species;
 - control of dog reproduction (see Article 7.7.18.);
 - arranging for the care of the dogs when the owner is unable to do so.
- 3) Achieving sustained and widespread responsible ownership requires an understanding of barriers and motivations for responsible behaviour and taking action to address these. This will likely require a combination of legislation, public awareness and enforcement, behaviour change campaigns, formal education in schools and encouragement through the building of social expectations. It may also be necessary to improve availability and accessibility to resources supporting responsible ownership, such as veterinary care, identification and *registration* services and measures for control of zoonotic *diseases*.

Article 7.7.18.

Reproductive control

- 1) Outcomes of controlling reproduction in dogs include the following:
- prevents the birth of unwanted puppies;
 - helps address the imbalance between reproduction and demand for dogs;
 - reduces the size of free-roaming dog population.
- 2) Efficient use of reproduction control does not require limiting overall population size. To ensure best use of resources, focus should be on controlling reproduction of females most likely to be the source of unwanted and free-roaming dogs.
- 3) Methods of controlling reproduction will require direct veterinary input to individual animals. Involvement of both private and public veterinary sectors may be required to meet demand for services. Subsidisation of sterilisation programmes by government or other organisations may be considered to encourage uptake. The control of reproduction in *owned dogs* is essentially the responsibility of owners and should be incorporated into promotion of responsible ownership (see Article 7.7.17.).
- 4) Methods for controlling reproduction in dogs include:
- surgical sterilisation;
 - non-surgical sterilisation or contraception, including chemical and immunological approaches;
 - separation/confinement of female dogs during oestrus from unsterilised males.

Annex 17 (contd)

- 5) Surgery has the primary advantage of being permanent. Surgical sterilisation must be carried out by a *veterinarian* and must include good surgical technique, a good standard of asepsis, appropriate anaesthesia and proactive, multi-modal pain management maintained throughout and adjusted to the individual animal as needed. This requires *monitoring* during and post-operatively for the whole recovery period. It requires suitably trained *veterinarians* and *veterinary paraprofessionals* and access to appropriate drugs and equipment. *Competent Authorities* are responsible for ensuring access to training and drugs to ensure surgical sterilisation can be performed safely.
- 6) Castration of male dogs is generally preferred over vasectomies, as unlike castration, vasectomy does not reduce sex hormone levels and therefore has no mechanism to reduce sex-specific behaviours, such as roaming, territory marking and fighting (Houlihan, 2017; McGreevy *et al.*, 2018). Females may be surgically sterilised by ovariectomy, ovariectomy, hysterectomy or tubal ligation. Tubal ligation and hysterectomy are not recommended as the female will be under ovarian hormonal influences and will continue to show sexual behaviour.
- 7) Any chemicals or drugs used in controlling reproduction should be shown to have appropriate safety, quality and efficacy for the function required and used in accordance with the manufacturer's recommendations and *Competent Authority's* regulations. In the case of non-surgical sterilant and contraceptives in the research phase, trials may need to be completed before use.

Article 7.7.19.

“Catch, Neuter and Return”

“Catch, Neuter and Return” provides an approach to controlling the reproduction of unowned dogs as a source of *free roaming dogs*. This is not a stand-alone solution to DPM and must be used in combination with other measures addressing other sources of *free-roaming dogs*. It can be considered a method of managing the current free roaming dog population *in situ* on the streets and hence an alternative to removal for reuniting and adoption (see Article 7.7.20.).

In collaboration with local community, identified unowned dogs are caught, provided with health care (including rabies *vaccination*), evaluated for adoption, if adoption is not feasible, sterilised, and released to their local community at or near the place of capture. This method is more likely to be accepted in the situation where the presence of *free-roaming dogs* is widespread and well tolerated by the local community.

This method is not applicable in all situations and may be illegal in countries or regions where legislation prohibits the abandonment of dogs. Problems caused by dogs, such as noise, faecal pollution, bite injuries and traffic accidents, would not be alleviated as dogs are returned to the local community and their movements are not restricted. Consideration should be given to the *risk* that “Catch, Neuter and Return” could encourage abandonment of unwanted dogs. In the situation where many free-roaming dogs are owned, a DPM programme that focuses on neutering and responsible ownership may be more appropriate.

It is recommended that before adopting this approach, a cost-benefit analysis is conducted. Factors such as the monetary costs, impact on culture of ownership and public safety should be assessed as well as the benefits for *disease control* and *animal welfare* as well as any societal benefits.

If this measure is implemented, the *Competent Authority* should ensure the following are addressed:

- engaging local communities to understand, support, design and be an active part of “Catch, Neuter and Return” activities and *monitoring* of released dogs, in particular in the case of dogs cared for by the community;
- use of humane methods for catching, transporting and holding dogs;
- correct surgical technique with a good standard of asepsis, anaesthesia and analgesia, followed by post-operative care (see Article 7.7.18.);
- *disease control* may include *vaccination* (e.g., rabies) and treatments and testing for *diseases* (e.g., leishmaniasis) followed, as appropriate by treatment or *euthanasia* of the dog;

Annex 17 (contd)

- “catch, neuter and return” is not suitable for all dogs and should be applied on an individual basis. Health assessment and behavioural observation may be used to assess if dogs are suitable for release; if not suitable for release or adoption, *euthanasia* should be considered;
- permanent marking (e.g., tattoo or microchip) to indicate that the animal has been sterilised; individual identification also allows for tracking of *vaccination* status and treatment history. A visible identification (e.g., collar, tag or ear notch) may also be used to prevent unnecessary recapture;
- the dog should be returned to a place that is as near as possible to the place of capture;
- the behaviour and welfare of dogs after release should be monitored and action taken if required.

Article 7.7.20.

Reuniting and adoption

Free roaming dogs can be removed to housing facilities for reuniting with their owners or adopted. This addresses only the current free roaming population and not the source of these dogs, hence must be used in combination with other measures to prevent replacement of removed dogs. Evidence collected about dogs and dog owner practices during DPM programme development must confirm that reuniting and adoption is probable and achievable before developing reuniting and adoption facilities. Without sufficient adoptive homes or systems for reuniting, facilities quickly fill to capacity creating an ineffective and expensive measure. The *Competent Authority* should ensure capture, transport, and holding of dogs is done humanely.

Dogs that are removed from a community may be reunited with the owner or adopted. There should be provision for holding the dogs for a reasonable period to allow for reuniting with the owner and, as appropriate, for rabies observation. Reuniting and adoption provide an opportunity to promote responsible ownership and good animal health care (including rabies *vaccination* and sterilisation). The suitability of dogs should be assessed and matched with available owners. The effectiveness of adoption may be limited by the number of adoptive homes.

Dogs that are removed from a community may be too numerous or may be unsuitable for adoption. If acceptable to the local community, “Catch, Neuter and Return” may provide an alternative approach (see Article 7.7.19.). If *euthanasia* of these unwanted animals is the only option, the procedure should be conducted in accordance with Article 7.7.27.

Article 7.7.21.

Access to veterinary care

Access to veterinary care delivered by *veterinary services* positively impacts animal health, *animal welfare*, and public health through provision of preventive and therapeutic veterinary care to dogs in a community. Increased interactions with *veterinary services* provide additional opportunities to educate dog owners on *responsible dog ownership* (see Article 7.7.17.). From a DPM perspective, the prevention of disease, treatment of illness and injury, and *euthanasia* to end suffering where treatment is not feasible, potentially reduces abandonment of sick or injured dogs.

Veterinary care should be part of DPM programmes and contribute to disease control by creating healthier populations of dogs with reduced population turnover. Herd immunity for rabies control is supported by DPM through improvement in the survival of vaccinated dogs and reducing birth of unvaccinated puppies through surgical sterilisation. Guidance on implementing dog rabies *vaccination* campaigns is provided in Chapter 8.14.

Preventive veterinary care is central to zoonotic disease control and *surveillance*. DPM programmes should encompass or align with all disease control measures relevant to dogs. This includes rabies *vaccination* for controlling dog-mediated rabies (see Chapter 8.14.) and deworming for *Echinococcus granulosus* (see Chapter 8.5).

Veterinary services should identify ‘at risk’ populations of dogs that do not have reliable access to basic veterinary care. *Competent Authorities* should facilitate access to veterinary care. Potential solutions may include subsidising costs and organising outreach *veterinary services*.

Article 7.7.22.

Environmental controls

Actions should be taken to exclude dogs from uncontrolled sources of food (e.g., rubbish dumps and *abattoirs* and installing animal-proof rubbish containers). Chapter 8.5. provides additional recommendations on environmental controls for the prevention and control of *Echinococcus granulosus*. Environmental control should be linked to other DPM measures, to avoid *animal welfare* problems from a sudden reduction in food sources.

Article 7.7.23.

Education in safe dog-human interaction

The most effective means of reducing *prevalence* of dog bites are education in safe interaction with dogs and owner responsibility for training and managing dogs as part of *responsible dog ownership* (see Article 7.7.17.). Young children are the group at highest *risk* for dog bites. Public education programmes focussed on appropriate dog-directed behaviour have been demonstrated to be effective in reducing dog bite *prevalence* and these programmes should be encouraged. *Competent Authorities* should seek advice from dog behaviour experts in developing dog safety education programmes.

Education programmes on appropriate bite treatment, and when necessary post-exposure prophylaxis, for all age groups is encouraged.

Article 7.7.24

Specific consideration for dog population management activities

Articles 7.7.25. to 7.7.27. are recommendations for activities that may be required as part of the implementation of the above measures:

- Dog capture and handling;
- Dog housing;
- *Euthanasia*.

Euthanasia of dogs, used alone, is not effective for DPM. If used, it should be done humanely (see Article 7.7.27.) and implemented in combination with other measures as part of a DPM programme.

Article 7.7.25.

Dog capture and handling

Humane capture and handling aim to prevent animal suffering and distress. It can also bring other benefits, including reduced injuries to handlers, easier handling of dogs in future and modelling positive handling to owners and public.

Competent Authorities should develop appropriate legislation and training to promote humane handling and enforce regulations against cruel methods, including the use of tongs and uncovered wire loops. *Animal welfare* and operator safety outcomes are improved when the personnel conducting capture and handling have a complete understanding of, and proficiency in, the capture and handling method to be used.

Competent Authorities and *veterinary services* should ensure their staff and volunteers expected to handle dogs have received rabies pre-exposure *vaccination* and are provided with clear protocols for treating injuries, including dog bites.

The least aversive method of capture and handling should be used to minimise harm and discomfort. Further, handlers should strive to make the handling experience as positive as possible from the perspective of the dog; this includes looking for ways to reward the dog during handling.

Annex 17 (contd)

Handlers should use minimum *restraint* to provide the dog with opportunities to exert choice and control, so that they cope better with the handling.

Article 7.7.26.

Dog housing

Competent Authorities should develop minimum standards for the housing (physical facilities) and care of dogs to ensure the physical, mental and social needs of dogs are met. Enforcement of standards are supported by licensing and inspection of facilities (Barnard *et al.*, 2014). The following minimum standards should be considered:

a) Facilities

- sustainable finances to cover ongoing running costs;
- site selection: access to drainage, waste disposal, water and electricity are essential and environmental factors such as noise and pollution should be considered;
- kennel size, design and occupancy taking exercise and expected length of stay into account and providing sufficient area for dogs to separate the functions of eating or drinking, resting, urinating and defecating;
- disease control measures including isolation and *quarantine station*;
- maximum capacity of the facility.

b) Management

- provision of adequate fresh water and nutritious food;
- regular hygiene and cleaning;
- routine inspection, handling and exercise of the dogs;
- *monitoring* of physical and behavioural health and provision of required veterinary treatments under veterinary supervision, including routine and preventive veterinary care and *euthanasia*;
- policies and procedures to respect the maximum capacity for the facility and action when this is reached, assessment of dog health and behaviour, animal care, intake, treatment, adoption, sterilisation and *euthanasia*;
- provision of sufficient numbers of appropriately skilled staff and training of staff in safe, appropriate and positive handling of dogs;
- record keeping, animal identification, and reporting to the *Competent Authority*.

c) Assessment

Dog housing performance may be assessed using the following measurables:

- body condition score, skin condition, disease *incidence*, injuries and mortality, reaction to humans and conspecifics;
- housing must provide adequate space appropriate to the age, size, weight, and breed of the dog, and that allows the dog to engage in normal body movements, including the ability to sit, stand up, turn about freely, or lie recumbent in a natural position, stretch, move their head, hold tail erect while standing, comfortably eat, drink, urinate and defecate;

Annex 17 (contd)

- hygiene, cleaning, drainage and housing materials should prevent an excessive accumulation of faeces and food waste, to prevent soiling of dogs in the enclosure, reduce disease *hazards*, insects, pests and odours;
- ventilation should allow dogs to comfortably maintain normal body temperature and provide good air quality;
- protection from harmful extremes of temperature, air movement, moisture, light and other climatic elements to ensure proper health and well-being of the dog.

Article 7.7.27.

Euthanasia

Euthanasia of dogs, used alone, is not effective for DPM. If used, it should be done humanely and implemented in combination with other measures as part of a DPM programme to achieve effective long-term management. Reducing dog population size is not an effective means of reducing the number of rabies cases [WHO, 2018].

As a process, *euthanasia* involves pre-*euthanasia* and handling procedures, *euthanasia* methods and agents, confirmation of *death*, and carcass disposal. When *euthanasia* is practised, the general principles in the *Terrestrial Code* should be applied, with the emphasis on using practical methods which achieve the most rapid, painless, and distress free-*death* possible while ensuring operator safety. *Euthanasia* should be conducted under the supervision of a *veterinarian*. To ensure *animal welfare* and operator safety, the personnel conducting *euthanasia* should have a complete understanding of, and proficiency in, the *euthanasia* method to be used.

a) Restraint

When a dog needs to be restrained for any procedure, including *euthanasia*, this should always be done with full regard for operator security and *animal welfare*. Animal handling should also minimise distress experienced by the dog prior to loss of consciousness. Some *euthanasia* methods should be used in with prior sedation or anaesthesia to be considered humane. Regardless the *euthanasia* method used, pre-*euthanasia* sedation or anaesthesia should be used to minimise anxiety or facilitate safe *restraint*.

b) Euthanasia methods

The following are recommended methods of canine *euthanasia*:

- intravenous barbiturates,
- intraperitoneal barbiturates in small dogs or puppies,
- intravenous anaesthetic overdose,
- inhaled anaesthetic overdose in small dogs (not neonates).

If anaesthetised:

- administration of barbiturates by alternate routes (intracardiac, intrarenal, intrahepatic, intraosseous).

If sedated:

- intravenous *euthanasia* specific formulation of embutramide, chloroquine and lidocaine;
- intravenous *euthanasia* specific formulation of embutramide, mebezonium and tetracaine.

Annex 17 (contd)

Methods, procedures and practices that are unacceptable as primary methods of *euthanasia* on *animal welfare* grounds include air embolism, asphyxiation, burning, chloral hydrate, chloroform, cyanide, decompression, drowning, exsanguination, formalin, household products and solvents, hypothermia, insulin, neuromuscular blocking agents (magnesium sulphate, potassium chloride, nicotine, and all curariform agents), manually applied blunt force trauma to the head, rapid freezing, thoracic compression, strychnine, nitrous oxide, ether, kill-trapping, CO from engine fumes, CO₂ if the required concentration and flow rates are not regulated and monitored, free-bullet without proper anatomic placement at close range by highly trained personnel, penetrating captive bolt, electrocution if not already under general anaesthesia, *stunning* without secondary kill method.

c) Confirmation of death

For all methods of *euthanasia* used, *death* should be confirmed before animals are disposed of or left unattended.

A combination of criteria is most reliable in confirming *death*, including lack of pulse, breathing, corneal reflex, and response to firm toe pinch; inability to hear respiratory sounds and heartbeat by use of a stethoscope; greying of the mucous membranes; and rigor mortis. None of these signs alone, except rigor mortis, confirms *death*. If an animal is not dead, another method of *euthanasia* should be performed.

d) Carcass disposal

Carcasses should be disposed of in a manner that complies with legislation. Attention should be paid to the *risk* of residues occurring in the carcass. Incineration is generally the safest way of carcass disposal (see Chapter 4.13.).

References [Note: references will be removed when the chapter is adopted.]

Barnard, S., Pedernera, C., Velarde, A., Dalla Villa, P. (2014). Shelter Quality: Welfare Assessment Protocol for Shelter Dogs. © Istituto Zooprofilattico Sperimentale dell'Abruzzo e del Molise "G. Caporale", 2014 (ISBN 9788890869167)

Houlihan, K.E. (2017). A literature review on the welfare implications of gonadectomy of dogs. JAVMA 250:10.

McGreevy P.D., Wilson B., Starling M.J., Serpell J.A. (2018). Behavioural risks in male dogs with minimal lifetime exposure to gonadal hormones may complicate population-control benefits of desexing. PLoS ONE 13(5): e0196284. <https://doi.org/10.1371/journal.pone.0196284>

Paolini, A.; Romagnoli, S.; Nardoia, M.; Conte, A.; Salini, R.; Podaliri Vulpiani, M.; Dalla Villa, P. (2020). Study on the Public Perception of "Community-Owned Dogs" in the Abruzzo Region, Central Italy. *Animals*, 10, 1227.

World Health Organization. (2018). WHO Expert Consultation on Rabies, third report. Geneva. (WHO Technical Report Series, No. 1012).

CHAPTER 8.8.

INFECTION WITH FOOT AND MOUTH DISEASE VIRUS

Article 8.8.1.

General provisions

- 1) Many different species belonging to diverse taxonomic orders are known to be susceptible to *infection* with foot and mouth disease virus (FMDV). Their epidemiological significance depends upon the degree of susceptibility, the husbandry system, the density and extent of populations and the contacts between them. Amongst *Camelidae*, only Bactrian camels (*Camelus bactrianus*) are sufficiently susceptible to have potential for epidemiological significance. Dromedaries (*Camelus dromedarius*) are not susceptible to *infection* with FMDV while South American camelids are not considered to be of epidemiological significance.
- 2) For the purposes of the *Terrestrial Code*, foot and mouth disease (FMD) is defined as an *infection* of animals of the suborder *ruminantia* and of the family *suidae* of the order *Artiodactyla*, and *Camelus bactrianus* with FMDV.
- 3) The following defines the occurrence of *infection* with FMDV:
 - a) FMDV has been isolated from a sample from an animal listed in point 2; or
 - b) ~~viral~~ antigen or ~~viral~~ ribonucleic acid specific to FMDV has been identified in a sample from an animal listed in point 2, showing clinical signs consistent with FMD, or epidemiologically linked to a suspected or confirmed *outbreak* of FMD, or giving cause for suspicion of previous association or contact with FMDV; or
 - c) antibodies to structural or non-structural proteins (NSP) of FMDV, that are not a consequence of *vaccination*, have been identified in a sample from an animal listed in point 2, showing clinical signs consistent with FMD, or epidemiologically linked to a suspected or confirmed *outbreak* of FMD, or giving cause for suspicion of previous association or contact with FMDV.
- 4) Transmission of FMDV in a vaccinated *population* is demonstrated by change in virological or serological evidence indicative of recent *infection*, even in the absence of clinical signs.
- 5) For the purposes of the *Terrestrial Code*, the *incubation period* of FMD shall be 14 days.
- 6) *Infection* with FMDV can give rise to *disease* of variable severity and to FMDV transmission of FMDV. FMDV may persist in the pharynx and associated lymph nodes of ruminants for a variable but limited period of time beyond 28 days after *infection*. Such animals have been termed carriers. ~~However, The only persistently infected species from which transmission of FMDV has been proven is the African buffalo (*Syncerus caffer*). However, transmission from this species to domestic livestock is rare.~~
- ~~7) This chapter deals not only with the occurrence of clinical signs caused by FMDV, but also with the presence of *infection* with FMDV and transmission of FMDV in the absence of clinical signs.~~
- 8) Standards for diagnostic tests and vaccines are described in the *Terrestrial Manual*.

Article 8.8.1bis.**Safe commodities**

When authorising import or transit of the following commodities, Veterinary Authorities should not require any type of FMD-related conditions, regardless of the FMD status of the exporting country or zone:

Annex 18 (contd)

- 1) UHT milk and derivatives thereof;
 - 2) meat in hermetically sealed container with a F_0 value of 3 or above;
 - 3) meat and bone meal and blood meal;
 - 4) gelatine;
 - 5) in vivo derived bovine embryos collected, processed and stored in accordance with Chapter 4.8.
- Other commodities of susceptible species can be traded safely if in accordance with the relevant articles in this chapter.

Article 8.8.2.

FMD-free Country or zone free from FMD where vaccination is not practised

In defining a *zone* where *vaccination* is not practised the principles of Chapter 4.34 should be followed.

Susceptible animals in the FMD-free country or zone free from FMD, where *vaccination* is not practised should be protected by the application of *biosecurity measures* that prevents the entry of FMDV into the free country or *zone*.

Taking into consideration physical or geographical barriers with any neighbouring infected country or *zone*, these measures may include a *protection zone*.

To qualify for inclusion in the list of FMD-free countries or zones free from FMD, where *vaccination* is not practised, a Member Country should:

- 1) have a record of regular and prompt animal *disease* reporting;
- 2) send a declaration to the OIE stating that during the past 12 months, within the proposed FMD free country or zone:
 - a) there has been no case of FMD;
 - b) no *vaccination* against FMD has been carried out;
- 3) supply documented evidence that for the past 12 months:
 - a) *surveillance* in accordance with Articles 8.8.40. to 8.8.42. has been implemented to detect clinical signs of FMD and demonstrate no evidence of:
 - i) *infection* with FMDV in unvaccinated animals;
 - ii) FMDV transmission of FMDV in previously vaccinated animals when the FMD free country or zone where *vaccination* is practised is seeking to become one where *vaccination* is not practised;
 - b) regulatory measures for the prevention and early detection of FMD have been implemented;
- 4) describe in detail and provide supply documented evidence that for the past 12 months ~~the following have been properly implemented and supervised:~~
 - a) ~~in the case of a FMD free zone~~, the boundaries of the any proposed FMD free zone have been established and effectively supervised;
 - b) the boundaries and *biosecurity measures* of a any protection zone, if applicable have been established and effectively supervised;
 - c) the system for preventing the entry of FMDV into the proposed FMD free country or zone has been established and effectively supervised;

Annex 18 (contd)

- d) the control of the movement of susceptible animals, their *meat* and other products, and fomites into the proposed FMD free country or zone, in particular the measures described in Articles 8.8.8., 8.8.9. and to 8.8.12. has been effectively implemented and supervised;
- e) measures to prevent the introduction of no vaccinated animals has been introduced, except in accordance with Articles 8.8.8. and 8.8.9., 8.8.9bis., 8.8.11. and 8.8.11bis. have been effectively implemented and supervised. Any vaccinated animals introduced for direct slaughter were subjected to ante- and post-mortem inspections in accordance with Chapter 6.2. with favourable results. For ruminants the head, including the pharynx, tongue and associated lymph nodes, was either destroyed or treated in accordance with Article 8.8.31.

The Member Country or the proposed free zone will be included in the list of FMD free countries or zones free from FMD, where vaccination is not practised only after the submitted evidence, based on the provisions of Article 1.6.6., has been accepted by the OIE.

Retention on the list requires that the information in points 2, 3 and 4 above be re-submitted annually and changes in the epidemiological situation or other significant events including those relevant to points 3b) and 4 should be reported to the OIE in accordance with the requirements in Chapter 1.1.

A country or zone free from FMD may maintain its free status despite an incursion of potentially infected African buffaloes provided that the surveillance programme substantiates the absence of transmission of FMDV.

Provided the conditions of points 1 to 4 3 are is fulfilled, the status of a country or zone will not be affected by applying official emergency vaccination to FMD susceptible animals in zoological collections in the face of a FMD threat identified by the *Veterinary Authorities*, provided that the following conditions are met:

- the zoological collection has the primary purpose of exhibiting animals or preserving rare species, has been identified, including the boundaries of the facility, and is included in the country's contingency plan for FMD;
- appropriate *biosecurity* measures are in place, including effective separation from other susceptible domestic populations or *wildlife*;
- the animals are identified as belonging to the collection and any movements can be traced;
- the vaccine used complies with the standards described in the *Terrestrial Manual*;
- *vaccination* is conducted under the supervision of the *Veterinary Authority*;
- the zoological collection is placed under *surveillance* for at least 12 months after *vaccination*.

In the event of the application for the status of a new FMD free zone where vaccination is not practised to be assigned to a new zone being adjacent to another FMD free zone of the same status where vaccination is not practised, it should be stated if the new zone is being merged with the adjacent zone to become one enlarged zone. If the two zones remain separate, details should be provided on the control measures to be applied for the maintenance of the status of the separate zones and particularly on the identification and the control of the movement of animals between the zones of the same status in accordance with Chapter 4.3.

In the case of an incursion of stray African buffalo, a protection zone according to Article 4.4.6. should be established to manage the threat and maintain the free status of the rest of the country.

If a protection zone used is established, to preserve the status of a free country or zone from a newly identified likelihood of introduction of FMDV it should comply with Article 4.43.6. If vaccination is implemented in the protection zone, this will not affect the freedom of the rest of the country or zone the animal health status of the rest of the country or zone is not affected.

Article 8.8.3.

FMD free Country or zone free from FMD where vaccination is practised

In defining a zone where vaccination is practised the principles of Chapter 4.3. should be followed.

Annex 18 (contd)

Susceptible animals in the FMD-free country or zone free from FMD where *vaccination* is practised should be protected by the application of *biosecurity* measures that prevent the entry of FMDV into the free country or *zone*. Taking into consideration physical or geographical barriers with any neighbouring infected country or *zone*, these measures may include a *protection zone*.

Based on the epidemiology of FMD in the country, it may be decided to vaccinate only a defined *subpopulation* comprised of certain species or other subsets of the total susceptible *population*.

To qualify for inclusion in the list of FMD-free countries or zones free from FMD where *vaccination* is practised, a Member Country should:

- 1) have a record of regular and prompt animal *disease* reporting;
- 2) send a declaration to the OIE stating that, based on the *surveillance* described in point 3, within the proposed FMD free country or zone:
 - a) there has been no case of FMD during the past two years;
 - ba) there has been no evidence of FMDV transmission of FMDV during the past 12 months;
 - b) there has been no case with clinical sign of FMD during the past 12 months;
- 3) supply documented evidence that:
 - a) surveillance to detect clinical signs of FMD has been implemented in accordance with Articles 8.8.40. to 8.8.42. has been implemented to detect clinical signs of FMD for the past two years and demonstrates no evidence of that there has been no:
 - i) infection with FMDV in unvaccinated animals for the past two years-12 months;
 - ii) FMDV transmission of FMDV in vaccinated animals for the past 12 months;
 - b) regulatory measures for the prevention and early detection of FMD have been implemented for the past 12 months two years;
 - c) compulsory systematic vaccination in the target population has been carried out to achieve adequate vaccination coverage and population immunity for the past 12 months two years;
 - d) vaccination has been carried out following appropriate vaccine strain selection for the past 12 months two years;
- 4) describe in detail and supply provide documented evidence that for the past 12 months ~~the following have been properly implemented and supervised:~~
 - a) in case of FMD free zone, the boundaries of the proposed FMD free zone have been established and effectively supervised;
 - b) the boundaries and biosecurity measures of any protection zone, if applicable have been established and effectively supervised;
 - c) the system for preventing the entry of FMDV into the proposed FMD free country or zone, in particular the measures described in Articles 8.8.8., 8.8.9. and 8.8.12. has been established and effectively supervised;
 - d) the control of the movement of susceptible animals and their products into the proposed FMD free country or zone has been effectively implemented and supervised.

The Member Country or the proposed free *zone* will be included in the list of FMD-free countries or zones free from FMD where *vaccination* is practised only after the submitted evidence, based on the provisions of Article 1.6.6., has been accepted by the OIE.

Annex 18 (contd)

Retention on the list requires that the information in points 2, 3 and 4 above be re-submitted annually and changes in the epidemiological situation or other significant events including those relevant to points 3b) and 4 should be reported to the OIE in accordance with the requirements in Chapter 1.1.

If a Member Country that meets the requirements of a FMD free country or zone free from FMD where *vaccination* is practised wishes to change its status to FMD free country or zone free from FMD where *vaccination* is not practised, it should notify the OIE in advance of the intended date of cessation of *vaccination* and apply for the new status within 24 months of the cessation. The status of this country or zone remains unchanged until compliance with Article 8.8.2. is approved by the OIE. If the dossier for the new status is not provided within 24 months then the status of the country or zone as being free with *vaccination* will be suspended. If the country does not comply with requirements of Article 8.8.2., evidence should be provided within three months that it complies with Article 8.8.3. Otherwise the status will be withdrawn.

If a Member Country that meets the requirements of a country or zone free from FMD where *vaccination* is not practised and is recognised by the OIE as such, wishes to change its status to country or zone free from FMD where *vaccination* is practised, it should provide the OIE with an application and a plan following the structure of the Questionnaire of Article 1.6.6, indicating the intended date of beginning of *vaccination*. The status as country or zone free from FMD where *vaccination* is not practised of this country or zone remains unchanged until the application and plan are approved by the OIE. As soon as recognised free with *vaccination* the country or zone will begin the *vaccination*. The Member Country should provide evidence within six months that it complies with Article 8.8.3. for this time period. Otherwise the status will be withdrawn.

If a country needs to define a protection zone in accordance with Article 4.34.6. in response to an increased risk, including by the application of *vaccination*, once a the protection zone has been approved by the OIE, the freedom of the rest of the country or zone remains unchanged.

In the event of the application for ~~the status of a new FMD free free zone where *vaccination* is practised to be assigned to a new zone being~~ adjacent to another FMD free zone of the same status where *vaccination* is practised, it should be stated if the new zone is being merged with the adjacent zone to become one enlarged zone. If the two zones remain separate, details should be provided on the control measures to be applied for the maintenance of the status of the separate zones and particularly on the identification and the control of the movement of animals between the zones of the same status in accordance with Chapter 4.3.

Article 8.8.4.

FMD free Compartment free from FMD where *vaccination* is not practised

A FMD free compartment free from FMD where *vaccination* is not practised can be established in either a FMD free any country or zone or in an infected country or zone. In defining such a *compartment* the principles of Chapters 4.34. and 4.45. should be followed. Susceptible animals in the FMD free compartment should be separated from any other susceptible animals by the effective application of an effective biosecurity plan management system.

A Member Country wishing to establish a FMD free compartment free from FMD where *vaccination* is not practised should:

- 1) have a record of regular and prompt animal *disease* reporting and, if not FMD free, have an *official control programme* and a *surveillance* system for FMD in place in accordance with Articles 8.8.40. to 8.8.42. that allows knowledge of the prevalence, distribution and characteristics of FMD in the country or zone;
- 2) declare for the FMD free compartment that:
 - a) there has been no case of FMD during the past 12 months;
 - b) no evidence of infection with FMDV has been found detected during the past 12 months;
 - c) *vaccination* against FMD is prohibited;
 - d) no animal vaccinated against FMD within the past 12 months is in the *compartment*;
 - e) animals, semen, embryos and animal products may only enter the *compartment* in accordance with relevant articles in this chapter;

Annex 18 (contd)

- f) documented evidence shows that *surveillance* in accordance with Articles 8.8.40. to 8.8.42. is in operation;
 - g) an *animal identification* and *traceability* system in accordance with Chapters 4.1. and 4.2. is in place;
- 3) describe in detail:
- a) the animal *subpopulation* in the *compartment*;
 - b) the *biosecurity plan* to mitigate the risks identified by the *surveillance* carried out in accordance with point 1.

The *compartment* should be approved by the *Veterinary Authority*. The first approval should only be granted when no case or transmission of FMD has occurred within a 10 ten-kilometre radius of the *compartment* during the past three months prior to the effective establishment of the *biosecurity plan*.

Article 8.8.4bis.**Compartment free from FMD where vaccination is practised**

A *compartment* free from FMD where *vaccination* is practised can be established in either a free country or *zone* where *vaccination* is practised or in an infected country or *zone*. In defining such a *compartment* the principles of Chapters 4.34. and 4.45. should be followed. Susceptible animals in the free *compartment* should be separated from any other susceptible animals by the application of an effective *biosecurity plan*.

A Member Country wishing to establish a *compartment* free from FMD where *vaccination* is practised should:

- 1) have a record of regular and prompt animal *disease reporting* and, if not free, have an *official control programme* and a *surveillance* system for FMD in place in accordance with Articles 8.8.40. to 8.8.42. that allows knowledge of the prevalence, distribution and characteristics of FMD in the country or *zone*;
- 2) declare for the free *compartment* where *vaccination* is practised that:
 - a) there has been no case of FMD during the past 12 months;
 - b) no *evidence of infection with transmission* of FMDV has been found during the past 12 months;
 - c) compulsory systematic *vaccination* is carried out using a vaccine that complies with the standards described in the *Terrestrial Manual*, including appropriate vaccine strain selection. The *vaccination* coverage and population immunity are closely monitored;
 - d) animals, semen, embryos and animal products may only enter the *compartment* in accordance with relevant articles in this chapter;
 - e) documented evidence shows that regular clinical, serological and virological *surveillance* in accordance with Articles 8.8.40. to 8.8.42. is in operation, so as to detect *infection* at an early stage with a high level of confidence;
 - f) an *animal identification* and *traceability* system in accordance with Chapters 4.1. and 4.2. is in place;
- 3) describe in detail:
 - a) the animal *subpopulation* in the *compartment*;
 - b) the *biosecurity plan* to mitigate the risks identified by the *surveillance* carried out according to point 1 and the *vaccination plan*;
 - c) implementation of points 2c), 2e) and 2f).

The compartment should be approved by the Veterinary Authority. The approval should only be granted when no case or transmission of FMD has occurred within a 10-kilometre radius of the compartment during the three months prior to the effective establishment of the biosecurity plan.

Article 8.8.5.

FMD-infected Country or zone infected with FMDV

For the purposes of this chapter, a ~~FMD-infected~~ country or zone infected with FMDV is one that does not fulfil the requirements to qualify as either ~~FMD free~~ where *vaccination* is not practised or ~~FMD free~~ where *vaccination* is practised.

Article 8.8.6.

Establishment of a containment zone within a FMD-free country or zone free from FMD

In the event of limited outbreaks within a ~~FMD-free~~ country or zone previously free from FMD, including within a *protection zone*, with or without *vaccination*, a single containment zone, which includes all epidemiologically linked outbreaks, may be established for the purpose of minimising the impact on the entire country or zone in accordance with Article 4.4.7.

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

- 1) on suspicion, a strict standstill has been imposed on the suspected *establishments* and in the country or zone animal movement control has been imposed and effective controls on the movement of other *commodities* mentioned in this chapter are in place;
- 2) on confirmation, an additional standstill of susceptible animals has been imposed in the entire *containment zone* and the movement controls described in point 1 have been reinforced;
- 3) the definitive boundaries of the containment zone have been established after an epidemiological investigation (trace-back, trace-forward) has demonstrated that the outbreaks are epidemiologically related and limited in number and geographic distribution;
- 4) investigations into the likely source of the *outbreaks* have been carried out;
- 5) a stamping-out policy, with or without the use of emergency vaccination, has been applied;
- 6) no new cases have been found in the containment zone within a minimum of two incubation periods as defined in Article 8.8.1. after the application of a stamping-out policy to the last detected case;
- 7) the susceptible domestic and captive wild animal populations within the containment zone are clearly identified as belonging to the containment zone;
- 8) surveillance in accordance with Articles 8.8.40. to 8.8.42. is in place in the *containment zone* and in the rest of the country or zone;
- 9) measures that prevent the spread of FMDV to the rest of the country or zone, taking into consideration physical and geographical barriers, are in place.

The free status of the areas outside the containment zone is suspended while the containment zone is being established. The free status of the these areas outside the containment zone may be reinstated irrespective of the provisions of Article 8.8.7., once the containment zone has been approved by the OIE as complying with points 1 to 9 above. Commodities from susceptible animals for international trade should be identified as to their origin, either from inside or outside the containment zone.

Annex 18 (contd)

In the event of recurrence of *infection* with FMDV in unvaccinated animals or FMDV transmission of FMDV in vaccinated animals in the *containment zone*, established in accordance with point 4a) of Article 4.4.7., the approval of the *containment zone* is withdrawn and the FMD status of the whole country or *zone* is suspended until the relevant requirements of Article 8.8.7. are fulfilled.

In the event of occurrence of *infection* with FMDV in unvaccinated animals or transmission of FMDV in vaccinated animals in the outer zone of a *containment zone* established in accordance with point 4a) of Article 4.4.7., the approval of the *containment zone* is withdrawn and the status of the whole country or *zone* is suspended until the relevant requirements of Article 8.8.7. are fulfilled.

The recovery of the FMD free status of the *containment zone* should be achieved within 12 months of its approval and follow the provisions of Article 8.8.7.

Article 8.8.7.

Recovery of free status (see Figures 1 and 2)

- 1) When a FMD case occurs in a FMD free country or *zone* previously free from FMD where *vaccination* is not practised, one of the following waiting periods is required to regain this free status:
 - a) three months after the disposal of the last animal killed where a *stamping-out policy*, without emergency *vaccination*, and *surveillance* are applied in accordance with Articles 8.8.40. to 8.8.42.; or
 - b) three months after the disposal of the last animal killed or the *slaughter* of all vaccinated animals, whichever occurred last, where a *stamping-out policy*, emergency *vaccination* and *surveillance* in accordance with Articles 8.8.40. to 8.8.42. are applied; or
 - c) six months after the disposal of the last animal killed or the last *vaccination*, whichever occurred last, where a *stamping-out policy*, emergency *vaccination* not followed by the slaughtering of all vaccinated animals, and *surveillance* in accordance with Articles 8.8.40. to 8.8.42. are applied. However, this requires a serological survey based on the detection of antibodies to non-structural proteins of FMDV to demonstrate no evidence of *infection* transmission of FMDV in the remaining vaccinated *population*. This period can be reduced to a minimum of three months if a country can submit sufficient evidence demonstrating absence of *infection* in the non-vaccinated *population*, and absence of transmission in the emergency vaccinated *population* based on the provisions of point 7 of Article 8.8.40. effectiveness of *vaccination* is demonstrated by a serological survey and serological *surveillance* for antibodies to nonstructural proteins is carried out in all vaccinated herds by sampling all vaccinated ruminants and their unvaccinated offspring, and a representative number of FMD susceptible animals of other species.

The country or *zone* will regain the its free status of FMD free country or *zone* where *vaccination* is not practised only after the submitted evidence, based on the provisions of Article 1.6.6., has been accepted by the OIE.

The time periods in points 1a) to 1c) are not affected if official emergency *vaccination* of zoological collections has been carried out following the relevant provisions of Article 8.8.2.

Where a *stamping-out policy* is not practised, the above waiting periods do not apply, and Article 8.8.2. applies.

- 2) When a FMD case of FMD occurs in a FMD free country or *zone* previously free from FMD where *vaccination* is not practised, the following waiting period is required to gain the status of FMD free country or *zone* free from FMD where *vaccination* is practised: six months after the disposal of the last animal killed where a *stamping-out policy* has been applied and a continued *vaccination* policy has been adopted, provided that *surveillance* is applied in accordance with Articles 8.8.40. to 8.8.42., and a serological survey based on the detection of antibodies to nonstructural proteins of FMDV demonstrates no evidence of FMDV transmission of FMDV.

The country or *zone* can gain the status of FMD free country or *zone* from FMD where *vaccination* is practised only after the submitted evidence, based on the provisions of Article 1.6.6., has been accepted by the OIE.

Where a *stamping-out policy* is not practised, the above waiting periods do not apply, and Article 8.8.3. applies.

Annex 18 (contd)

- 3) When a case of infection with FMDV occurs in a FMD-free country or zone previously free from FMD where vaccination is practised, one of the following waiting periods is required to regain this free status:
- six months after the disposal of the last animal killed where a stamping-out policy, with emergency vaccination, and surveillance in accordance with Articles 8.8.40. to 8.8.42. are applied, provided that serological surveillance based on the detection of antibodies to nonstructural proteins of FMDV demonstrates no evidence of virus transmission of FMDV. This period can be reduced to a minimum of three months if a country can submit sufficient evidence demonstrating absence of infection in the non-vaccinated population and absence of transmission of FMDV in the vaccinated population based on the provisions of points 7 and 8 of Articles 8.8.40. as appropriate; or
 - 12 months after the detection of the last case where a stamping-out policy is not applied, but where emergency vaccination and surveillance in accordance with Articles 8.8.40. to 8.8.42. are applied, provided that serological surveillance based on the detection of antibodies to nonstructural proteins of FMDV demonstrates no evidence of virus transmission of FMDV.

The country or zone will regain its free status only after the submitted evidence, based on the provisions of Article 1.6.6., has been accepted by the OIE.

When ~~re~~ emergency vaccination is not applied, the above waiting periods do not apply, and Article 8.8.3. applies.

~~The country or zone will regain the status of FMD free country or zone where vaccination is practised only after the submitted evidence, based on the provisions of Article 1.6.6., has been accepted by the OIE.~~

- When a FMD case of infection with FMDV occurs in a FMD-free compartment free from FMD, Article 8.8.4. or Article 8.8.4bis. applies.
- Member Countries applying for the recovery of status should do so only when the respective requirements for the recovery of status are met. When a containment zone has been established, the restrictions within the containment zone should be lifted in accordance with the requirements of this article only when ~~the disease~~ FMD has been successfully eradicated within the containment zone.

For Member Countries not applying for recovery within 24 months after suspension, the provisions of Article 8.8.2., Article 8.8.3. or Article 8.8.4. apply.

Article 8.8.8.

Direct transfer of FMD susceptible animals from an infected zone for slaughter in a free zone (whether vaccination is practised or not)

In order not to jeopardise the status of a free zone, FMD susceptible animals should only leave the infected zone if transported directly ~~to~~ for slaughter in the nearest designated slaughterhouse/abattoir under the following conditions:

- no FMD susceptible animal has been introduced into the establishment of origin and no animal in the establishment of origin has shown clinical signs of FMD for at least 30 days prior to movement;
- the animals were kept in the establishment of origin for at least three months prior to movement;
- FMD has not occurred within a 10-kilometre radius of the establishment of origin for at least four weeks prior to movement;
- the animals ~~should be~~ are transported under the supervision of the Veterinary Authority in a vehicle, which was cleansed and disinfected before loading, directly from the establishment of origin to the slaughterhouse/abattoir without coming into contact with other susceptible animals;
- such a slaughterhouse/abattoir is not approved for the export of fresh meat during the time it is handling the meat of animals from the infected zone;

Annex 18 (contd)

- 6) *vehicles* and the *slaughterhouse/abattoir* ~~should be~~ are subjected to thorough cleansing and *disinfection* immediately after use.

The animals should have been subjected to ante- and post-mortem inspection within 24 hours before and after *slaughter* with no evidence of FMD, and the *meat* derived from them treated in accordance with point 2 of Article 8.8.22. or Article 8.8.23. Other products obtained from the animals and any products coming into contact with them should be treated in accordance with Articles 8.8.31. to 8.8.38. in order to destroy any FMDV potentially present.

Article 8.8.9.

Direct transfer of FMD susceptible animals from a containment zone for slaughter in a free zone (whether vaccination is practised or not)

In order not to jeopardise the status of a free zone, FMD susceptible animals should only leave the *containment zone* if transported directly ~~to~~ for *slaughter* in the nearest designated *slaughterhouse/abattoir* under the following conditions:

- 1) the *containment zone* has been officially established in accordance with the requirements in Article 8.8.6.;
- 2) the animals ~~should be~~ are transported under the supervision of the *Veterinary Authority* in a *vehicle*, which was cleansed and disinfected before *loading*, directly from the *establishment* of origin to the *slaughterhouse/abattoir* without coming into contact with other susceptible animals;
- 3) such an *slaughterhouse/abattoir* is not approved for the export of *fresh meat* during the time it is handling the *meat* of animals from the *containment zone*;
- 4) *vehicles* and the *slaughterhouse/abattoir* ~~should be~~ are subjected to thorough cleansing and *disinfection* immediately after use.

The animals should have been subjected to ante- and post-mortem inspection within 24 hours before and after *slaughter* with no evidence of FMD and the *meat* derived from them treated in accordance with point 2 of Article 8.8.22. or Article 8.8.23. Other products obtained from the animals and any products coming into contact with them should be treated in accordance with Articles 8.8.31. to 8.8.38. in order to destroy any FMDV potentially present.

Article 8.8.9bis.**Direct transfer of FMD vaccinated animals from a free zone free from FMD where vaccination is practised or not for slaughter in a free zone where vaccination is not practised**

In order not to jeopardise the status of a free zone where vaccination is not practised, FMD vaccinated animals should only leave the free zone if transported directly for slaughter in the nearest designated slaughterhouse/abattoir under the following conditions:

- 1) no animal in the establishment of origin has shown clinical signs of FMD for at least 30 days prior to movement;
- 2) the animals were kept in the country or zone of origin for at least three months prior to movement;
- 3) the animals are transported under the supervision of the Veterinary Authority in a vehicle, directly from the establishment of origin to the slaughterhouse/abattoir;
- 4) if transiting an infected zone, the animals were not exposed to any source of FMDV during transportation to the place of shipment.

Article 8.8.10.

Recommendations for importation from FMD free countries, or zones or compartments free from FMD where vaccination is not practised or FMD free compartments free from FMD

For FMD susceptible animals

Annex 18 (contd)

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

- 1) showed no clinical sign of FMD on the day of shipment;
- 2) were kept since birth or for at least the past three months in a FMD-free country, or zone or compartment free from FMD where *vaccination* is not practised or a FMD-free compartment free from FMD;
- 3) if transiting an infected *zone*, were not exposed to any source of FMDV during transportation to the *place of shipment*;
- 4) if previously vaccinated, comply with point 4 of Article 8.8.11.

Article 8.8.11.

Recommendations for importation from FMD-free countries, ~~or zones~~ or compartments free from FMD where vaccination is practised

For domestic ruminants and pigs

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

- 1) showed no clinical sign of FMD on the day of shipment;
- 2) were kept since birth or for at least the past three months in a FMD-free country, or zone or compartment free from FMD where *vaccination* is practised;
- 3) if not vaccinated were subjected to a virological and serological tests for FMD with negative results on samples collected not earlier than 14 days before the shipment;
- 4) if vaccinated were subjected to virological and NSP serological tests for FMD with negative results on samples collected not earlier than 14 days before the shipment;
- 5) if transiting an infected zone, were not exposed to any source of FMDV during transportation to the *place of shipment*.

Article 8.8.11bis.

Recommendations for the importation from a free country, zone or compartment free from FMD where vaccination is practised

For vaccinated animals destined for slaughter

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

- 1) no animal in the establishment of origin has shown clinical signs of FMD for at least 30 days prior to shipment;
- 2) the animals were kept in the country, zone or compartment of origin since birth or for at least three months prior to shipment;
- 3) the animals were transported under the supervision of the *Veterinary Authority* directly from the establishment of origin in sealed vehicles/vessels;
- 4) if transiting an infected zone, the animals were not exposed to any source of FMDV during transportation to the *place of shipment*.

Annex 18 (contd)

Article 8.8.12.

Recommendations for importation from ~~FMD-infected~~ countries or zones infected with FMDV, where an official control programme existsFor domestic ruminants and pigs

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

- 1) the animals showed no clinical sign of FMD on the day of shipment;
- ~~2)~~ pigs have not been fed swill not complying with Article 8.8.31bis.;
- ~~32)~~ prior to isolation, the animals were kept in the *establishment* of origin:
 - a) for 30 days, or since birth if younger than 30 days, if a *stamping-out policy* is applied to control FMD in the *exporting country or zone*, or
 - b) for three months, or since birth if younger than three months if a *stamping-out policy* is not applied to control FMD in the *exporting country or zone*;
- ~~43)~~ the *establishment of origin* is covered by the *official control programme* and FMD has not occurred within it ~~the *establishment of origin*~~ for the relevant period as defined in points 2a) and 2b) above;
- ~~54)~~ the animals were isolated in an *establishment* for the 30 days prior to shipment, and all animals in isolation were subjected to diagnostic virological and serological tests for evidence of FMDV with negative results on samples collected at least 28 days after the start of isolation period, and that FMD did not occur within a 10-kilometre radius of the *establishment* during that period, or the *establishment* is a *quarantine station*;
- ~~65)~~ the animals were not exposed to any source of FMDV during their transportation from the *establishment* to the *place of shipment*.

Article 8.8.13.

~~Recommendations for importation from FMD free countries, or zones free from FMD where vaccination is not practised or FMD free compartments free from FMD~~For fresh semen of domestic ruminants and pigs

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

- 1) the donor males:
 - a) showed no clinical sign of FMD on the day of collection of the semen;
 - b) were kept for at least three months prior to collection in a FMD free country, or zone free from FMD where vaccination is not practised or FMD free compartments free from FMD;
 - e) were kept in an *artificial insemination centre* where none of the animals had a history of *infection* with FMDV;
- 2) the semen was collected, processed and stored in accordance with Chapters 4.5. and 4.6.

Article 8.8.14.

Recommendations for importation from ~~FMD free countries, or zones~~ or compartments free from FMD where vaccination is not practised or ~~FMD free~~ compartments free from FMDFor ~~fresh and~~ frozen semen of domestic ruminants and pigs

Annex 18 (contd)

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

- 1) the donor males:
 - a) showed no clinical sign of FMD on the day of collection of the semen ~~and for the following 30 days;~~
 - b) were kept for at least three months prior to collection in a ~~FMD-free country, or zone or compartment free from FMD~~ where *vaccination* is not practised ~~or FMD-free compartments free from FMD;~~
 - c) were kept in an artificial insemination centre;
- 2) the semen was collected, processed and stored in accordance with Chapters 4.5. and 4.6.

Article 8.8.15.

Recommendations for importation from ~~FMD-free countries or~~ zones or compartments free from FMD where *vaccination* is practised

For frozen semen of domestic ruminants and pigs

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

- 1) the donor males:
 - a) showed no clinical sign of FMD on the day of collection of the semen and for the following 30 days;
 - b) were kept for at least three months prior to collection in a ~~FMD-free country, or~~ zone or compartment free from FMD where *vaccination* is practised;
 - c) either
 - i) have been vaccinated at least twice, with the last *vaccination* not ~~less more~~ than ~~one~~ six months ~~and not more than six months prior to collection~~, unless protective immunity has been demonstrated for more than six months, and not less than one month prior to collection;
 - or
 - ii) were subjected, not less than 21 days after collection of the semen, to tests for antibodies against FMDV, with negative results;
- 2) the semen:
 - a) was collected, processed and stored in accordance with Chapters 4.5. and 4.6.;
 - b) was stored in the country of origin for a period of at least one month following collection, and during this period no animal on the *establishment* where the donor ~~animals~~ males were kept showed any sign of FMD.

Article 8.8.16.

Recommendations for importation from ~~FMD-infected countries or zones~~ infected with FMDV

For frozen semen of domestic ruminants and pigs

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

- 1) the donor males:
 - a) showed no clinical sign of FMD on the day of collection of the semen and for the following 30 days;

Annex 18 (contd)

- b) were kept in an *artificial insemination centre* ~~where to which~~ no animal had been added in the 30 days before collection, and within a 10-kilometre radius of which, that FMD has not occurred within a 10-kilometre radius of the artificial insemination centre for in the 30 days before and after collection;
- c) either
- i) have been vaccinated at least twice, with the last *vaccination* not ~~less~~ more than ~~one~~ six months ~~and not more than six months prior to collection~~, unless protective immunity has been demonstrated for more than six months, and not less than one month prior to collection;
- or
- ii) were subjected, not less than 21 days after collection of the semen, to tests for antibodies against FMDV, with negative results;
- 2) the semen:
- a) was collected, processed and stored in accordance with Chapters 4.5. and 4.6.;
- b) was subjected, with negative results, to a test for evidence of FMDV if the donor male has been vaccinated within the 12 months prior to collection;
- c) was stored in the country of origin for a period of at least one month following collection, and that during this period no animal on the *establishment* where the donor males were kept showed any sign of FMD.

Article 8.8.17.

Recommendations for the importation of *in vivo* derived embryos of bovines cattle

~~Irrespective of the FMD status of the exporting country, zone or compartment, Veterinary Authorities should authorise without restriction on account of FMD the import or transit through their territory of *in vivo* derived embryos of bovines cattle subject to the presentation of an international veterinary certificate attesting that the embryos were collected, processed and stored in accordance with the relevant provisions of Chapters 4.7. and 4.9., as relevant.~~

Article 8.8.18.

Recommendations for importation from FMD-free countries or, zones or compartments free from FMD where vaccination is not practised or FMD-free compartments free from FMDFor *in vitro* produced embryos of bovines cattle

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

- 1) the donor females:
- a) showed no clinical sign of FMD at the time of collection of the oocytes;
- b) were kept for at least three months prior to collection in a FMD-free country, or zone or compartment free from FMD where *vaccination* is not practised or FMD-free compartments free from FMD;
- 2) fertilisation was achieved with semen meeting the conditions referred to in Articles 8.8.13., 8.8.14., 8.8.15. or 8.8.16., as relevant;
- 3) the oocytes were collected, and the embryos were processed and stored in accordance with Chapters 4.8. and 4.9., as relevant.

Article 8.8.19.

Recommendations for importation from FMD-free countries ~~or~~ zones or compartments free from FMD where vaccination is practisedFor *in vitro* produced embryos of bovines ~~cattle~~

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

- 1) the donor females:
 - a) showed no clinical sign of FMD at the time of collection of the oocytes;
 - b) were kept for at least three months prior to collection in a FMD-free country, ~~or~~ zone or compartment free from FMD where *vaccination* is practised;
 - c) either
 - i) have been vaccinated at least twice, with the last *vaccination* not less more than ~~one~~ six months ~~and not more than six months prior to collection~~, unless protective immunity has been demonstrated for more than six months, and not less than one month prior to collection;
 - or
 - ii) were subjected, not less than 21 days after collection, to tests for antibodies against FMDV, with negative results;
- 2) fertilisation was achieved with semen meeting the conditions referred to in Articles 8.8.13., 8.8.14., 8.8.15. or 8.8.16., as relevant;
- 3) the oocytes were collected, and the embryos were processed and stored in accordance with Chapters 4.8. and 4.9., as relevant.

Article 8.8.20.

Recommendations for importation from FMD-free countries ~~or~~ zones or compartments free from FMD where vaccination is not practised ~~or FMD-free compartments free from FMD~~For fresh meat or meat products of FMD susceptible animals

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 FMD-free country or zone or compartment free from FMD where *vaccination* is not practised ~~or FMD-free compartment free from FMD~~, or which have been imported in accordance with Article 8.8.10., Article 8.8.11. or Article 8.8.12.;
- 2) have been slaughtered in an approved *slaughterhouse/abattoir* and have been subjected to ante- and post-mortem inspections with favourable results.

Article 8.8.21.

Recommendations for importation from FMD-free countries ~~or~~ zones or compartments free from FMD where vaccination is practisedFor fresh meat and meat products of ruminants and pigs

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

Annex 18 (contd)

- 1) have been kept in the ~~FMD free~~ country or zone or compartment free from FMD where *vaccination* is practised, or which have been imported in accordance with Article 8.8.10., Article 8.8.11. or Article 8.8.12.;
- 2) have been slaughtered in an approved *slaughterhouse/abattoir* and have been subjected to ante- and post-mortem inspections ~~for FMD~~ with favourable results;
- 3) for ruminants the head, including the pharynx, tongue and associated lymph nodes, has been excluded from the shipment.

Article 8.8.22.

Recommendations for importation from ~~FMD-infected~~ countries or zones infected with FMDV, where an official control programme exists

For fresh meat of bovines cattle and water buffaloes (*Bubalus bubalis*) (excluding feet, head and viscera)

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

- 1) comes from animals which:
 - a) have remained, for at least three months prior to *slaughter*, in a *zone* of the *exporting country* where bovines cattle and water buffaloes are regularly vaccinated against FMD and where an *official control programme* is in operation;
 - b) have been vaccinated at least twice with the last *vaccination* not more than six months, unless protective immunity has been demonstrated for more than six months, and not less than one month prior to *slaughter*;
 - c) were kept for the past 30 days in:
 - = a quarantine station; or in
 - = an establishment, within a ten 10-kilometre radius of which and that FMD has not occurred within a 10 kilometre radius of the establishment during that period, or the establishment is a quarantine station;
 - d) have been transported, in a *vehicle* which was cleansed and disinfected before the bovines cattle and water buffaloes were loaded, directly from the *establishment* of origin or *quarantine station* to the approved *slaughterhouse/abattoir* without coming into contact with other FMD susceptible animals which do not fulfil the required conditions for export;
 - e) have been slaughtered in an approved *slaughterhouse/abattoir*:
 - i) which is officially designated for export;
 - ii) in which no FMD has been detected during the period between the last *disinfection* carried out before *slaughter* and the shipment for export has been dispatched;
 - f) were subjected to ante- and post-mortem inspections in accordance with Chapter 6.2., with favourable results ~~have been subjected, with favourable results, to ante-mortem inspection within 24 hours of slaughter and to post-mortem inspections within 24 hours before and after slaughter with no evidence of FMD;~~
- 2) comes from deboned carcasses:
 - a) from which the major lymphatic nodes have been removed;

Annex 18 (contd)

- b) which, prior to deboning, have been submitted to maturation at a temperature greater than + 2°C for a minimum period of 24 hours following *slaughter* and in which the pH value was less than 6.0 when tested in the middle of both the longissimus dorsi muscle.

Article 8.8.22bis.**Recommendations for importation from countries or zones infected with FMDV, where an official control programme exists**For fresh meat of domestic pigs

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

- 1) the meat comes from animals complying with points 1 to 6 of Article 8.8.12.:
- 2) the animals were transported, in a vehicle which was cleaned and disinfected before the pigs were loaded, directly from the establishment of origin or quarantine station to the approved slaughterhouse/abattoir without coming into contact with other FMD susceptible animals that do not fulfil the conditions required for export, either during transport or at the slaughterhouse/abattoir.
- 3) the animals were slaughtered in an approved slaughterhouse/abattoir.
 - a) which is officially designated for export;
 - b) in which no FMD has been detected during the period between the last disinfection carried out before slaughter and the shipment for export has been dispatched;
- 4) the animals were subjected to ante- and post-mortem inspections in accordance with Chapter 6.2., with favourable results;
- 5) the carcasses were not released earlier than 24 hours after slaughter and not before Veterinary Authorities have confirmed that FMD has not occurred in the establishment of origin.

Article 8.8.23.**Recommendations for importation from ~~FMD-infected~~ countries or zones infected with FMDV**For meat products of FMD susceptible animals

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

- 1) the entire consignment of *meat products* come from animals which have been slaughtered in an approved *slaughterhouse/abattoir* and have been subjected to ante- and post-mortem inspections ~~for FMD~~ with favourable results;
- 2) the *meat products* have been processed to ensure the destruction of FMDV in accordance with one of the procedures in Article 8.8.31.;
- 3) the necessary precautions were taken after processing to avoid contact of the *meat products* with any potential source of FMDV.

Article 8.8.24.**Recommendations for importation from ~~FMD-free~~ countries or, zones or compartments free from FMD where ~~whether~~ vaccination either is practised or is not practised or ~~FMD-free~~ compartments free from FMD**

For milk and milk products (other than those defined in Article 8.8.1bis.) intended for human consumption and for products of animal origin (from FMD susceptible animals) intended for use in animal feeding or for agricultural or industrial use

Annex 18 (contd)

Veterinary Authorities should require the presentation of an *international veterinary certificate* attesting that these products come from animals which have been kept in a ~~FMD-free~~ country, zone or compartment free from FMD, or which have been imported in accordance with Article 8.8.10., Article 8.8.11. or Article 8.8.12.

Article 8.8.25.

Recommendations for importation from ~~FMD-infected~~ countries or zones infected with FMDV, where an official control programme exists

For milk and milk products (other than those defined in Article 8.8.1bis.)

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

- 1) these products:
 - a) originate from *establishments* which were not infected or suspected of being infected with FMD at the time of *milk* collection;
 - b) have been processed to ensure the destruction of FMDV in accordance with one of the procedures in Article 8.8.35. and in Article 8.8.36.;
- 2) the necessary precautions were taken after processing to avoid contact of the products with any potential source of FMDV.

Article 8.8.26.

Recommendations for importation from ~~FMD-infected~~ countries or zones infected with FMDV

For blood meal and meat meals from FMD susceptible animals

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

- 1) the manufacturing method for these products included heating to a minimum core temperature of 70°C for at least 30 minutes.;
- 2) the necessary precautions were taken after processing to avoid contact of the products with any potential source of FMDV.

Article 8.8.27.

Recommendations for importation from ~~FMD-infected~~ countries or zones infected with FMDV

For wool, hair, bristles, raw hides and skins from FMD susceptible animals

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

- 1) these products have been processed to ensure the destruction of FMDV in accordance with one of the procedures in Articles 8.8.32., 8.8.33. and 8.8.34.;
- 2) the necessary precautions were taken after collection or processing to avoid contact of the products with any potential source of FMDV.

Veterinary Authorities should authorise, without restriction, the import or transit through their territory of semi-processed hides and skins (limed hides, pickled pelts, and semi-processed leather such as wet blue and crust leather), provided that these products have been submitted to the usual chemical and mechanical processes in use in the tanning industry.

Article 8.8.28.

Recommendations for importation from ~~FMD-infected~~ countries or zones infected with FMDV

For straw and forage

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

- 1) are free of grossly identified contamination with material of animal origin;
- 2) have been subjected to one of the following treatments, which, in the case of material sent in bales, has been shown to penetrate to the centre of the bale:
 - a) either to the action of steam in a closed chamber such that the centre of the bales has reached a minimum temperature of 80°C for at least ~~ten~~ 10 minutes,
 - b) or to the action of formalin fumes (formaldehyde gas) produced by its commercial solution at 35-40% in a chamber kept closed for at least eight hours and at a minimum temperature of 19°C;

OR

- 3) have been kept in bond for at least four months before being released for export.

Article 8.8.29.

Recommendations for importation from ~~FMD-free countries~~, zones or compartments free from FMD, where whether vaccination either is practised or is not practised

For skins and trophies derived from FMD susceptible wildlife

Veterinary Authorities should require the presentation of an *international veterinary certificate* attesting that these products are derived from animals that have been killed in ~~such~~ a country or zone free from FMD or which have been imported from a country, *zone* or *compartment* free from FMD.

Article 8.8.30.

Recommendations for importation from ~~FMD-infected~~ countries or zones infected with FMDV

For skins and trophies derived from FMD susceptible wildlife

Veterinary Authorities should require the presentation of an *international veterinary certificate* attesting that these products have been processed to ensure the destruction of FMDV in accordance with the procedures in Article 8.8.37.

Article 8.8.31.

Procedures for the inactivation of FMDV in meat and meat products

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

1. Canning

Meat and *meat products* are subjected to heat treatment in a hermetically sealed container to reach an internal core temperature of at least 70°C for a minimum of 30 minutes or to any equivalent treatment which has been demonstrated to inactivate FMDV.

Annex 18 (contd)2. Thorough cooking

Meat, previously deboned and defatted, and *meat products* are subjected to a heat treatment that results in a core temperature of at least 70°C for a minimum of 30 minutes.

After cooking, they should be packed and handled in such a way they are not exposed to a source of FMDV.

3. Drying after salting

When *rigor mortis* is complete, the *meat* is deboned, treated with salt (NaCl) and 'completely dried'. It should not deteriorate at ambient temperature.

'Completely dried' is defined as a moisture protein ratio that is not greater than 2.25:1 or a water activity (Aw) that is not greater than 0.85.

Article 8.8.31bis.**Procedures for the inactivation of FMDV in swill**

For the inactivation of FMDV in swill, one of the following procedures should be used:

- 1) the swill is maintained at a temperature of at least 90°C for at least 60 minutes, with continuous stirring; or
- 2) the swill is maintained at a temperature of at least 121°C for at least ten minutes at an absolute pressure of 3 bar; or
- 3) the swill is subjected to an equivalent treatment that has been demonstrated to inactivate FMDV.

Article 8.8.32.

Procedures for the inactivation of FMDV in wool and hair

For the inactivation of FMDV present in wool and hair for industrial use, one of the following procedures should be used:

- 1) for wool, industrial washing, which consists of the immersion ~~of the wool~~ in a series of baths of water, soap and sodium hydroxide (~~soda-NaOH~~) or potassium hydroxide (~~potash-KOH~~);
- 2) chemical depilation by means of slaked lime or sodium sulphide;
- 3) fumigation with formaldehyde in a hermetically sealed chamber for at least 24 hours;
- 4) for wool, industrial scouring which consists of the immersion ~~of wool~~ in a water-soluble detergent held at 60-70°C;
- 5) for wool, storage ~~of wool~~ at 4°C for four months, 18°C for four weeks or 37°C for eight days.

Article 8.8.33.

Procedures for the inactivation of FMDV in bristles

For the inactivation of FMDV present in bristles for industrial use, one of the following procedures should be used:

- 1) boiling for at least one hour; or
- 2) immersion for at least 24 hours in a 1% aqueous solution of formaldehyde.

Article 8.8.34.

Procedures for the inactivation of FMDV in raw hides and skins

For the inactivation of FMDV present in raw hides and skins for industrial use, the following procedure should be used: treatment for at least 28 days with salt (NaCl) containing 2% sodium carbonate (Na₂CO₃).

Article 8.8.35.

Procedures for the inactivation of FMDV in milk and cream for human consumption

For the inactivation of FMDV present in *milk* and cream for human consumption, one of the following procedures should be used:

- 1) a process applying a minimum temperature of 132°C for at least one second (ultra-high temperature [UHT]); or
- 2) if the *milk* has a pH less than 7.0, a process applying a minimum temperature of 72°C for at least 15 seconds (high temperature - short time pasteurisation [HTST]); or
- 3) if the *milk* has a pH of 7.0 or greater, the HTST process applied twice.

Article 8.8.36.

Procedures for the inactivation of FMDV in milk for animal consumption

For the inactivation of FMDV present in *milk* for animal consumption, one of the following procedures should be used:

- 1) the HTST process applied twice; or
- 2) HTST combined with another physical treatment, e.g., maintaining a pH 6 for at least one hour or additional heating to at least 72°C combined with desiccation; or
- 3) UHT combined with another physical treatment referred to in point 2 above.

Article 8.8.37.

Procedures for the inactivation of FMDV in skins and trophies from susceptible wildlife ~~susceptible to the disease~~

For the inactivation of FMDV present in skins and trophies from susceptible wildlife ~~wild animals susceptible to FMD~~, one of the following procedures should be used prior to complete taxidermal treatment

- 1) boiling in water for an appropriate time so as to ensure that any matter other than bone, horns, hooves, claws, antlers or teeth is removed; or
- 2) gamma irradiation at a dose of at least 20 kiloGray at room temperature (20°C or higher); or
- 3) soaking, with agitation, in a 4% (weight/volume) solution of sodium carbonate (Na₂CO₃) maintained at pH 11.5 or greater for at least 48 hours; or
- 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 pH less than 3.0 for at least 48 hours; wetting and dressing agents may be added; or
- 5) in the case of raw hides, treating for at least 28 days with salt (NaCl) containing 2% sodium carbonate (Na₂CO₃).

Annex 18 (contd)

Article 8.8.38.

Procedures for the inactivation of FMDV in casings of ruminants and pigs

For the inactivation of FMDV present in casings of ruminants and pigs, the following procedures should be used: treating for at least 30 days either with dry salt (NaCl) or with saturated brine (NaCl, $a_w < 0.80$), or with phosphate supplemented salt containing 86.5% NaCl, 10.7% Na₂HPO₄ and 2.8% Na₃PO₄ (weight/weight/weight), either dry or as a saturated brine ($a_w < 0.80$), and kept at a temperature of greater than 12°C during this entire period.

Article 8.8.39.

OIE endorsed official control programme for FMD

The overall objective of an OIE endorsed *official control programme* for FMD is for countries to progressively improve the situation and eventually attain ~~FMD~~ free status. The *official control programme* should be applicable to the entire country even if certain measures are directed towards defined *subpopulations* only.

Member Countries may, on a voluntary basis, apply for endorsement of their *official control programme* for FMD when they have implemented measures in accordance with this article.

For a Member Country's *official control programme* for FMD to be endorsed by the OIE, the Member Country should:

- 1) have a record of regular and prompt animal *disease* reporting in accordance with the requirements in Chapter 1.1.;
- 2) submit documented evidence of the capacity of the *Veterinary Services* to control FMD; one way of providing this evidence is through the OIE PVS Pathway;
- 3) submit a detailed plan of the programme to control and eventually eradicate FMD in the country or *zone* including:
 - a) the timeline;
 - b) the performance indicators for assessing the efficacy of the control measures to be implemented;
 - c) documentation indicating that the *official control programme* for FMD is applicable to the entire country;
- 4) submit a dossier on the epidemiology of FMD in the country describing the following:
 - a) the general epidemiology in the country highlighting the current knowledge and gaps and the progress that has been made in controlling FMD;
 - b) the measures implemented to prevent introduction of *infection*, the rapid detection of, and response to, all FMD *outbreaks* in order to reduce the incidence of FMD *outbreaks* and to eliminate ~~FMDV~~ transmission of FMDV in at least one *zone* in the country;
 - c) the main livestock production systems and movement patterns of FMD susceptible animals and their products within and into the country;
- 5) submit evidence that ~~FMD surveillance is in place~~:
 - a) ~~FMD surveillance is in place, taking into account provisions in accordance with~~ Chapter 1.4. and the provisions on *surveillance* of this chapter;
 - b) ~~it has have~~ diagnostic capability and procedures, including regular submission of samples to a *laboratory* that carries out diagnosis and further characterisation of strains;
- 6) where *vaccination* is practised as a part of the *official control programme* for FMD, provide:
 - a) evidence (such as copies of legislation) that *vaccination* of selected *populations* is compulsory;

- b) detailed information on *vaccination* campaigns, in particular on:
- i) target populations for *vaccination*;
 - ii) monitoring of *vaccination* coverage, including serological monitoring of population immunity;
 - iii) technical specification of the vaccines used, including matching with the circulating FMDV strains, and description of the licensing procedures in place;
 - iv) the proposed timeline for the transition to the use of vaccines fully compliant with the standards and methods described in the *Terrestrial Manual*;
- 7) provide an emergency preparedness and response plan to be implemented in case of *outbreaks*.

The Member Country's *official control programme* for FMD will be included in the list of programmes endorsed by the OIE only after the submitted evidence, based on the provisions of Article 1.6.11., has been accepted by the OIE. Retention on the list requires an annual update on the progress of the *official control programme* and information on significant changes concerning the points above. Changes in the epidemiological situation and other significant events should be reported to the OIE in accordance with the requirements in Chapter 1.1.

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

- non-compliance with the timelines or performance indicators of the programme; or
- significant problems with the performance of the *Veterinary Services*; or
- an increase in the incidence or an extension of the distribution of FMD that cannot be addressed by the programme.

Article 8.8.40.

General principles of surveillance

Articles 8.8.40. to 8.8.42. define the principles and provide a guide for the *surveillance* of FMD in accordance with Chapter 1.4. applicable to Member Countries seeking establishment, maintenance or recovery of freedom from FMD at the country, *zone* or *compartment* level or seeking endorsement by the OIE of their *official control programme* for FMD, in accordance with Article 8.8.39. *Surveillance* aimed at identifying *disease* and FMDV infection with, or transmission of, FMDV should cover domestic and, where appropriate, *wildlife* species as indicated in point 2 of Article 8.8.1.

1. Early detection

A *surveillance* system in accordance with Chapter 1.4. should be the responsibility of the *Veterinary Authority* and should provide an early warning system to report suspected cases throughout the entire production, marketing and processing chain. A procedure should be in place for the rapid collection and transport of samples to a *laboratory* for FMD diagnosis. This requires that sampling kits and other equipment be available to those responsible for *surveillance*. Personnel responsible for *surveillance* should be able to seek assistance from a team with expertise in FMD diagnosis and control.

2. Demonstration of freedom

The impact and epidemiology of FMD widely differ in different regions of the world and therefore it is inappropriate to provide specific recommendations for all situations. *Surveillance* strategies employed for demonstrating freedom from FMD in the country, *zone* or *compartment* at an acceptable level of confidence should be adapted to the local situation. For example, the approach to demonstrating freedom from FMD following an *outbreak* caused by a pig-adapted strain of FMDV should differ significantly from an approach designed to demonstrate freedom from FMD in a country or *zone* where African buffaloes (*Syncaerus caffer*) provide a potential reservoir of *infection*.

Annex 18 (contd)

Surveillance for FMD should be in the form of a continuing programme. Programmes to demonstrate no evidence of *infection with FMDV* and transmission of FMDV should be carefully designed and implemented to avoid producing results that are insufficient to be accepted by the OIE or trading partners, or being excessively costly and logistically complicated.

The strategy and design of the *surveillance* programme will depend on the historical epidemiological circumstances including whether ~~or not~~ *vaccination* has been ~~used~~ practised or not.

A Member Country wishing to substantiate FMD freedom where *vaccination* is not practised should demonstrate no evidence of *infection with FMDV*.

A Member Country wishing to substantiate FMD freedom where *vaccination* is practised should demonstrate that FMDV has not been transmitted in any susceptible *populations*. Within vaccinated *populations*, serological surveys to demonstrate no evidence of ~~FMDV~~ transmission of FMDV should target animals that are less likely to show vaccine-derived antibodies to nonstructural proteins, such as young animals vaccinated a limited number of times, or unvaccinated animals. In any unvaccinated *subpopulation*, *surveillance* should demonstrate no evidence of *infection with FMDV*.

Surveillance strategies employed for establishing and maintaining a *compartment* should identify the prevalence, distribution and characteristics of FMD outside the *compartment*.

3. OIE endorsed official control programme

Surveillance strategies employed in support of an OIE endorsed *official control programme* should demonstrate evidence of the effectiveness of any *vaccination* used and of the ability to rapidly detect all FMD *outbreaks*.

Therefore considerable latitude is available to Member Countries to design and implement *surveillance* to establish that the whole territory or part of it is free from ~~FMDV~~ *infection with*, and transmission of FMDV and to understand the epidemiology of FMD as part of the *official control programme*.

The Member Country should submit a dossier to the OIE in support of its application that not only explains the epidemiology of FMD in the region concerned but also demonstrates how all the risk factors, including the role of *wildlife*, if appropriate, are identified and managed. This should include provision of scientifically based supporting data.

4. Surveillance strategies

The strategy employed to establish the prevalence of *infection with FMDV* or to substantiate freedom from ~~FMDV~~ *infection with*, or transmission of FMDV may be based on randomised or targeted clinical investigation or sampling at an acceptable level of statistical confidence, as described in Articles 1.4.4. and 1.4.5. If an increased likelihood of *infection* in particular localities or species can be identified, targeted sampling may be appropriate. Clinical inspection may be targeted at particular species likely to exhibit clear clinical signs (e.g., bovines ~~cattle~~ and pigs). The Member Country should justify the *surveillance* strategy chosen and the frequency of sampling as adequate to detect the presence of ~~FMDV~~ *infection with*, or transmission of FMDV in accordance with Chapter 1.4. and the epidemiological situation.

The design of the sampling strategy should incorporate an epidemiologically appropriate design prevalence. The sample size selected for testing should be adequate to detect *infection* or transmission 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 Country should justify the choice of design prevalence and confidence level based on the objectives of *surveillance* and the prevailing or historical epidemiological situation, in accordance with Chapter 1.4.

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

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

Annex 18 (contd)

The sensitivity and specificity of the diagnostic tests employed, including the performance of confirmatory tests, are key factors in the design, sample size determination and interpretation of the results obtained. The sensitivity and specificity of the tests used should be validated for the *vaccination* or *infection* history and production class of animals in the target population.

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

Laboratory results should be examined in the context of the epidemiological situation. Corollary information needed to complement the serological survey and assess the possibility of viral transmission includes but is not limited to:

- characterisation of the existing production systems;
- results of clinical *surveillance* of the suspects and their cohorts;
- description of number of, and protocol for, *vaccinations* performed in the area under assessment;
- *biosecurity* and history of the *establishments* with reactors;
- identification and traceability of animals and control of their movements;
- other parameters of regional significance in historic ~~FMDV~~ transmission of FMDV.

6. Demonstration of population immunity

Following routine *vaccination*, evidence should be provided to demonstrate the effectiveness of the *vaccination* programme such as adequate *vaccination* coverage and population immunity. This can help to reduce reliance on post-*vaccination* surveys for residual *infection* and transmission.

In designing serological surveys to estimate population immunity, blood sample collection should be stratified by age to take account of the number of *vaccinations* the animals have received. The interval between last *vaccination* and sampling depends upon the intended purpose. Sampling at one or two months after *vaccination* provides information on the efficiency of the *vaccination* programme, while sampling before or at the time of revaccination provides information on the duration of immunity. When multivalent vaccines are used, tests should be carried out to determine the antibody level at least for each serotype, if not for each antigen blended into the vaccine. The test cut-off for an acceptable level of antibody should be selected with reference to protective levels demonstrated by vaccine-challenge test results for the antigen concerned. Where the threat from circulating virus has been characterised as resulting from a field virus with significantly different antigenic properties from the vaccine virus, this should be taken into account when interpreting the protective effect of population immunity. Figures for population immunity should be quoted with reference to the total of susceptible animals in a given *subpopulation* and in relation to the subset of vaccinated animals.

7. Additional measures for early recovery of free status without vaccination or early recovery of free status with vaccination in the area(s) where emergency vaccination has been applied but not followed by the slaughtering of all vaccinated animals

In addition to the general conditions described in this chapter, a Member Country seeking either recovery of status of a country or zone previously free from FMD where vaccination is not practiced, including a containment zone, or recovery of status of a country or zone previously free from FMD where vaccination is practiced, earlier than the six months as specified respectively under point 1c) of Article 8.8.7. or under point 3a) of Article 8.8.7. should justify the circumstances and measures that demonstrate sufficient confidence to substantiate a claim for freedom. This may be achieved when answering the relevant questionnaire in Chapter 1.11. by demonstrating compliance with either a) or b) and c) below, in the area(s) where emergency vaccination has been applied. It is advisable that countries should consider the different options for the recovery of a free status when control measures are first implemented at the onset of the outbreak in order to plan for the applicable requirements to be met.

- a) The following serological surveys have been conducted in the area where emergency vaccination has been applied and have demonstrated the absence of infection in unvaccinated animals and the absence of transmission in emergency vaccinated animals:

Annex 18 (contd)

- i) for vaccinated ruminants, serological surveys using nonstructural protein tests to detect antibodies in all vaccinated ruminants and their non-vaccinated offspring in all *epidemiological units* (census serosurveillance);
 - ii) for vaccinated pigs and their non-vaccinated offspring, serological surveys using nonstructural protein tests to detect antibodies in all vaccinated *epidemiological units* with maximum 5% within *herd* design prevalence (95% confidence level);
 - iii) for non-vaccinated susceptible species that do not show reliable clinical signs, serological surveys with maximum design prevalence of 1% at *herd* level and 5% within *herds* (95% confidence level).
- b) The following *surveillance* components have been implemented in the area where emergency *vaccination* has been applied and have demonstrated the absence of *infection* in unvaccinated *animals* and the absence of transmission in vaccinated *animals*:
- i) risk-based serological *surveillance* in vaccinated *herds* with stratification according to relevant factors such as proximity to known infected *herds*, region/*establishment* with numerous movement of animals, epidemiological links to infected *herds*, species, production management systems and *herd* size;
 - ii) random serological *surveillance* in vaccinated *herds* with maximum design prevalence of 1% at *herd* level and 5% within *herds* (95% confidence level) in each emergency *vaccination* area;
 - iii) intensified clinical and *slaughterhouse/abattoir surveillance*;
 - iv) for non-vaccinated susceptible species that do not show reliable clinical signs, serological surveys with maximum design prevalence of 1% at *herd* level and 5% within *herds* (95% confidence level);
 - v) virological *surveillance* to investigate the status of vaccinated *herds* may also be conducted to contribute to additional confidence in demonstrating freedom.
- c) Vaccine efficacy and *vaccination* effectiveness of the emergency *vaccination* deployed have been demonstrated by documenting the following:
- i) Vaccine efficacy
 - ▬ vaccine potency of at least 6PD50 or equivalent probability of protection and evidence of a good match between the vaccine strain and the field virus;
 - ▬ evidence that the vaccine used can protect against the field strain that has caused the *outbreak*, demonstrated through the results of a heterologous challenge test or indirect serological assay (i.e., sera from vaccinated *animals* tested against the field virus). This should also establish the cut-off titre for protection to be used in the test for population immunity studies.
 - ii) Vaccination effectiveness
 - ▬ objective and strategy of the emergency *vaccination* deployed;
 - ▬ evidence of the timeliness of the emergency *vaccination* (start and completion dates);
 - ▬ evidence of *vaccination* delivery including preservation of vaccine (e.g., cold chain) and at least 95% *vaccination* coverage achieved in the targeted and eligible *population*;
 - ▬ evidence of high population immunity at *herd* and individual level through serological *surveillance*.
8. Additional measures for early recovery of free status with *vaccination* in the area outside of the area(s) where emergency *vaccination* has been applied.

Annex 18 (contd)

In addition to the general conditions described in this chapter, a Member Country seeking recovery of status of a country or *zone* previously free from FMD where *vaccination* is practiced in the area outside of the area(s) where *emergency vaccination* has been applied, earlier than six months as specified under point 3a) of Article 8.8.7, should justify the circumstances and measures that demonstrate sufficient confidence to substantiate a claim for freedom. This may be achieved either by meeting the requirements listed in a) below or by demonstrating compliance with the requirements listed in b) and c) below, when answering the questionnaire in Article 1.11.2. or Article 1.11.4.

With regard to the *surveillance* requirements listed in b), it should be noted that clinical signs may not be apparent in the routinely vaccinated *population*. The expression of clinical signs would depend on the relationship between the virus strain used in the routine *vaccination* to the virus that caused the *outbreak*. For example, following an incursion of a new serotype it would be expected that the routinely vaccinated animals would show clinical signs if infected. In contrast, following an incursion of a serotype or strain covered by the vaccine it would be expected that most of the routinely vaccinated animals would be protected and therefore less likely to be infected and to show clinical signs if infected. Other factors such as *vaccination* coverage and timing of *vaccination* could influence the likelihood of *infection* and expression of clinical signs.

It is advisable that countries should consider the different options for the recovery of a free status when control measures are first implemented at the onset of the *outbreak* in order to plan for the applicable requirements to be met.

a) Establishment of a containment zone

A *containment zone* that includes all *emergency vaccination* area(s) has been established based on the provisions of Article 8.8.6. to provide assurance that FMD has not occurred in the area outside the *emergency vaccination* area(s).

b) The following *surveillance* components have been implemented in the area outside of the area(s) where *emergency vaccination* has been applied and have demonstrated the absence of *infection* in unvaccinated *animals* and the absence of transmission in vaccinated *animals*:

- i) risk-based serological *surveillance* in vaccinated *herds* with stratification according to relevant factors such as proximity to the *emergency vaccination* area, region/*establishment* with numerous movement of *animals*, epidemiological links to infected *herds*, species and age, production management systems, *herd* size;
- ii) random serological *surveillance* in vaccinated *herds* with maximum design prevalence of 1% at *herd* level and 5% within *herds* (95% confidence level);
- iii) intensified clinical and *slaughterhouse/abattoir surveillance*;
- iv) serological survey in non-vaccinated susceptible species that do not show reliable clinical signs with risk-based stratification according to factors such as proximity to the *emergency vaccination* area, region/*establishment* with numerous movement of *animals*, epidemiological links to infected *herds*, species, production management systems, *herd* size;
- v) virological *surveillance* to investigate the status of vaccinated *herds* may also be conducted to contribute to additional confidence in demonstrating freedom.

The efficacy of the routine vaccine against the virus that caused the *outbreak(s)* has been documented.

The entire investigative process should be documented within the *surveillance* programme.

All the epidemiological information should be substantiated, and the results should be collated in the final report.

Annex 18 (contd)

Article 8.8.41.

Methods of surveillance1. Clinical surveillance

Farmers and workers who have day-to-day contact with livestock, as well as *veterinary para-professionals*, *veterinarians* and diagnosticians, should report promptly any suspicion of FMD. The *Veterinary Services Authority* should implement programmes to raise awareness among them.

Clinical *surveillance* requires the physical examination of susceptible *animals*. Although significant emphasis is placed on the diagnostic value of mass serological screening, *surveillance* based on clinical inspection may provide a high level of confidence of detection of *disease* if a sufficient number of clinically susceptible *animals* is examined at an appropriate frequency and investigations are recorded and quantified.

Clinical examination and diagnostic testing should be applied to clarify the status of suspected cases. Diagnostic testing may confirm clinical suspicion, while clinical *surveillance* may contribute to confirmation of positive laboratory test results. Clinical *surveillance* may be insufficient in *wildlife* and domestic species that usually do not show clinical signs or husbandry systems that do not permit sufficient observations. In such situations, serological *surveillance* should be used. Hunting, capture and non-invasive sampling and observation methods can be used to obtain information and diagnostic samples from *wildlife* species.

2. Virological surveillance

Establishment of the molecular, antigenic and other biological characteristics of the causative virus, as well as its source, is mostly dependent upon clinical *surveillance* to provide samples. FMDV isolates should be sent regularly to an OIE Reference Laboratory.

Virological *surveillance* aims to:

- a) confirm clinically suspected cases;
- b) follow up positive serological results;
- c) characterise isolates for epidemiological studies and vaccine matching;
- d) monitor *populations* at risk for the presence and transmission of the virus.

3. Serological surveillance

Serological *surveillance* aims to detect antibodies resulting from *infection* or *vaccination* using nonstructural protein tests or structural protein tests.

Serological *surveillance* may be used to:

- a) estimate the prevalence or substantiate freedom from FMDV infection with, or transmission of FMDV;
- b) monitor population immunity.

Serum collected for other purposes can be used for FMD *surveillance*, provided the principles of survey design described in this chapter are met.

The results of random or targeted serological surveys are important in providing reliable evidence of the FMD situation in a country, *zone* or *compartment*. It is therefore essential that the survey be thoroughly documented.

Article 8.8.42.

The use and interpretation of serological tests (see Figure 3)

The selection and interpretation of serological tests should be considered in the context of the epidemiological situation. Test protocols, reagents, performance characteristics and validation of all tests used should be known. Where combinations of tests are used, the overall test system performance characteristics should also be known.

Animals infected with FMDV produce antibodies to both the structural proteins and the nonstructural proteins of the virus. Vaccinated *animals* produce antibodies mainly or entirely to the structural proteins of the virus depending upon vaccine purity. The structural protein tests are serotype specific and for optimal sensitivity one should select an antigen or virus closely related to the field strain expected. In unvaccinated *populations*, structural protein tests may be used to screen sera for evidence of FMDV infection with, or transmission of FMDV or to detect the introduction of vaccinated *animals*. In vaccinated *populations*, structural protein tests may be used to monitor the serological response to the *vaccination*.

Nonstructural protein tests may be used to screen sera for evidence of *infection* or transmission of all serotypes of FMDV regardless of the *vaccination* status of the *animals* provided the vaccines comply with the standards of the *Terrestrial Manual* with respect to purity. However, although *animals* vaccinated and subsequently infected with FMDV develop antibodies to nonstructural proteins, the levels may be lower than those found in infected *animals* that have not been vaccinated. To ensure that all *animals* that had contact with FMDV have seroconverted, it is recommended that for each *vaccination* area samples for nonstructural protein antibody testing are taken not earlier than 30 days after the last case and in any case not earlier than 30 days after the last *vaccination*.

Positive FMDV antibody test results can have four possible causes:

- *infection* with FMDV;
- *vaccination* against FMD;
- maternal antibodies (maternal antibodies in bovines cattle are usually found only up to six months of age but in some individuals and in some other species, maternal antibodies can be detected for longer periods);
- non-specific reactivity of the serum in the tests used.

1. Procedure in case of positive test results

The proportion and strength of seropositive reactors should be taken into account when deciding if they are *laboratory* confirmed reactors or further investigation and testing are required.

When false positive results are suspected, seropositive reactors should be retested in the *laboratory* using repeat and confirmatory tests. Tests used for confirmation should be of high diagnostic specificity to minimise false positive test results. The diagnostic sensitivity of the confirmatory test should approach that of the screening test.

All *herds* with at least one ~~laboratory confirmed~~ reactor that has been confirmed in a laboratory should be investigated. The investigation should examine all evidence, which may include the results of ~~virological tests and~~ of any further serological tests ~~that might used to~~ confirm or refute the hypothesis that the positive results to the serological tests employed in the initial survey were due to FMDV transmission of FMDV, as well as of virological tests. This investigation should document the status for each positive *herd*. Epidemiological investigation should be continued concurrently.

Clustering of seropositive results within *herds* or within a region should be investigated as it may reflect any of a series of events, including the demographics of the *population* sampled, vaccinal exposure or the presence of *infection* or transmission. As clustering may signal *infection* or transmission, the investigation of all instances should be incorporated in the survey design.

Paired serology can be used to identify FMDV transmission of FMDV by demonstrating an increase in the number of seropositive *animals* or an increase in antibody titre at the second sampling.

Annex 18 (contd)

The investigation should include the reactor *animals*, susceptible *animals* of the same *epidemiological unit* and susceptible *animals* that have been in contact or otherwise epidemiologically associated with the reactor *animals*. The *animals* sampled should be identified as such and remain in the *establishment* pending test results, should be ~~clearly identified~~, accessible and should not be vaccinated during the investigations, so that they can be retested after an appropriate period of time. Following clinical examination, a second sample should be taken, after an appropriate time has lapsed, from the *animals* tested in the initial survey with emphasis on *animals* in direct contact with the reactors. If the *animals* are not individually identified, a new serological survey should be carried out in the *establishments* after an appropriate time, repeating the application of the primary survey design. If FMDV is not circulating, the magnitude and prevalence of antibody reactivity observed should not differ in a statistically significant manner from that of the primary sample.

In some circumstances, unvaccinated sentinel *animals* may also be used. These can be young *animals* from unvaccinated dams or *animals* in which maternally conferred immunity has lapsed and preferably of the same species as in the positive sampling units. If other susceptible, unvaccinated *animals* are present, they could act as sentinels to provide additional serological evidence. The sentinels should be kept in close contact with the *animals* of the *epidemiological unit* under investigation for at least two *incubation periods*, and if there is no transmission of FMDV, they should will remain serologically negative ~~if FMDV is not circulating~~.

2. Follow-up of field and laboratory findings

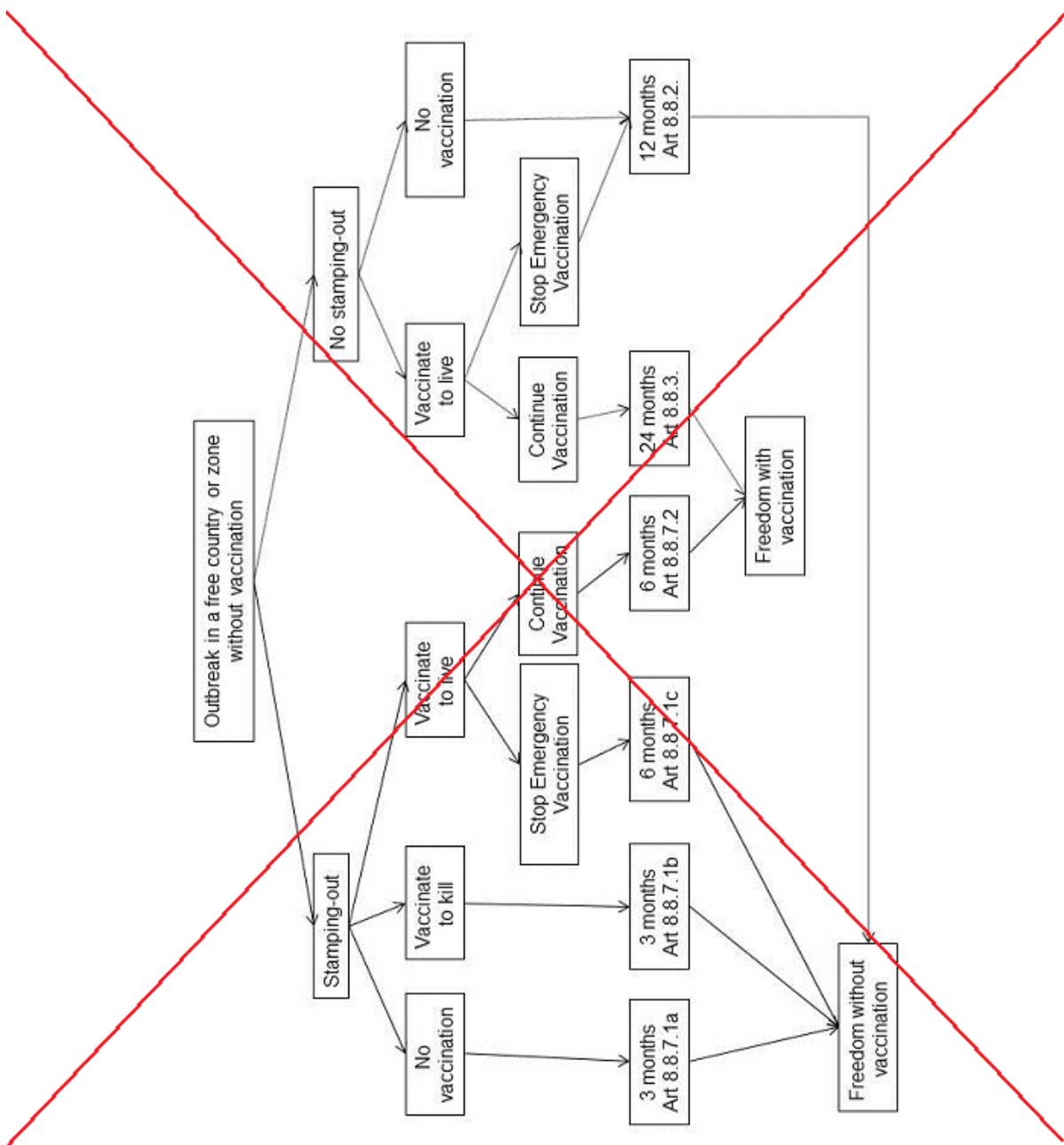
If transmission is demonstrated, an *outbreak* is declared.

It is difficult to determine ~~The~~ significance of small numbers of seropositive *animals* in the absence of current FMDV transmission ~~is difficult to determine~~. Such findings may be an indication of past *infection* followed by recovery or by the development of a carrier state, in ruminants, or due to non-specific serological reactions. Antibodies to nonstructural proteins may be induced by repeated *vaccination* with vaccines that do not comply with the requirements for purity. However, the use of such vaccines is not permissible in countries or *zones* applying for an official status. In the absence of evidence of FMDV infection with, and transmission of, FMDV, such findings do not warrant the declaration of a new *outbreak* and the follow-up investigations may be considered complete.

However, if the number of seropositive *animals* is greater than the number of false positive results expected from the specificity of the diagnostic tests used, susceptible *animals* that have been in contact or otherwise epidemiologically associated with the reactor *animals* should be investigated further.

Abbreviations and acronyms:	
ELISA	Enzyme-linked immunosorbent assay
VNT	Virus neutralisation test
NSP	Nonstructural protein(s) of foot and mouth disease virus (FMDV)
3ABC	NSP antibody test
SP	Structural protein of foot and mouth disease virus

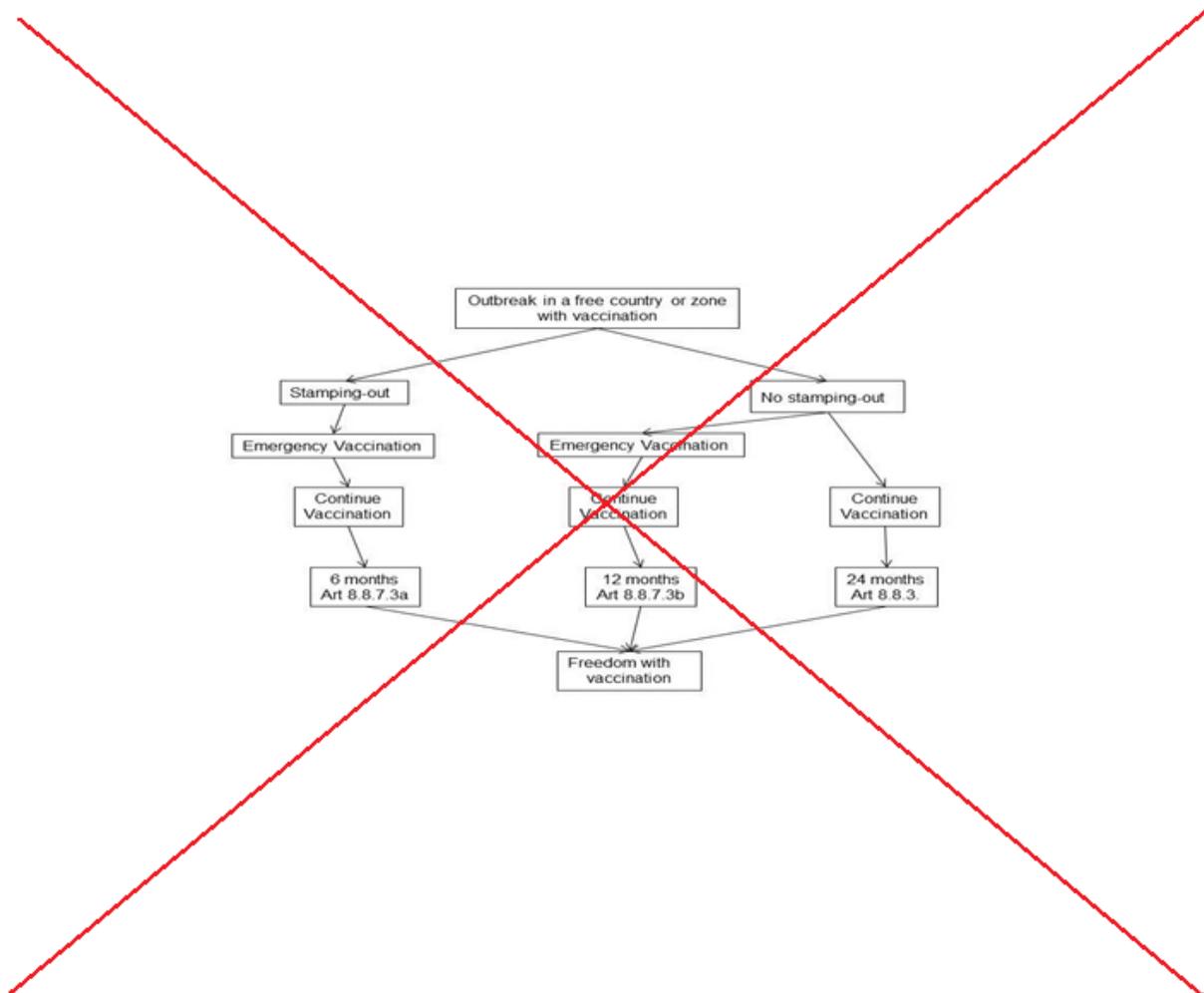
Fig. 1. Schematic representation of the minimum waiting periods and pathways for recovery of FMD free status after an outbreak of FMD in a previously free country or zone where vaccination is not practised



Waiting periods are minima depending upon outcome of surveillance specified in respective articles. If there are multiple waiting periods because of different control measures, the longest applies.

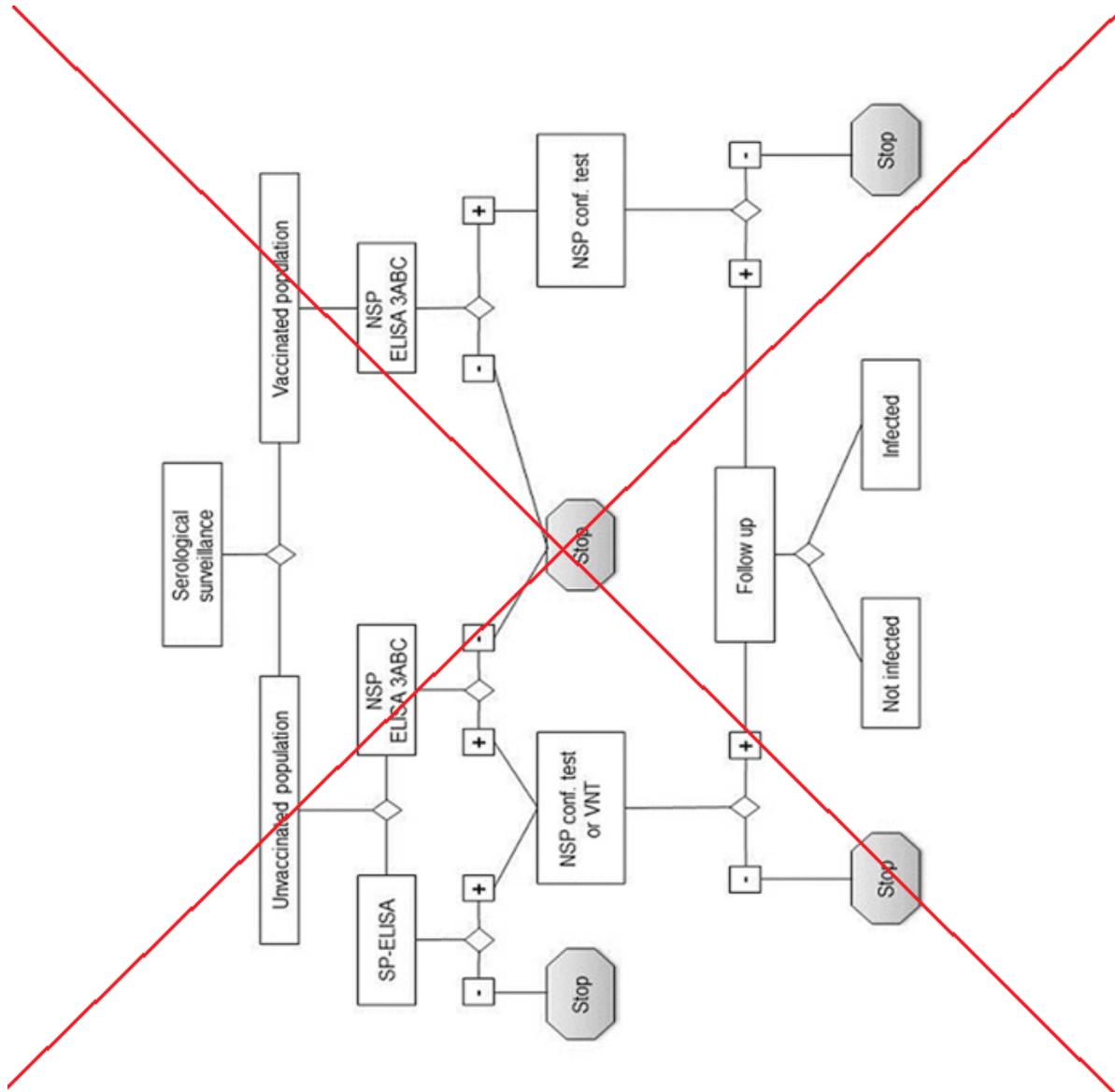
Annex 18 (contd)

Fig. 2. Schematic representation of the minimum waiting periods and pathways for recovery of FMD free status after an outbreak of FMD in a previously free country or zone where vaccination is practised



Waiting periods are minima depending upon outcome of surveillance specified in respective articles. If there are multiple waiting periods because of different control measures, the longest applies.

Fig. 3. Schematic representation of laboratory tests for determining evidence of infection with FMDV by means of serological surveys



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CHAPTER 8.16.

INFECTION WITH RINDERPEST VIRUS

Article 8.16.1.

General provisions

- 1) The global eradication of rinderpest has been achieved and was announced in mid-2011 based on the following:
 - a) Evidence demonstrating that there is no significant likelihood that rinderpest virus (RPV) remains in susceptible domesticated or *wildlife* host populations anywhere in the world.
 - b) OIE Member and non-member countries have completed the pathway defined by the OIE for recognition of national rinderpest freedom and have been officially recognised by the OIE as free from *infection* with RPV.
 - c) All *vaccinations* against rinderpest are banned and have ceased throughout the world. A ban on vaccination against rinderpest means a ban on administering any vaccine containing RPV or any components derived from RPV to any animal.

However, RPV-containing material including live vaccines continue to be held in a number of institutions around the world and this poses a *risk* of virus re-introduction into susceptible animals. Therefore, manipulation of existing RPV-containing material, and synthesis or other forms of production of RPV-containing material, is forbidden unless authorised by the FAO and OIE.

As sequestration and destruction of virus stocks proceed, the *risks* of re-occurrence of *infection* are expected to progressively diminish. The possibility of deliberate or accidental release of virus demands continuing vigilance, especially in the case of those countries hosting an institution holding RPV-containing material.

This chapter takes into account the global freedom status of rinderpest and provides recommendations to prevent re-emergence of the disease, to ensure adequate *surveillance* and protection of livestock and to manage any re-emergence and facilitate recovery of global freedom from rinderpest.

- 2) For the purposes of the *Terrestrial Code*:
 - a) Rinderpest is defined as an *infection* of susceptible animals with RPV, with or without clinical signs;
 - b) The following defines the occurrence of a *case* of *infection* with RPV,
 - i) RPV has been isolated from a susceptible animal or a product derived from that animal and identified; or
 - ii) viral antigen or viral RNA specific to RPV has been identified in samples from a susceptible animal; or
 - iii) antibodies to RPV have been identified in a susceptible animal with either epidemiological links to a confirmed or suspected *outbreak* of rinderpest, or showing clinical signs consistent with recent *infection* with RPV.
 - c) The following defines a 'suspected case' of rinderpest:
 - i) a potential *case* for which other diseases compatible with 'stomatitis-enteritis syndrome' have been ruled out by clinical or laboratory investigation; or
 - ii) a potential *case* which has given a positive reaction in a diagnostic test for RPV conducted outside of an OIE Reference Laboratory for rinderpest; or

Annex 19 (contd)

- iii) the detection of RPV-specific antibodies in a susceptible animal with or without clinical signs.
- d) The *incubation period* for rinderpest shall be 21 days.
- e) RPV-containing material means field and laboratory strains of RPV; vaccine strains of RPV including valid and expired vaccine stocks; tissues, sera and other material from animals known or suspected to be infected; laboratory-generated diagnostic material containing live virus, recombinant morbilliviruses (segmented or nonsegmented) containing unique RPV nucleic acid or amino acid sequences, and full length genomic material including virus RNA and its cDNA copies.

Subgenomic fragments of RPV genome (either as plasmid or incorporated into recombinant viruses) that cannot be incorporated into a replicating morbillivirus or morbillivirus-like virus are not considered to be RPV-containing material, neither are sera that have been either heat-treated to at least 56°C for at least two hours, or shown to be free from RPV genome sequences by a validated RT-PCR assay.

3) For the purposes of this chapter:

- a) 'Susceptible animals' means domestic, *feral*, *captive wild* and *wild* artiodactyls.
- b) A 'potential case' means a susceptible animal showing clinical signs consistent with 'stomatitis-enteritis syndrome' and where these signs cannot be ascribed to another disease compatible with 'stomatitis-enteritis syndrome' by epidemiological considerations or appropriate laboratory investigation.

The occurrence of a potential case should draw special attention if it is linked to identified risks such as proximity to facilities holding RPV-containing material.

- c) 'Stomatitis-enteritis syndrome' is defined as fever with ocular and nasal discharges in combination with clinical signs of erosions in the oral cavity with diarrhoea, dysentery, dehydration or death or necropsy findings of haemorrhages on serosal surfaces, haemorrhages and erosions on alimentary mucosal surfaces and lymphadenopathy.
- 4) Standards for diagnostic tests and vaccines are described in the *Terrestrial Manual*.

Article 8.16.2

1. Safe commodities during global freedom

When authorising import or transit of the *commodities* of susceptible animals, *Veterinary Authorities* should not require any conditions related to rinderpest.

2. Safe commodities in the event of re-emergence of rinderpest

Regardless of the rinderpest status of the *exporting country*, *Veterinary Authorities* should not require any conditions related to rinderpest for:

- a) semi-processed hides and skins (limed hides, pickled pelts, and semi-processed leather, e.g., wet blue and crust leather) which have been submitted to the usual chemical and mechanical processes in use in the tanning industry;
- b) *meat products* in hermetically sealed containers with a F_0 value of 3 or above;
- c) gelatine.

First section: applicable during global freedom

Article 8.16.3.

Ongoing surveillance post global freedom

All countries in the world, whether or not Member Countries of the OIE, have completed all the procedures necessary to be recognised as free from rinderpest *infection*, and annual re-confirmation of rinderpest absence is no longer required. However, rinderpest should still be notifiable in the whole territory and countries are still required to carry out general *surveillance* in accordance with Chapter 1.4. to detect rinderpest should it recur and to comply with OIE reporting obligations concerning the occurrence of unusual epidemiological events in accordance with Chapter 1.1. Countries should either maintain the capacity for local investigation of potential cases or have protocols in place to send samples from such cases to an OIE Reference Laboratory for routine checking. Countries should also maintain national contingency plans for responding to events suggestive of rinderpest including the checking of potential cases and the prompt identification of suspected cases.

The Global Rinderpest Action Plan (GRAP) complements all national and regional contingency plans and lays out the roles and responsibilities of all relevant stakeholders to prepare for, prevent, detect, respond and recover from a rinderpest *outbreak*. If needed, expertise from the region or continent, or international organisations may be requested to provide resources to help confirm or rule out if the potential case meets the definition for a suspected case of rinderpest.

Article 8.16.4.

Annual update on RPV-containing material

Annual reports on RPV-containing material should be submitted to the OIE each year by the *Veterinary Authority* of a Member Country hosting an institution or institutions holding RPV-containing material using the online platform designated for such a purpose. A final report should be submitted to the OIE for each institution when all materials have been destroyed and no new activities are foreseen.

Second section: applicable in the event of re-emergence of rinderpest

Article 8.16.5.

Response to a recurrence of rinderpest1. Procedures to be followed in the event of the suspicion of rinderpest

Any suspected case should be immediately notified to the *Veterinary Authority*.

Veterinary Authorities shall immediately notify any suspected case to the OIE.

Upon detection of a suspected case, the national contingency plan should be implemented immediately. If the presence of rinderpest cannot be ruled out, samples should be collected in accordance with the *Terrestrial Manual* and dispatched to one of the appointed OIE Reference Laboratories for rinderpest for confirmation and, if applicable, for molecular characterisation of the virus to facilitate identification of its source. A full epidemiological investigation should be conducted simultaneously to provide supporting information and to assist in identifying the possible source and spread of the virus.

2. Procedures to be followed after confirmation of rinderpest

Veterinary Authorities shall immediately notify any case to the OIE.

A case shall constitute a global emergency requiring immediate, concerted action for its investigation and elimination.

Annex 19 (contd)

Immediately following the confirmation of the presence of RPV, viral RNA or antibody as described in Article 8.16.1., the appointed OIE Reference Laboratory for rinderpest should inform the country concerned, the OIE and the FAO, allowing the initiation of the response operations described in the GRAP.

When epidemiological investigation has indicated the extent of the infected area, zoning can be implemented for the purposes of disease control. In the event of a limited *outbreak*, a *containment zone* may be established in accordance with Article 8.16.8.

Emergency *vaccination* is acceptable only with rinderpest vaccines produced in accordance with the *Terrestrial Manual*. Vaccinated animals should always be clearly and permanently identified at the individual level.

Global rinderpest freedom is suspended and the sanitary measures for trade with the infected country or countries shall be those in Articles 8.16.12. and 8.16.13.

Article 8.16.6

Country free from rinderpest

In the event of re-emergence of rinderpest, all OIE Member Countries without a case will remain free from rinderpest. However, all OIE Member Countries will be asked to provide a *risk assessment* to the OIE and free status will be suspended if their *risk assessment* is not accepted by the OIE.

Some countries will be at heightened *risk*. In particular, countries meeting the conditions below would be regarded as being at heightened risk and should carry out appropriate *surveillance*, capable of detecting the presence of *infection* even in the absence of clinical signs; this may be achieved through a *surveillance* programme in accordance with Article 8.16.11. in addition to ongoing *surveillance* in accordance with Article 8.16.3.:

- 1) countries that are adjacent to a country infected with RPV; or
- 2) countries that have relevant epidemiological or ecological links through trade or animal movements to a country infected with RPV.

Article 8.16.7

Country infected with RPV

A country infected with RPV is one in which a *case* of rinderpest has occurred.

Article 8.16.8.

Establishment of a containment zone within a country previously free from rinderpest

In the event of a limited *outbreak* within a country previously free of rinderpest, a *containment zone* for the purposes of disease control and eradication can be established in accordance with Article 4.4.7. Notwithstanding the establishment of a *containment zone* for disease control and eradication, *international trade* in *commodities* of susceptible species from the entire country will be limited to the *safe commodities* listed in point 2 of Article 8.16.2. until free status is recovered.

Article 8.16.9.

Recovery of free status for a country

Should a *case* of rinderpest occur, a country is considered infected with RPV until shown to be free in accordance with the procedures below.

The time needed to recover rinderpest free status of a country depends on the methods employed to achieve the elimination of *infection*.

Annex 19 (contd)

One of the following waiting periods is applicable:

- 1) when a *stamping-out policy* has been applied:
 - a) three months after the *disinfection* of the last affected *establishment* where a *stamping-out policy* without *vaccination* and targeted *surveillance* in accordance with Article 8.16.11. have been applied; or
 - b) three months after the *disinfection* of the last affected *establishment* and the *slaughter* of all vaccinated animals, where a *stamping-out policy*, emergency *vaccination* and targeted *surveillance* in accordance with Article 8.16.11. have been applied; or
 - c) 18 months after the *disinfection* of the last affected *establishment* and the last *vaccination*, where a *stamping-out policy*, emergency *vaccination* not followed by the *slaughter* of all vaccinated animals, and targeted *surveillance* in accordance with Article 8.16.11. have been applied;
- 2) when a *stamping-out policy* is not practised, the above waiting periods do not apply. Instead, the country must be in compliance with the requirements below:
 - a) have a record of regular and prompt animal disease reporting in accordance with Chapter 1.1.
 - b) send a declaration to the OIE stating that:
 - i) there has been no case of rinderpest during the past 24 months,
 - ii) no suspected case of RPV *infection* has been found during the past 24 months,
 - iii) no *vaccination* against rinderpest has been carried out during the past 24 months,
 - c) supply documented evidence that targeted *surveillance* for *infection* with RPV in accordance with Chapter 1.4. and Article 8.16.11. is in operation and that regulatory measures for the prevention and control of rinderpest have been implemented,
 - d) not have imported, since the cessation of *vaccination*, any animals vaccinated against rinderpest.

In the scenarios mentioned in points 1a), b) and c) and in point 2) above, the recovery of free status requires an international expert mission to verify the successful application of containment and eradication measures, as well as a review of documented evidence by the OIE. The country shall be considered free only after the submitted evidence has been accepted by the OIE.

Article 8.16.10.

Recovery of global freedom

The suspension of global freedom will be lifted when all countries infected with RPV have recovered freedom in accordance with Article 8.16.9.

Unless it is verified through an OIE expert mission that the conditions below are met for all countries having experienced an outbreak within 12 months of suspension, then global rinderpest freedom is lost and recovery of freedom would require an assessment of free status of all countries by the OIE. If the conditions below are met within 12 months, then global freedom will remain suspended, subject to periodic review by the OIE.

- 1) The *outbreak* is limited to a country or *zone*, without any further *outbreaks* outside the ecosystem of the first *outbreak*.
- 2) The *outbreak* is handled in a prompt and efficient manner, with robust control measures including movement controls, which were rapidly implemented and were shown to be successful in mitigating the spread of rinderpest and reducing its incidence.

Annex 19 (contd)

Article 8.16.11.

Surveillance for recovery of rinderpest free status

A country infected with RPV applying for recovery of rinderpest free status in accordance with Article 8.16.9. should provide evidence demonstrating effective *surveillance* in accordance with Chapter 1.4. and the points below.

- 1) The target for *surveillance* should be all populations of rinderpest susceptible species within the country. In certain areas some *wildlife* populations, such as African buffaloes, act as sentinels for rinderpest *infection*.
- 2) An awareness programme should be established for all animal health professionals including *veterinarians*, both official and private, and livestock owners to ensure that rinderpest's clinical and epidemiological characteristics and *risks* of its recurrence are understood. Farmers and workers who have day-to-day contact with livestock, as well as diagnosticians, should report promptly any potential case.
- 3) Differing clinical presentations can result from variations in levels of innate host resistance (*Bos indicus* breeds being more resistant than *B. taurus*), and variations in the virulence of the attacking strain. In the case of sub-acute (mild) cases, clinical signs are irregularly displayed and difficult to detect. Experience has shown that syndromic *surveillance* strategies i.e., *surveillance* based on a predefined set of clinical signs (i.e., 'stomatitis-enteritis syndrome') are useful to increase the sensitivity of the system.
- 4) Given these differing clinical presentations, virological *surveillance* should be conducted in addition to clinical surveillance. A procedure should be established for the rapid collection and transport of samples from suspected cases to an appointed OIE Reference Laboratory for rinderpest.
- 5) Since rinderpest is an acute *infection* with no known carriers, serological *surveillance* should be conducted to detect mild *infections* that are not detected clinically. There are no serological means to differentiate animals infected with field virus from vaccinated animals. Consequently, serological surveys should target unvaccinated animals and young animals devoid of maternal antibodies.

Article 8.16.12.

Recommendations for importation of rinderpest susceptible animals and their products except safe commodities in point 2 of Article 8.16.2 from countries free from rinderpest

- 1) For rinderpest susceptible animals, *Veterinary Authorities* should require the presentation of an *international veterinary certificate* attesting that the animals remained in a country free from rinderpest since birth or for at least 30 days prior to shipment. Animals must not transit through a country infected with RPV, in accordance with Chapter 5.7.
- 2) For *fresh meat* or *meat products* of susceptible animals, for *milk* or *milk products* from susceptible animals, and for all products of animal origin intended for use in animal feeding, for agricultural use or for industrial use, *Veterinary Authorities* should require the presentation of an *international veterinary certificate* attesting the entire consignment of product is derived from animals that remained in a country free from rinderpest since birth or for at least 30 days prior to *slaughter* or harvesting of the product.
- 3) For semen and oocytes of susceptible animals, *Veterinary Authorities* should require the presentation of an *international veterinary certificate* attesting that:
 - a) the donor animals showed no clinical sign of rinderpest on the day of collection and had been kept in a country free from rinderpest for at least 30 days prior to collection;
 - b) the semen and oocytes were collected, processed and stored in conformity with the provisions of Chapters 4.6., 4.7. or 4.9., as relevant.

Annex 19 (contd)

- 4) For *in vivo* derived embryos of susceptible animals, *Veterinary Authorities* should require the presentation of an *international veterinary certificate* attesting that:
- a) the donor females showed no clinical sign of rinderpest on the day of collection and had been kept in a country free from rinderpest for at least 30 days prior to collection;
 - b) the embryos were collected, processed and stored in conformity with the provisions of Chapters 4.8. and 4.10., as relevant.

Article 8.16.13.

Recommendations for importation from countries infected with rinderpest

In the event of re-emergence of rinderpest, only *safe commodities* in point 2 of Article 8.16.2. can be traded.

CHAPTER 11.4.

BOVINE SPONGIFORM ENCEPHALOPATHY

Article 11.4.1.

General provisions

- 1) The recommendations in this chapter are intended to mitigate the human and animal health risks associated with the presence of the bovine spongiform encephalopathy (BSE) agents in cattle only. BSE manifests in two main forms: classical BSE and atypical BSE. Atypical BSE is a condition that occurs at a very low rate and is assumed to occur spontaneously in any cattle population. Oral exposure to contaminated *feed* is the main route of transmission of classical BSE. Given that cattle have been experimentally infected by the oral route with a low molecular weight type of atypical BSE (L-type BSE₇), atypical BSE is also ~~potentially considered~~ capable of being recycled in a cattle population if cattle are orally exposed to contaminated *feed*.
- 2) BSE primarily affects cattle. Other animal species may be naturally and experimentally susceptible to BSE, but they are not regarded as being epidemiologically significant, particularly when feeding ruminants with ruminant-derived protein meal is not practiced.
- 3) For the purposes of the *Terrestrial Code*:
 - 4a) BSE is an invariably fatal neurological prion disease of cattle caused by PrP^{BSE}, including both classical (C-type BSE) and atypical strains (H- and L-type BSE), for respectively having a protease-resistant PrP^{BSE} fragment of higher and lower molecular mass than classical BSE. The term 'BSE' includes both classical and atypical forms, unless otherwise specified.
 - 2b) The occurrence of a BSE case is defined by the immunohistochemical (IHC) or immunochemical detection of PrP^{BSE} in brain tissue of a bovid of the species *Bos taurus* or *Bos indicus*, with discrimination between atypical and classical BSE strains based on the Western immunoblot banding pattern, as described in the *Terrestrial Manual*.
- 4) For the purposes of this chapter:
 - 3a) 'Cattle' means a bovids of the species *Bos taurus* or *Bos indicus*.
 - 4b) 'Protein meal' means any final or intermediate solid protein-containing product, obtained when animal tissues are rendered, excluding blood and blood products, peptides of a molecular weight less than 10,000 daltons and amino-acids.
- 5) When *commodities* are imported in accordance with this chapter, the BSE risk of the *importing country* or *zone* of destination is not affected by the BSE risk of the *exporting country, zone or compartment* of origin.
- 6) Standards for diagnostic tests are described in the *Terrestrial Manual*.

Article 11.4.1bis.

Safe commodities

When authorising the importation or transit of the following commodities derived from cattle, *Veterinary Authorities* should not require any conditions related to BSE, regardless of the BSE risk posed by the cattle population of the *exporting country, zone or compartment*.

Annex 20 (contd)

- 1) *milk and milk products*;
- 2) semen and *in vivo* derived cattle embryos collected and handled in accordance with the relevant chapters of the *Terrestrial Code*;
- 3) hides and skins;
- 4) gelatine and collagen;
- 5) tallow with maximum level of insoluble impurities of 0.15% in weight and derivatives made from this tallow;
- 6) ~~tallow derivatives~~;
- 7) ~~dicalcium phosphate (with no trace of protein or fat)~~;
- 7) foetal blood.

Other *commodities* of cattle can be traded safely if in accordance with the relevant articles of this chapter.

Article 11.4.2.

The General criteria for the determination of the BSE risk of the cattle population of a country, zone or compartment

~~The~~ Due to its etiological and epidemiological features, the BSE risk of the ~~cattle population of a country, zone or compartment~~ is determined on the basis of the following criteria:

- 1) a BSE risk assessment, in accordance with the provisions of ~~Chapter 1.8~~ the "Application for official recognition by the OIE of risk status for bovine spongiform encephalopathy" that evaluates the likelihood risk of BSE being recycled within the cattle population by identifying all potential factors associated with the occurrence of BSE and their historic perspective. Member Countries should review the *risk assessment* annually to determine whether the situation has changed.

~~The~~ risk assessment for the purpose of BSE, based on the framework provided by Article 2.1.4, consists of:

a) Entry assessment

~~An~~ The entry assessment evaluates the likelihood that the classical BSE agent has been introduced into the country, *zone* or *compartment* ~~via imported~~ through the importation of the following commodities in the preceding eight years:

- i) Cattle;
- ii) Ruminant-derived protein meal;
- iii) Feed (not intended for pets) that contains ruminant-derived protein meal;
- iv) Fertilizers that contain ruminant-derived protein meal;
- v) Any other commodity that either is or could be contaminated by commodities listed in Article 11.4.14.

b) Exposure assessment

~~An~~ The exposure assessment evaluates the likelihood of cattle being exposed to BSE during the preceding eight years, either through imported *commodities* or as a result of the presence of BSE agents in the indigenous cattle population of the country, *zone* or *compartment*.

Annex 20 (contd)

The first step in the exposure assessment involves an evaluation of livestock industry practices through a consideration of the impact of:

- i) Livestock industry practices on preventing cattle from being fed ruminant-derived protein meal, taking account of:
 - ≡ demographics of the cattle population and production systems;
 - ≡ feeding practices;
 - ≡ slaughtering and waste management practices;
 - ≡ rendering practices;
 - ≡ feed production, distribution and storage.

Depending on the outcome from this step, an evaluation of mitigation measures specifically targeting BSE may also need to be included through a consideration of the impact of:

- ii) Specific risk mitigation measures on preventing cattle from being fed ruminant-derived protein meal, taking account of:
 - ≡ the nature and scope of a feed ban on feeding ruminants with protein meal derived from ruminants;
 - ≡ the fate of commodities with the greatest BSE infectivity (those commodities listed in point 1 of Article 11.4.14.);
 - ≡ parameters of the rendering process;
 - ≡ prevention of cross-contamination during rendering, feed production, transport, storage and feeding;
 - ≡ awareness programme under the scope of the feed ban;
 - ≡ monitoring and enforcement of the feed ban.

Depending on the outcome of the exposure assessment, a consequence assessment (in point c) below) may not be required.

c) Consequence assessment

The consequence assessment evaluates the likelihood of cattle becoming infected with following exposure to the BSE agents together with the likely extent and duration of any subsequent recycling and amplification within the cattle population during the preceding eight years. The factors to be considered in the consequence assessment are:

- i) age at exposure;
- ii) production type;
- iii) the impact of cattle industry practices or the implementation of BSE specific mitigation measures under a feed ban.

Annex 20 (contd)

d) Risk estimation

~~The~~ risk estimation combines the results and conclusions arising from the entry, exposure and consequence assessments to provide an overall measure of the risk that BSE agents have been recycled in the cattle population through the feeding of ruminant-derived protein meal, with indigenous cases arising ~~as a consequence~~;

- 2) the ongoing implementation of a *surveillance* programme for classical BSE in the cattle population in accordance with Article 11.4.18;
- 3) the history of occurrence and management of BSE cases.

Article 11.4.3.

Negligible BSE risk

The BSE risk of ~~the cattle population of~~ a country, *zone* or *compartment* can be considered to be negligible if the following conditions for the cattle population are met for at least the preceding eight years:

- 1) A *risk assessment* as described in Article 11.4.2. that has identified all potential risk factors associated with the occurrence of BSE has been conducted, and the Member Country has demonstrated through documented evidence that the likelihood risk of BSE agents being recycled in the cattle population has been negligible ~~as the result of~~;

EITHER:

- a) ~~livestock industry practices ensuring that protein meal derived from ruminants has not been fed to ruminants;~~

OR

- b) ~~effective and continuous mitigation of each identified risk ensuring that protein meal derived from ruminants has not been fed to ruminants.~~

- 2) The *surveillance* provisions as described in Article 11.4.~~2018~~ have been implemented.

- 3) EITHER:

- a) there has been no case of BSE or, if there has been a case, every case of BSE has been demonstrated to have been imported or has been diagnosed as atypical BSE as defined in this chapter;

OR

- b) if there has been an indigenous case of classical BSE:

EITHER:

- i) all cases were born at least eight years ago;

OR

- ii) where a case was born within the preceding eight years, subsequent investigations have confirmed that the likelihood risk of BSE being recycled within the cattle population has continued to be negligible.

- 4) Any cases of BSE that have been detected have been completely destroyed or disposed of to ensure that they do not enter the animal *feed* chain.

Annex 20 (contd)

The country or the *zone* will be included in the list of countries or *zones* posing a negligible risk for BSE in accordance with Chapter 1.6. Retention on the list requires annual confirmation of the conditions in points 1 to 4 above. Documented evidence should be resubmitted annually for points 1 to 4 above.

Any changes in the epidemiological situation or other significant events should be notified to the OIE in accordance with Chapter 1.1.

Article 11.4.3bis.

Recovery of negligible BSE risk status

~~When~~Should an indigenous case of classical BSE is reported in an animal born within the preceding eight years occur in a country or *zone* recognised as ~~having~~posing a negligible BSE risk for BSE, the status, of the negligible BSE risk status country or zone is suspended ~~and the recommendations for controlled BSE risk status apply, pending. The status may be recovered when~~ the outcome of subsequent investigations ~~confirming~~confirms that the ~~likelihood~~risk of BSE being recycled within the cattle population continues to be negligible. ~~The~~In the interim, the provisions for a country or zone will regain with a controlled BSE risk status apply.

The negligible BSE risk status of the country or zone will be reinstated only after the submitted evidence has been accepted by the OIE.

Article 11.4.4.

Controlled BSE risk

The BSE risk of the cattle population of a country, *zone* or *compartment* can be considered to be controlled provided the conditions of Article 11.4.3. are met, but at least one of the conditions has not been met for at least the preceding eight years.

The country or the *zone* will be included in the list of countries or *zones* posing a controlled risk for BSE in accordance with Chapter 1.6. Retention on the list requires annual confirmation of the conditions in points 1 to 4 of Article 11.4.3. Documented evidence should be resubmitted annually for points 1 to 4 of Article 11.4.3.

Any changes in the epidemiological situation or other significant events should be notified to the OIE in accordance with Chapter 1.1.

Article 11.4.5.

Undetermined BSE risk

The BSE risk of the cattle population of a country, *zone* or *compartment* is considered to be undetermined if it cannot be demonstrated that it meets the requirements for negligible or controlled BSE risk.

Article 11.4.6.

~~Recommendations for importation of cattle from a country, zone or compartment posing a negligible BSE risk~~

~~Veterinary Authorities should require the presentation of an international veterinary certificate attesting that cattle selected for export came from a country, zone or compartment posing a negligible BSE risk.~~

Article 11.4.7.

Recommendations for importation of cattle from a country, zone or compartment posing a negligible or controlled BSE risk

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

Annex 20 (contd)

- 1) the cattle selected for export:
- 4) came from a country, zone or compartment posing a negligible or controlled BSE risk and are identified through an animal identification system enabling each animal to be traced throughout its lifetime;

AND EITHER:

- 2) the cattle selected for export were born in the country, zone or compartment during the period when the likelihood of the BSE agents being recycled in the cattle population has been demonstrated to be negligible;

OR

- 3)-
 - a) ~~are identified by a permanent individual identification system from birth enabling each animal to be traced throughout its lifetime; and~~
 - b) are it is demonstrated as having that the cattle selected for export have not been fed protein meal derived from ruminants.

Article 11.4.8.

Recommendations for importation of cattle from a country, zone or compartment posing an undetermined BSE risk

Veterinary Authorities should require the presentation of an *international veterinary certificate* attesting that ~~cattle selected for export:~~

- 1) the cattle selected for export are identified by a permanent individual ~~through an animal identification system from birth~~ enabling each animal to be traced throughout its lifetime;
- 2) ~~are it is demonstrated as having that the cattle selected for export have~~ not been fed protein meal derived from ruminants.

Article 11.4.9.

Recommendations for importation of fresh meat and meat products from a country, zone or compartment posing a negligible BSE risk

~~*Veterinary Authorities* should require the presentation of an *international veterinary certificate* attesting that the cattle from which the *fresh meat* and *meat products* were derived:~~

- 1) came from a country, zone or compartment posing a negligible BSE risk;
- 2) have been subjected to an ante-mortem inspection with favourable results.

Article 11.4.10.

Recommendations for importation of fresh meat and meat products from a country, zone or compartment posing a negligible or controlled BSE risk

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

- 1) the cattle from which the *fresh meat* and *meat products* were derived came from a country, zone or compartment posing a ~~controlled BSE risk~~ negligible or controlled BSE risk and are identified through an animal identification system;

Annex 20 (contd)

2) they have been subjected to an ante-mortem inspection with favourable results;

AND EITHER:

3) they were born in the country, *zone* or *compartment* during the period when the ~~likelihood-risk~~ of the BSE agents being recycled in the cattle population has been demonstrated to be negligible;

OR

4) the *fresh meat* and *meat products*:

- a) derived from cattle not subjected to a *stunning* process with a device injecting compressed air or gas into the cranial cavity, or to a pithing process, or to any other procedure that can contaminate blood with nervous tissue, prior to *slaughter*; and
- b) were produced and handled in a manner which ensures that such products do not contain and are not contaminated with:
 - i) the *commodities* listed in points 1) ~~a) and 1) b)~~ of Article 11.4.14.;
 - ii) mechanically separated meat from the skull ~~and/or~~ from the vertebral column from cattle over 30 months of age.

Article 11.4.11.

Recommendations for importation of fresh meat and meat products from a country, zone or compartment posing an undetermined BSE risk

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

1) the cattle from which the fresh meat and meat products were derived:

~~a)~~ are identified through an *animal identification system*;

~~2)~~ it is demonstrated as having that the cattle from which the *fresh meat* and *meat products* were derived have not been fed protein meal derived from ruminants;

~~b3)~~ the cattle from which the *fresh meat* and *meat products* were derived:

a) were subjected to an ante-mortem inspection with favourable results;

eb) were not subjected to a *stunning* process with a device injecting compressed air or gas into the cranial cavity, or to a pithing process, or to any other procedure that can contaminate blood with nervous tissue, prior to *slaughter*;

~~24)~~ the *fresh meat* and *meat products* were produced and handled in a manner which ensures that such products do not contain and are not contaminated with:

a) the *commodities* listed in points 1) ~~a) and 1) b)~~ of Article 11.4.14.;

b) mechanically separated meat from the skull ~~and/or~~ from the vertebral column from cattle over 30 months of age.

Annex 20 (contd)

Article 11.4.12.

Recommendations for importation of cattle-derived protein meal from a country, zone or compartment posing a negligible BSE risk

Veterinary Authorities should require the presentation of an *international veterinary certificate* attesting that the cattle from which the protein meal was derived ~~came from a country, zone or compartment posing a negligible BSE risk;~~

- 1) came from a country, zone or compartment posing a negligible BSE risk;
- 2) are identified through an animal identification system and were born in the country, zone or compartment during the period when the risk of the BSE agents being recycled in the cattle population has been demonstrated to be negligible.

Article 11.4.13.

Recommendations for importation of blood and blood products derived from cattle (except foetal blood)

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

EITHER:

- 1) the blood and blood products came from a country, zone or compartment posing a negligible or controlled BSE risk; and

OR

- 2) ~~the blood and blood products came from a country, zone or compartment posing a controlled BSE risk and the cattle from which the blood and blood products were derived~~ are identified through an animal identification system and were born in the country, zone or compartment during the period when the likelihood risk of the BSE agents being recycled in the cattle population has been demonstrated to be negligible;

OR

- 3) the blood and blood products were:
 - a) collected from cattle not subjected to a stunning process, or to any other procedure that can contaminate the blood with nervous tissue, with a device injecting compressed air or gas into the cranial cavity, or to a pithing process, prior to slaughter, and
 - b) collected and processed in a manner that ensures they are not contaminated with nervous tissue.

Article 11.4.14.

Recommendations in relation to the trade of the commodities with the greatest BSE infectivity

4) ~~Unless covered by other articles in this chapter, the following commodities originating from a country, zone or compartment posing a controlled or undetermined BSE risk, and any commodity contaminated by them, should not be traded for the preparation of food, feed, fertilisers, cosmetics, pharmaceuticals including biologicals, or medical devices:~~

- a1) ~~distal~~ Distal ileum from cattle of any age; ~~b) skull, brain, eyes, vertebral column and spinal cord from cattle that were at the time of slaughter over 30 months of age; or any commodity contaminated by them, for the preparation of protein products, food, feed, fertilisers, cosmetics, pharmaceuticals including biologicals, or medical devices, which originate from a country, zone or compartment posing:~~

Annex 20 (contd)

- a) an undetermined BSE risk;
- b) a controlled BSE risk or a negligible BSE risk if the commodities are derived from cattle born before the period when the risk of the BSE agents being recycled in the cattle population has been demonstrated to be negligible.
- 2) Protein products, food, *feed*, fertilisers, cosmetics, pharmaceuticals including biologicals, or medical devices prepared using *commodities* listed in points 1) a) or 1) b) above of this article, which originate from a country, zone or *compartment* posing a controlled or undetermined BSE risk, ~~should not be traded.~~
- 3) Cattle-derived protein meal, or any *commodities* containing such products, which originate from a country, zone or *compartment* posing a controlled or undetermined BSE risk, ~~should not be traded.~~

~~These points do not apply to cattle in a country or zone with a controlled BSE risk when they are born during the period when the likelihood of the BSE agents being recycled in the cattle population has been demonstrated to be negligible.~~

Article 11.4.15.

Recommendations for importation of tallow (other than as defined in Article 11.4bis.) intended for food, feed, fertilisers, cosmetics, pharmaceuticals including biologicals, or medical devices

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

- 1) ~~the tallow~~ came from a country, zone or *compartment* posing a negligible BSE risk; or
- 2) ~~the tallow~~ is derived from cattle which have been subjected to an ante-mortem inspection with favourable results, and has not been prepared using the *commodities* listed in ~~points~~point 1) a) and 1) b) of Article 11.4.14.

Article 11.4.16.

Recommendations for importation of dicalcium phosphate (other than as defined in Article 11.4.1bis.) intended for food, feed, fertilisers, cosmetics, pharmaceuticals including biologicals, or medical devices

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

- 1) ~~the dicalcium phosphate~~ came from a country, zone or *compartment* posing a negligible BSE risk; or
- 2) ~~the dicalcium phosphate~~ is a co-product of bone gelatine.

Article 11.4.16bis.

Recommendations for importation of tallow derivatives (other than as defined in Article 11.4.1bis.) intended for food, feed, fertilisers, cosmetics, pharmaceuticals including biologicals, or medical devices

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

Annex 20 (contd)

- 1) originate from a country, zone or compartment that poses a negligible BSE risk; or
- 2) are derived from tallow that meets the conditions referred to in Article 11.4.15.; or
- 3) have been produced by hydrolysis, saponification or transesterification that uses high temperature and pressure.

Article 11.4.17.

Procedures for reduction of BSE infectivity in protein meal

The following procedure should be used to reduce the infectivity of any ~~transmissible spongiform encephalopathy~~ BSE agents ~~which that~~ may be present during the production of protein meal containing ruminant proteins.

- 1) The raw material should be reduced to a maximum particle size of 50 mm before heating;
- 2) The raw material should be heated under saturated steam conditions to a temperature of not less than 133°C for a minimum of 20 minutes at an absolute pressure of 3 bar.

Article 11.4.18.

Surveillance

- 4) ~~Surveillance for BSE consists of the regular reporting of animals with clinical signs suggestive of BSE to the Veterinary Authority for subsequent investigation and diagnosis. The credibility of the surveillance programme is supported by:~~
 - a) ~~compulsory notification of BSE throughout the whole territory by all those stakeholders involved in the rearing and production of livestock including farmers, herdsmen, veterinarians, transporters and slaughterhouse/abattoir workers;~~
 - b) ~~an ongoing awareness programme to ensure that all stakeholders are familiar with the clinical signs suggestive of BSE as well as the reporting requirements;~~
 - e) ~~appropriate laboratory investigations in accordance with the Terrestrial Manual and follow up field investigation as necessary of all clinical suspects.~~
- 21) BSE is a progressive, fatal disease of the nervous system of cattle that usually has an insidious onset that is refractory to treatment. A range of clinical signs that vary in severity and between animals have been described for classical BSE:
 - a) progressive behavioural changes that are refractory to treatment such as increased excitability, depression, nervousness, excessive and asymmetrical ear and eye movements, apparent increased salivation, increased licking of the muzzle, teeth grinding, hypersensitivity to touch and/or sound (hyperaesthesia), tremors, excessive ~~vocalization~~ vocalisation, panic-stricken response and excessive alertness;
 - b) postural and locomotory changes such as abnormal posture (dog sitting), abnormal gait (particularly pelvic limb ataxia), low carriage of the head (head shyness), difficulty avoiding obstacles, inability to stand and recumbency;
 - c) ~~generalized~~ generalised non-specific signs such as reduced *milk* yield, loss of body condition, weight loss, bradycardia and other disturbances of cardiac rhythm.

Annex 20 (contd)

Some of these signs are also likely to be relevant for atypical BSE, particularly those associated with difficulty in rising and recumbency. A nervous form of atypical BSE resembling classical BSE may be observed with over-reactivity to external stimuli, unexpected startle responses and ataxia. In contrast, a dull form of atypical BSE may be observed with dullness combined with a low head carriage and compulsive behaviour (licking, chewing, pacing in circles).

The clinical signs of BSE usually progress over a few weeks to several months, but ~~in~~ on rare occasions cases can develop acutely and progress rapidly. In the continuum of the disease spectrum, the The final stages are characterised by recumbency, coma and death.

~~Cattle displaying some of the above mentioned progressive neurological signs without signs of infectious illness, and that are refractory to treatment, are candidates for examination.~~

Since these signs are not pathognomonic for either classical or atypical BSE, all Member Countries with cattle populations ~~may are likely to observe~~ individual animals displaying clinical signs suggestive of BSE. ~~The rate at which they are likely to occur~~ General statements about the likely frequency of occurrence of such animals cannot be ~~reliably predicted~~ made as they will vary depending on the epidemiological situation in a particular country. ~~In addition, in~~

2) Surveillance for BSE consists of the reporting of all animals that lie on the continuum of the BSE spectrum to the Veterinary Authority for subsequent investigation and follow-up.

In those countries where cattle are intensively reared and subjected to regular observation, it is likely that ~~such~~ animals that display clinical signs suggestive of BSE will be more readily seen. Behavioural changes, that may be very subtle in the early clinical phase, are best identified by those who handle animals on a daily basis and who can monitor them closely for a progression of the signs. In more extensive systems however, where cattle are not monitored as closely, situations may ~~inevitably~~ arise where an animal might be considered as a clinical suspect, yet if it was not observed for a period of time, it may only be initially seen as a downer (non-ambulatory) or found dead (fallen stock). ~~Under such circumstances, if there is an appropriate supporting clinical history, these animals that lie on the continuum of a progressive disease from clinical suspect to downer to fallen stock may still be suitable candidates for surveillance.~~

The investigation of potential surveillance candidates should take into account that the vast majority of BSE cases arise as single, isolated events. The concurrent occurrence of multiple animals with behavioural or neurological signs, non-ambulatory or fallen stock is most likely associated with other causes.

The following animals that lie on the continuum of the disease spectrum should be targeted for BSE surveillance:

- a) those displaying some of the progressive clinical signs mentioned in point 1 of Article 11.4.18. suggestive of BSE that are refractory to treatment, and where other common causes of behavioural or neurological signs (e.g., infectious, metabolic, traumatic, neoplastic or toxic causes) have been ruled out;
- b) those showing behavioural or neurological signs that have been subjected to an ante-mortem inspection with unfavourable results at slaughterhouses/abattoirs;
- c) those presented as downers (non-ambulatory), with an appropriate supporting clinical history;
- d) those found dead (fallen stock), with an appropriate supporting clinical history.

All these animals should be followed up with appropriate laboratory testing in accordance with the Terrestrial Manual to accurately confirm or rule out the presence of BSE agents.

Annex 20 (contd)

3) The credibility of the *surveillance* programme is supported by:

- a) ongoing awareness and training programmes to ensure that all those stakeholders involved in the rearing and production of livestock including farmers, herdsmen, veterinarians, transporters and slaughterhouse/abattoir workers are familiar with the clinical signs suggestive of BSE as well as the statutory reporting requirements;
 - b) the fact that BSE is a compulsorily *notifiable disease* throughout the whole territory;
 - c) appropriate *laboratory* testing in accordance with the *Terrestrial Manual*;
 - d) robust, documented, evaluation procedures and protocols for the identification and reporting of potential candidates for BSE *surveillance*, for determination of animals to be subjected to laboratory testing, for the collection and submission of samples for laboratory testing, and for follow-up epidemiological investigation for BSE positive findings.
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DRAFT CHAPTER 1.8.

APPLICATION FOR OFFICIAL RECOGNITION BY THE OIE OF RISK STATUS FOR BOVINE SPONGIFORM ENCEPHALOPATHY

Article 1.8.1.

Guidelines

In accordance with Article 11.4.2., the bovine spongiform encephalopathy (BSE) risk of the cattle (*Bos indicus* and *Bos taurus*) population of a country or *zone* is determined on the basis of a *risk assessment* that evaluates the risk of BSE agents (classical and atypical) being recycled within the cattle population by identifying all potential factors associated with the occurrence of BSE, the ongoing implementation of a *surveillance* programme, and the history of occurrence and management of BSE cases.

In this chapter, "BSE" refers to both classical and atypical forms, unless specified otherwise.

The information specified in Articles 1.8.2. to 1.8.6. should be provided by OIE Member Countries in support of their application for official recognition of BSE risk status in accordance with Chapter 11.4. of the *Terrestrial Code*. The structure of the dossier should follow guidelines provided in the "Standard Operating Procedure for official recognition of disease status and for the endorsement of national official control programmes of Member Countries" (available on the OIE website).

Each element of the core document of the dossier provided to the OIE, should be clearly and concisely addressed with an explanation, where relevant, of how each one complies with the provisions of the *Terrestrial Code* for the BSE risk status for which the Member is applying. The rationale leading to the conclusions reached for each section needs to be clearly explained and as appropriate, figures, tables and maps should be provided. The core document of the dossier should include the following sections:

- The history of occurrence and management of BSE cases in the country or *zone* (Article 1.8.2.)
- Legislation (Article 1.8.3.)
- Veterinary system (Article 1.8.4.)
- BSE risk assessment (Article 1.8.5.)
- BSE surveillance (Article 1.8.6.)

The terminology defined in the *Terrestrial Code* and *Terrestrial Manual* should be referred to and used in the dossier. The dossier and all of its annexes should be provided in one of the OIE official languages.

Article 1.8.2.

History of occurrence and management of BSE cases in the country or zone

Describe the history of occurrence and management of BSE cases by providing the following documentary evidence:

- 1) If a case of BSE has ever been diagnosed in the country or *zone*, indicate the total number of BSE cases, and:

Annex 21 (contd)

- a) Provide a table of aggregated data on all cases of BSE encountered in the country or zone, by type (classical or atypical), origin (indigenous or, if imported, the country of origin), and the year of birth;
 - b) For the past eight years, provide a table to indicate, for each case, the year of occurrence, the origin (indigenous or, if imported, the country of origin), the type (classical or atypical), and the year of birth of each indigenous case of classical BSE.
- 2) If there have been cases of BSE, confirm that they were excluded from the feed chain and describe how this was achieved. In the table under Article 1.8.3. provide details of the national legislation, regulations and *Veterinary Authority* directives that describe these procedures.

Article 1.8.3.

Legislation

Provide a table listing all relevant legislation, regulations, *Veterinary Authority* directives, legal instruments, rules, orders, acts, decrees, etc., related to BSE. For each, provide the date of promulgation and implementation as well as a brief description of the relevance to mitigating against the risks associated with BSE. The table should include the legislation, regulations and directives referred to in the core document of the dossier. These instruments may be provided as annexes or as weblinks to supporting documents.

Article 1.8.4.

Veterinary system

The quality of the *Veterinary Services* of a Member is important to the establishment and maintenance of confidence in its *international veterinary certificates* by the *Veterinary Services* of other Members (Article 3.1.1.). It also supports an evaluation of the BSE risk status of the cattle population of a country or zone.

- 1) Describe how the *Veterinary Services* of the country comply with the provisions of Chapters 1.1., 3.1. and 3.2.
- 2) The applicant Member may provide information on any recent (not older than five years) OIE PVS evaluation conducted in the country and follow-up steps within the PVS Pathway, and highlight the results relevant to BSE.
- 3) Describe how the *Veterinary Services* supervise, control, enforce and monitor all BSE-related activities.
- 4) Provide a description of the involvement and the participation of industry; producers; farmers; herdsman; private *veterinarians*; *veterinary paraprofessionals*; transporters; workers at livestock *markets*, auctions and *slaughterhouses/abattoirs*; and other relevant non-governmental stakeholders in the control of BSE.
- 5) Describe the official cattle identification, registration, *traceability* and movement control system. Provide evidence of its effectiveness. In the table under Article 1.8.3., provide any legislation, regulation or directives relevant to this topic. Indicate if there are any industry associations or organisations involved in cattle identification, registration, *traceability* and movement control systems that provide guidance, set standards or provide third party audits; include a description of their role, membership and interaction with the *Veterinary Services* or other *Competent Authority*.

Article 1.8.5.

BSE risk assessment1. Entry assessment

As described in Article 11.4.2., an entry assessment evaluates the likelihood that the classical BSE agent has been introduced into the country or zone through the importation of *commodities*.

Annex 21 (contd)

For the purposes of undertaking an entry assessment, the period of interest is the preceding eight years (Articles 11.4.3. and 11.4.4.).

The *commodities* to be considered in the entry assessment are:

- Cattle.
 - Ruminant-derived protein meal.
 - *Feed* (not intended for pets) that contains ruminant-derived protein meal.
 - Fertilizers that contain ruminant-derived protein meal.
 - Any other *commodity* that either is or could be contaminated by *commodities* listed in Article 11.4.14. e.g., over 30 months old cattle carcass or half carcass from which the spinal cord and vertebral column were not removed, originating from a country, *zone* or *compartment* posing a controlled or undetermined BSE risk.
- a) For each *commodity* listed above indicate if they were imported in the preceding eight years, and if so, from which countries.

For each *commodity* listed above describe the import requirements applied by the applicant country or *zone* and how they are related to the BSE risk status of the *exporting country* or *zone* and whether or not they are consistent with, or provide an equivalent level of assurance with, the recommendations laid out in Chapter 11.4. for the importation of such a *commodity*. Where the import requirements are not consistent with the recommendations in Chapter 11.4. but are considered to provide an equivalent level of assurance, provide an explanation outlining the rationale and supporting evidence. In situations where an import requirement does not provide an equivalent level of assurance to the relevant measure in Chapter 11.4., provide an explanation of how this is likely to impact the entry assessment.

Describe the importation process for these *commodities* and how are they controlled, regulated and monitored by the *Competent Authority* with references as appropriate to the relevant legislation in the table under Article 1.8.3. Provide supporting evidence of the importation process including, where relevant, import permits or their equivalent, and examples of *international veterinary certificates* issued by *exporting countries*.

Describe the intended end use of the imported *commodities*, for example: cattle may be imported for breeding or immediate *slaughter*; rendered products may be imported for incorporation into *feed* for non-ruminant species such as pigs or *poultry*. Provide information on any systems in place and their results to monitor or track imported *commodities* to ensure they are used as intended.

Describe the actions available under national legislation to prevent illegal introduction of the *commodities* considered above and provide information on any illegal introductions detected and the actions taken.

- b) Conclusions for the entry assessment.

Given the sanitary measures applied (if any), what was the likelihood that, during the preceding eight years, any of the *commodities*, in the form that they were imported, harboured or were contaminated by the classical BSE agent?

Clearly and concisely describe the rationale leading to the conclusions reached.

Annex 21 (contd)2. Exposure assessment

As emphasised in Article 11.4.1., atypical BSE is a condition that occurs at a very low rate and is assumed to occur spontaneously in any cattle population. Although uncertainty remains regarding the potential transmissibility of atypical BSE through oral exposure to contaminated *feed*, this is the main route of transmission of classical BSE. Considering that atypical BSE may potentially be capable of being recycled in a cattle population if cattle were to be exposed to contaminated *feed*, it is necessary to undertake an exposure assessment regardless of the outcome of the entry assessment.

As described in Article 11.4.2., an exposure assessment evaluates the likelihood of cattle being exposed to the BSE agents either through imported *commodities* (classical BSE) or as a result of the presence of BSE agents (classical or atypical BSE) in the indigenous cattle population of the country or *zone*.

For the purposes of undertaking an exposure assessment for the evaluation of BSE status, the period of interest is the preceding eight years (Articles 11.4.3. and 11.4.4.). At its discretion, the applicant Member may provide the information requested for a different period (i.e., longer than eight years for those applying for a negligible risk status, or for the time they have the information if applying for a controlled risk status) to establish the period when the likelihood of the BSE agents being recycled in the cattle population has been demonstrated to be negligible (i.e., to determine the period of time to be attested in point 2 of Articles 11.4.6., 11.4.7., 11.4.9., 11.4.12. and 11.4.13.).

As indicated in point 1b) of Article 11.4.2., the first step in the exposure assessment involves an evaluation of the impact of livestock industry practices on preventing cattle from being fed ruminant-derived protein meal and, depending on the outcome of this step, an evaluation of the impact of specific mitigation measures on preventing cattle from being fed ruminant-derived protein meal.

a) Livestock industry practices.

Because oral exposure to contaminated *feed* is the principal route of transmission of the BSE agents, the exposure assessment begins with a detailed description of the cattle population and associated industry practices with a particular emphasis on feeding practices; disposal of dead stock and waste from slaughtered animals; rendering; and production, distribution and storage of *feed* that may lead to cattle being exposed to potentially contaminated *feed*.

The intent of this section is not to describe the implementation and enforcement of measures specifically targeting the exposure of the cattle population to BSE agents (such as a legislated *feed* ban) as they will be considered where relevant in Section *b) An evaluation of BSE specific mitigation measures*. The intention here is to evaluate the likelihood and extent of exposure of the cattle population to the BSE agents, given the ongoing livestock industry practices in a country or *zone*.

i) Demographics of the cattle population and production systems.

Describe the composition of the cattle population and how the cattle industry is structured in the country or *zone* considering the types of production systems, including all that apply, such as dairy, beef, feedlot, fattening and finishing, intensive, extensive, semi intensive, transhumant, pastoral, agropastoral, and mixed-species farming.

ii) Feeding practices.

For each type of production system, describe the rearing and production practices related to feeding ruminants of various ages, including the types of *feed* and *feed ingredients* (animal or plant based). Where animal based ingredients are used, describe whether or not they are derived from rendered products of ruminant or non-ruminant origin as well as the respective proportions used.

Provide an indication of the proportion of the national *feed* production prepared commercially (including local mills) or mixed on farm using either imported or domestically produced ingredients.

Annex 21 (contd)

Describe whether or not fertilizers containing ruminant-derived protein meal, composted materials derived from fallen stock (i.e., cattle of any age which were found dead or were killed on a farm, during transportation or at a *slaughterhouse/abattoir*), *slaughterhouse/abattoir* waste or animals condemned at *ante mortem* inspections or any other materials derived from or that incorporate ruminant protein are applied to land where cattle graze or where forage is harvested for feeding to cattle. Where such fertilizers or composted materials are used, provide information on the extent and frequency of use.

Describe, for mixed-species farms that include ruminants, the number and size of such farms and whether or not there are any practices in place to ensure that ruminants are not likely to be fed with *feed* meant for non-ruminant species or that ruminant *feed* is not likely to be cross-contaminated with *feed* intended for non-ruminants that may contain rendered products of ruminant origin.

iii) Slaughtering and waste management practices.

Describe the practices for fallen stock that occur on farm, during transport, at livestock *markets* or auctions or prior to *slaughter*, with particular reference to their transportation, disposal or destruction, including composting, burial, rendering or incineration. In the table under Article 1.8.3., provide any legislation, regulation or directives relevant to this topic.

Describe the places where cattle are slaughtered (for example, on farm, at a *slaughterhouse/abattoir* or *market*) together with the respective proportions and associated ages.

Describe whether or not places where animals are slaughtered are required to be registered or approved by the *Veterinary Services* or other *Competent Authority* and if they are subject to official veterinary supervision. In the table under Article 1.8.3., provide any legislation, regulation or directives relevant to this topic.

Describe how animals condemned at *ante mortem* inspection and waste declared as unfit for human consumption from slaughtered animals are processed, disposed of or destroyed, including composting, burial, rendering, incineration or other industrial uses such as salvaging and crushing bones for use in animal *feed*. In the table under Article 1.8.3., provide any legislation, regulation or directives relevant to this topic.

iv) Rendering practices.

Rendering is a process by which animal material is transformed into products such as protein meal that may be used in animal *feed*. It provides the pathway for the introduction of the BSE agents (classical or atypical) into the animal feed chain.

Describe whether or not there are any rendering facilities in the country or *zone*, if they are required to be registered or approved by the *Veterinary Services* or other *Competent Authority* and if they are subject to official veterinary control or supervision. In the table under Article 1.8.3., provide any legislation, regulation or directives relevant to this topic.

Using tables as appropriate, for each of the preceding eight years, provide a breakdown of the number of rendering facilities operating, indicating for each facility:

- the source and types of raw materials handled;
- whether or not they receive and process material from a particular species or process mixed materials including those derived from ruminants;
- whether or not ruminant waste is segregated from non-ruminant waste and if so how segregation is maintained to avoid potential cross-contamination of non-ruminant rendered materials during processing, storage and transport of rendered products, for example through dedicated lines, storage bins or silos, transport vehicles or establishments;

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- the parameters of the rendering process (time, temperature, pressure, etc.);
- the type and intended end use of rendered products produced. If available, provide the amount of rendered products produced annually by type and intended end use;
- if materials derived from imported cattle are managed differently, describe the process.

Indicate if there are any industry associations or organisations involved in the rendering industry that provide guidance, set standards or provide third party audits in relation to Hazard Analysis and Critical Control Points (HACCP) programs, *good manufacturing practices*, etc. Include a description of their role, membership and interaction with the *Veterinary Services* or other *Competent Authority*.

v) Feed production, distribution and storage.

Where rendered products are used as ingredients in the production of animal feed the exposure of cattle to the BSE agents (classical and atypical) may arise as a result of the use of rendered products containing materials of ruminant origin as ingredients in cattle *feed* or as a result of cattle *feed* being cross-contaminated when such products are used in the production of *feed* for other species.

Describe whether or not facilities producing *feed* for ruminant or non-ruminant livestock as well as pets are required to be registered or approved by the *Veterinary Services* or other *Competent Authority* and if they are subject to official veterinary control or supervision. In the table under Article 1.8.3., provide any legislation, regulation or directives relevant to this topic.

For each of the preceding eight years, provide a breakdown using tables as appropriate of the number and types of facilities producing *feed*, indicating for each facility:

- excluding those listed in Article 11.4.1bis., whether or not rendered ruminant products were used as ingredients in *feed* for ruminants, non-ruminants and pets;
- whether or not each facility was dedicated to manufacturing *feed* for a particular species or manufactured *feed* for multiple species including ruminants.

Where facilities manufactured *feed* for multiple species including ruminants, indicate whether or not there were any practices in place to avoid ruminant *feeds* from being contaminated with rendered ruminant products during *feed* manufacture, storage and transport.

Indicate if there are any industry associations or organisations involved in *feed* production, distribution and storage that provide guidance, set standards or provide third party audits in relation to HACCP programs, *good manufacturing practices*, etc. Include a description of their role, membership and interaction with the *Veterinary Services* or other *Competent Authority*.

vi) Conclusions for livestock industry practices.

- Given the livestock industry practices described above, is the likelihood that the cattle population has been exposed to either classical or atypical BSE during the preceding eight years negligible or non-negligible?
- Clearly and concisely describe the rationale leading to the conclusion reached.
- Where the likelihood estimate is negligible, proceed to *Section 4) Risk estimation*.
- Where the likelihood estimate is non-negligible, proceed to *Section b) An evaluation of BSE specific mitigation measures*.

Annex 21 (contd)

b) An evaluation of BSE specific risk mitigation measures.

For those countries that have reported classical BSE cases in indigenous cattle, it is apparent that their historic livestock industry practices did not prevent the recycling of the BSE agent in their cattle population. These countries, together with others whose livestock industries practices would have been conducive to recycling may have implemented specific measures, such as through a legislated *feed* ban to ensure that the likelihood of recycling would be negligible. To qualify for official recognition of a BSE risk status, these countries need to demonstrate that the measures specifically targeting BSE have been and continue to be effectively implemented and enforced.

i) The nature and scope of a feed ban.

Indicate if there is a ban on feeding ruminants with protein meal derived from ruminants.

Where a *feed* ban has been implemented, clearly and concisely describe the date it was introduced, its nature and scope and how it has evolved over time.

In addition, if the *feed* ban has been implemented through national legislation, provide pertinent information in the table under Article 1.8.3. and a summary of any relevant legislation with references as appropriate.

ii) Commodities with the greatest BSE infectivity.

Indicate whether or not any of those *commodities* listed in point 1 of Article 11.4.14. are removed from the carcass at the time of *slaughter* or subsequent fabrication or processing.

If so, also:

- Describe how they are disposed or destroyed through burial, composting, rendering, alkaline hydrolysis, thermal hydrolysis, gasification, incineration, etc.
- Describe any measures in place that ensure *slaughter* waste declared as unfit for human consumption that is rendered is not cross-contaminated with these *commodities*.
- Describe whether these *commodities* from fallen stock and animals condemned at *ante mortem* inspection are excluded from rendering and how this is done.
- Where these *commodities* are not excluded from *slaughter* waste declared as unfit for human consumption, describe the final disposal of this waste, and how it is handled and processed.
- Describe whether or not all these processes and methods are subject to approval and oversight by the *Veterinary Services* or other *Competent Authority*.

In addition, if there is specific national legislation concerning the definition, identification, removal and disposal or destruction of those *commodities* listed in point 1 of Article 11.4.14., provide pertinent information in the table under Article 1.8.3. and a summary of any relevant legislation with references as appropriate.

iii) Parameters of the rendering process.

Describe whether or not the parameters of the rendering process are prescribed in legislation and if they are consistent with, or provide an equivalent level of assurance to, the procedures for the reduction of BSE infectivity in ruminant-derived protein meal as described in Article 11.4.17. Provide details of the legislation, if applicable, in the table under Article 1.8.3.

Annex 21 (contd)

iv) Cross-contamination.

Describe the measures in place to prevent cross-contamination during rendering, *feed* production, transport, storage and feeding such as dedicated facilities, lines and equipment, as well as measures to prevent misfeeding, such as the use of warning labels. Provide information as to whether any of these measures are prescribed in legislation and if facilities involved in rendering and *feed* production are required to be registered or approved under the *feed* ban by the *Veterinary Services* or other *Competent Authority*.

v) Awareness programme under the scope of the feed ban.

Provide information on the existence of any ongoing awareness programmes or other forms of guidance given to all those stakeholders involved in rendering, *feed* production, transport, storage, distribution, sale and feeding under the scope of the *feed* ban. Provide examples of communication materials including publications, brochures and pamphlets.

vi) Monitoring and enforcement of the feed ban.

Describe how the *feed* ban, if implemented, has been and continues to be monitored and enforced. Provide information on:

- official oversight from the *Veterinary Authority*, other *Competent Authority* or a third party;
- training and accreditation programmes for inspectors;
- the planned frequency of inspections, the procedures involved including manuals and inspection forms;
- sampling programmes and *laboratory* testing methods used to check the level of compliance with the *feed* ban and cross-contamination;
- options available to deal with infractions (non-compliances) such as recalls, destruction and monetary penalties.

Provide information on the ongoing results of the official inspection programme for each of the preceding eight years using tables as appropriate:

- planned *versus* actual delivery inspections at rendering facilities, *feed* mills, farms, etc., with an explanation of any significant variance and how they may have impacted the programme;
- number and type of samples taken during inspections to verify that ruminant *feed* does not contain or is not cross contaminated with rendered products containing ruminant material (excluding those listed in Article 11.4.1.bis.). Provide information by year, by source (rendering facility, *feed* mill or farm), indicating the *laboratory* test(s) used and the results obtained;
- the types of infractions (non-compliance) that occurred and corrective actions undertaken;
- any infractions (non-compliances) that were likely to have led to cattle being exposed to *feed* contaminated with ruminant material (excluding those listed in Article 11.4.1.bis) and how they were resolved.

vii) Conclusions for the evaluation of BSE specific risk mitigation measures.

- In evaluating the effectiveness of a *feed* ban, if implemented, for each of the preceding eight years, consideration needs to be given to:
 - the management of *commodities* listed in point 1 of Article 11.4.14., and the associated likelihood that these materials, or other materials cross contaminated by them, may have entered the animal feed chain;
 - the rendering industry and the associated likelihood that rendered products containing ruminant material may retain BSE infectivity;

Annex 21 (contd)

- the *feed* industry, and the associated likelihood that *feed* for cattle may contain or has been cross-contaminated with ruminant-derived protein meal.
- Given the evaluation of BSE specific risk mitigation measures and their enforcement as described above, is the likelihood that, during the preceding eight years, the cattle population has been exposed to either classical or atypical BSE negligible or non-negligible?
Clearly and concisely describe the rationale leading to the conclusion reached.
- Where the likelihood estimate is negligible, proceed to *Section 4) Risk estimation*.
- Where the likelihood estimate is non-negligible, proceed to *Section 3) Consequence assessment*.

3. Consequence assessment

While uncertainty remains regarding the potential transmissibility of atypical BSE through oral exposure to contaminated *feed*, it is reasonable to assume for the purposes of a consequence assessment, that the likelihood of cattle becoming infected would be similar to classical BSE.

As described in Article 11.4.2., a consequence assessment evaluates the likelihood of cattle becoming infected following exposure to the BSE agents (classical or atypical) together with the likely extent and duration of any subsequent recycling and amplification.

For the purposes of undertaking a consequence assessment for the evaluation of BSE risk status, the period of interest is the preceding eight years.

Considering that, for all practical purposes, oral exposure to contaminated *feed* is the principal, if not the only route of transmission of the BSE agents, to initiate a cycle of BSE infectivity within a cattle population the following series of events would need to unfold:

- *commodities* listed in point 1 of Article 11.4.14. from an infected animal are included in raw materials that are rendered into ruminant-derived protein meal;
- the rendering process does not destroy infectivity of the BSE agent(s);
- the ruminant-derived protein meal is incorporated as an ingredient in cattle *feed*, or cattle *feed* is cross-contaminated during *feed* production, distribution and storage, or cattle are incorrectly fed with *feed* intended for non-ruminant species that includes the ruminant-derived protein meal as an ingredient;
- one or more animals that ingest contaminated *feed* become infected;
- the infected animal survives long enough to reach the later stages of a protracted incubation period when the levels of the BSE agent in those *commodities* listed in point 1 of Article 11.4.14. would begin to rise dramatically;
- *commodities* listed in point 1 of Article 11.4.14. are then included in raw materials that are rendered into ruminant-derived protein meal, completing one cycle.

Recycling arises when this cycle is repeated one or more times. Any level of recycling within a given period is sufficient to conclude that the consequences of exposure to contaminated *feed* for that period within the cattle population are non-negligible.

- a) Factors to consider when evaluating the likely extent of recycling of the BSE agents within a cattle population:
 - i) Age at exposure.
Animals less than 12 months of age are considered to be much more susceptible to infection than older animals, which are likely to be increasingly refractory to *infection* as they mature.

Annex 21 (contd)

ii) Production type.

- Calves reared as replacement animals for the breeding *herd*.

Cattle exposed to BSE agents at less than 12 months of age and destined to enter the breeding *herd* are much more likely to become infected and survive long enough to reach the later stages of a protracted incubation period when the levels of the BSE agent in those *commodities* listed in point 1 of Article 11.4.14. would begin to rise dramatically. If these materials were rendered and subsequently contaminated cattle *feed*, it is highly likely that some level of recycling would occur.

- Feedlot cattle.

Even if cattle reared in a feedlot that were destined to be slaughtered within the next two to six months were to become infected after consuming contaminated *feed*, the likelihood that they would have reached the later stages of a protracted incubation period (when the levels of the BSE agent in those *commodities* listed in point 1 of Article 11.4.14. would begin to rise dramatically) would essentially be negligible.

Considering that mature cattle are likely to be much more refractory to *infection* than animals within their first year of life, even if they were to consume contaminated *feed*, it is highly unlikely that those *commodities* listed in point 1 of Article 11.4.14. would pose a threat if they were rendered and subsequently contaminated cattle *feed*.

iii) The impact of livestock industry practices or the implementation of measures under a feed ban.

When evaluating the potential for the recycling of the BSE agents in the cattle population where an infraction (non-compliance) has occurred that may have led to *feed* being cross-contaminated, it is important to consider the impact of both the livestock industry practices and the ongoing measures under a *feed* ban. Even if an infraction that arose several years ago led to susceptible young animals becoming infected, in evaluating the likelihood of recycling in future years, consideration would need to be given to the effectiveness of the *feed* ban in subsequent years or whether or not any changes to livestock industry practices may have influenced the exposure risk.

b) Conclusions for the consequence assessment.

Where the outcome of the evaluation of livestock industry practices or the evaluation of BSE specific mitigation measures, that include the nature and scope of the *feed* ban and its enforcement, has concluded that there was a non-negligible likelihood that the cattle population has been exposed to the BSE agents, what is the likelihood that they have been recycled within the cattle population during the preceding eight years?

Clearly describe the rationale leading to the conclusions reached.

4. Risk estimation

As described in Article 11.4.2., risk estimation combines the results and the conclusions arising from the entry, exposure and consequence assessments to provide an overall measure of the risk that BSE agents have been recycled in the cattle population through the feeding of ruminant-derived protein meal.

- a) Provide a summary of the entry and exposure assessments and the conclusions reached.
- b) If applicable, provide a summary of the consequence assessment, and the conclusions reached.
- c) When the condition of point 1 of Article 11.4.3. has not been met, that is, it cannot be demonstrated that for at least eight years the risk that the BSE agents have been recycled in the cattle population has been negligible, provide an explanation for the period of time within the preceding eight years for which it can be considered that the risk has been negligible. Clearly describe the rationale leading to the conclusions reached.

Article 1.8.6.

BSE surveillance

Article 11.4.18. describes the criteria that underpin a credible *surveillance* programme together with an overview of the range and progression of clinical signs that cattle affected by BSE are likely to exhibit.

Requirements under point 2 of Article 11.4.18. are focused on subsets of the cattle population where disease is more likely to be detected, if it is actually present.

The Member applying for recognition of a negligible or a controlled BSE risk status should submit documentary evidence that the provisions of point 3 of Article 11.4.18. have been effectively implemented.

For the purposes of *surveillance*, the period of interest is the preceding eight years (Articles 11.4.3. and 11.4.4.).

Animals that lie on the continuum of the disease spectrum (i.e., from clinically ill to non-ambulatory to fallen stock) should be targeted for BSE surveillance and include those animals described in points 2a) to 2d) of Article 11.4.18.

1. Awareness and training programmes (point 3a) of Article 11.4.18.)

Ongoing awareness and training programmes are essential to ensure that all stakeholders are familiar with clinical signs suggestive of BSE (those described in point 1 of Article 11.4.8.) as well as their statutory reporting requirements.

- a) Describe the stakeholder groups targeted for BSE awareness and training programmes. Describe the methods used to identify stakeholder groups within the jurisdiction and methods used to identify how, for example, the size and characteristics of the stakeholder group changes over time.
- b) Describe the type(s) of awareness and training programmes implemented for specific stakeholder groups. Describe how these programmes are adapted to meet the specific obligations and activities of each stakeholder group by those involved in caring for livestock, as well as the protocols for sample collection and submission by *veterinarians* and animal health technicians).
- c) Provide information on the number of awareness and training activities, the stakeholder groups targeted, the number of individuals reached per activity (if available), and the geographic coverage for these activities.
- d) Provide a description including examples of materials used in the awareness programme including training manuals, supporting documents such as publications in local newspapers and farming magazines, pamphlets and videos (weblinks to supporting documents in one of the official languages of the OIE may also be provided, where they exist).
- e) Provide details on how the effectiveness of the awareness and training programmes is evaluated.
- f) Provide details of any contingency or preparedness plan for BSE.

2. Compulsory notification (point 3b) of Article 11.4.18.)

To ensure the reporting and further investigations of any animals that lie on the continuum of the BSE spectrum, appropriate legislation, policies and incentives to support compulsory notification, investigation and verification should be in place.

- a) Indicate the date of implementation of any supporting legislation and associated policies making notification of BSE compulsory. Indicate if a definition for a "BSE suspect" exists. If appropriate, outline relevant legislation in the table under Article 1.8.3.
- b) Describe the supportive measures in place for notification of animals that lie on the continuum of the BSE spectrum, such as incentives, compensations or penalties.

Annex 21 (contd)

- c) Describe the guidance given to all stakeholders involved in the rearing and production of livestock including farmers, herdsmen, *veterinarians*, transporters, workers at livestock *markets*, auctions and *slaughterhouses/abattoirs* in terms of the criteria for reporting animals that lie on the continuum of the BSE spectrum. What mechanisms are in place to ensure that these guidelines reach those stakeholders?
- d) Describe the reporting framework for animals that lie on the continuum of the BSE spectrum for evaluation. Has this framework evolved over time and, if so, how?

3. Laboratory testing (point 3c) of Article 11.4.18.)

Provide documentary evidence that the relevant provisions of Chapter 3.4.5. of the *Terrestrial Manual* are applied, including the following:

- a) If BSE samples are submitted to a *laboratory* in the country or *zone* for testing provide an overview of how many are involved in testing BSE samples, how they are approved or certified, their number, location and diagnostic procedures and the time frame for reporting results.
- b) If the BSE samples are not submitted to a *laboratory* in the country or *zone* for testing or suspicious or positive samples are referred to a *laboratory* outside the country, provide the names of the *laboratories* in other countries providing the service as well as the arrangements in place, including logistics for shipment of samples and the time frame for reporting results.
- c) Describe the diagnostic protocol and tests used for processing samples for classical and atypical BSE and how they may have evolved over time, indicating: what is the primary test used?; what would be the series of secondary tests performed, if any, depending on the results of the primary test (i.e., negative, positive and inconclusive)?; and what test would be undertaken if discordant results between primary and secondary tests arise (e.g., primary positive result followed by a secondary negative result)?
- 4. Evaluation procedures and protocols to identify and report potential candidates for BSE surveillance, to determine animals to be subjected to laboratory testing, to collect and submit samples for laboratory testing, and to follow up with epidemiological investigation BSE positive findings (point 3d) of Article 11.4.18.)

Because the incidence of BSE is likely to be very low in Member Countries it is important that *surveillance* efforts focus on subsets of the cattle population where disease is more likely to be detected, if it is actually present. Hence, those animals described in points 2a) to 2d) of Article 11.4.18. must be targeted for BSE *surveillance*.

Considering that BSE is a progressive disease and that animals to be included in the *surveillance* programme may arise at the farm, the *slaughterhouse/abattoir*, or during transportation, procedures and protocols should be in place covering all points in the livestock production chain for: (1) the identification and reporting of animals potentially lying on the continuum of the BSE spectrum (e.g., by the farmer, *animal handler*, *veterinarian*, etc.), (2) the criteria to determine which of these reported animals need to be tested for BSE (e.g., the criteria used by the *veterinarian* that allows the discrimination of reported animals subject to laboratory testing), (3) the collection and submission of samples for testing in a laboratory, and (4) a follow-up epidemiological investigation for BSE positive findings.

It is important that appropriate procedures and protocols are in place to ensure that BSE can be definitively ruled out on the list of differential diagnoses.

- a) List the common cattle disorders with clinical signs compatible with BSE in the country or zone. If available, provide the incidence/prevalence of these disorders, ideally by production system (e.g., dairy, beef) and by age group.
- b) Describe the procedures and protocols in place for reporting animals potentially lying on the continuum of the BSE spectrum (those described in points 2a) to 2d) of Article 11.4.18.) to the *Competent Authority*. For example, these procedures and protocols may include the steps that a farmer may follow once an animal with clinical signs suggestive of BSE is identified. These procedures and protocols should cover the clinical continuum of the disease spectrum ranging from clinical suspects to non-ambulatory to fallen stock.

Annex 21 (contd)

- c) Describe the procedures and protocols in place for the investigation of reported animals potentially lying on the continuum of the BSE spectrum (those described in points 2a) to 2d) of Article 11.4.18.) that allow the discrimination of reported animals to be subjected to laboratory testing. For example, these procedures and protocols may include the range of clinical signs to be considered, and how the age, the clinical history of the animal and epidemiological data of the *herd* are taken into account. An evaluation procedure may, for example, be in the form of a protocol, a checklist or a decision tree, and should cover the clinical continuum of the disease spectrum ranging from clinical suspects to non-ambulatory to fallen stock.
- d) Describe the methods applied to assess the age of animals investigated, such as individual identification or dentition.
- e) Describe the procedures and protocols for the transport of live or dead animals for sampling, and transfer of samples to laboratories for testing, including details of the cattle identification system, the maintenance of the chain of custody of the carcass and the samples, and the reconciliation of samples with the animals they were collected from.
- f) Provide the procedures and protocols for a follow-up epidemiological investigation of BSE positive results.
- g) Provide a summary table for each year (Table 1) of the number of animals reported and the number of animals subjected to BSE testing for each clinical presentation (those in points 2a) to 2d) of Article 11.4.18.).

Table 1.		
Year: _____		
Table 1 - Summary of all animals that were reported and evaluated for testing by the Veterinary Authority		
Clinical presentation (see point 2 of Article 11.4.18.)	Number of reported animals	Number of animals subjected to BSE testing
(A) Cattle displaying progressive behavioural or neurological signs suggestive of BSE that are refractory to treatment		
(B) Cattle showing behavioural or neurological signs that did not pass the ante-mortem inspection at slaughterhouses/abattoirs		
(C) Cattle presented as downers (non-ambulatory) with an appropriate supporting clinical history		
(D) Cattle found dead (fallen stock) with an appropriate supporting clinical history		

5. Animals subjected to laboratory testing

- a) Provide in Table 2 details of all animals that were subjected to laboratory testing (see point 2 of Article 11.4.18.).

Annex 21 (contd)

Table 2. Details of the animals that were subjected to laboratory testing.							
Year notified	Laboratory identification number or individual identification number	Age (in months) at first detection	Type of production system (dairy, beef, mixed, etc.)	Description of observed clinical signs	Clinical presentation (A, B, C or D)	Final diagnosis (if BSE, specify the strain)	For a BSE case, indicate the origin (indigenous or imported; if imported, indicate the country of birth)

Article 1.8.7.**Recovery of BSE risk status**

Following the occurrence of an indigenous case of classical BSE in an animal born within the preceding eight years in a negligible BSE risk status of a country or *zone*, the outcome of the investigation together with any additional measures implemented that confirm or ensure that the risk of BSE being recycled within the cattle population continues to be negligible should be provided with reference to the provisions in Article 1.8.5. as appropriate. Information in relation to other sections need to only be supplied if relevant.

CHAPTER 11.10.

**INFECTION WITH *THEILERIA ANNULATA*,
T. ORIENTALIS AND *T. PARVA***

Article 11.10.1.

General provisions

Animals susceptible to *infection* with *Theileria* are bovines (*Bos indicus*, *B. taurus* and *B. grunniens*), water buffaloes (*Bubalus bubalis*), African buffaloes (*Syncaerus caffer*), sheep (*Ovis aries*), goats (*Capra hircus*), camels (*Camel dromedarius* and *C. bactrianus*) and some *wild* ruminants.

Infection with *Theileria* can give rise to disease of variable severity and to *Theileria* transmission. *Theileria* may persist in ruminants for their lifetime. Such *animals* are considered carriers.

For the purposes of the *Terrestrial Code*, *infection* with *Theileria annulata*, *T. orientalis* and *T. parva* ~~are~~ is defined as a tickborne *infection* of bovines and water buffaloes with *T. annulata*, *T. orientalis* Ikeda, *T. orientalis* Chitose and *T. parva*.

For the purposes of this chapter, *Theileria* means *T. annulata*, *T. orientalis* Ikeda, *T. orientalis* Chitose and *T. parva*.

The following defines the occurrence of *infection* with *Theileria*:

- 1) *Theileria* has been identified in a sample from a bovine or water buffalo; or
- 2) antigen or nucleic acid specific to *Theileria* has been identified in a sample from a bovine or water buffalo showing clinical signs consistent with *infection* with *Theileria*, or epidemiologically linked to a suspected or confirmed case, or giving cause for suspicion of previous association with *Theileria*; or
- 3) antibodies specific to *Theileria* have been detected in a sample from a bovine or water buffalo that either shows clinical signs consistent with *infection* with *Theileria*, or is epidemiologically linked to a suspected or confirmed case or giving cause for suspicion of previous association with *Theileria*.

For the purposes of the *Terrestrial Code*, the *incubation period* for *infection* with *Theileria* shall be 35 days.

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

Article 11.10.2.

Safe commodities

When authorising import or transit of the following *commodities*, *Veterinary Authorities* should not require any *Theileria*-related conditions regardless of the *infection* with *Theileria* status of the *animal population* of the *exporting country*:

- 1) *meat* and *meat products*;
- 2) *casings*;
- 3) *milk* and *milk products*;
- 4) gelatine and collagen;
- 5) tallow;

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- 6) semen and embryos;
- 7) hooves and horns;
- 8) bones.

Article 11.10.3.

Country or zone free from infection with *Theileria*

- 1) A country or a *zone* may be considered free from *infection* with *Theileria* when the disease is notifiable in the entire country, importation of bovines and water buffaloes and their *commodities* is carried out in accordance with this chapter, and:
 - a) the country or *zone* is historically free as described in Article 1.4.6.; or
 - b) a *surveillance* programme in accordance with Chapter 1.4. has demonstrated no evidence of *infection* with *Theileria* in the country or *zone* for at least two years; or
 - c) an ongoing *surveillance* programme in accordance with Chapter 1.5. has found no competent tick *vectors* for at least two years in the country or *zone*.
- 2) A country or *zone* free from *infection* with *Theileria* in which ongoing *vector surveillance*, performed in accordance with Chapter 1.5., has found no competent tick *vectors* will not lose its free status through the introduction of vaccinated, test-positive or infected bovines or water buffaloes from infected countries or *zones*.
- 3) A country or *zone* free from *infection* with *Theileria* will not lose its status as a result of introduction of seropositive or vaccinated bovines, water buffaloes or their *commodities*, provided they were introduced in accordance with this chapter.

Article 11.10.4.

Recommendations for importation from countries or zones free from infection with *Theileria*For bovines and water buffaloes

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

- 1) showed no clinical sign of *infection* with *Theileria* on the day of shipment;
- 2) come from a country or *zone* free from *infection* with *Theileria*.

Article 11.10.5.

Recommendations for importation from countries or zones not free from infection with *Theileria*For bovines and water buffaloes

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

- 1) showed no clinical sign of *infection* with *Theileria* and no *infestation* with tick *vectors* on the day of shipment;
- 2) were kept isolated for at least 35 days prior to shipment, in an *establishment* where no case of *infection* with *Theileria* has occurred during the preceding two years;

Annex 22 (contd)

- 3) were treated with a registered acaricide the efficacy of which has been confirmed in relation to the area of origin of the animals, at the entrance of the isolation establishment and then at regular intervals, according to manufacturer's instructions, allowing continuous protection against ticks until their shipment 48 hours prior to entry to the establishment, no more than two days after entering the establishment and three days prior to shipment;
- 4) were subjected to serological and agent detection tests with negative results on samples taken on entry to the *establishment* and five days before shipment.

Article 11.10.6.

Recommendations for importation of hides and skins from countries or zones not free from infection with *Theileria*

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

- 1) dry-salted or wet-salted for a period of at least 14 days prior to dispatch; or
- 2) treated for a period of at least seven days in salt (NaCl) with the addition of 2% sodium carbonate (Na₂CO₃); or
- 3) dried for a period of at least 42 days at a temperature of at least 20°C; or
- 4) frozen to at least -20°C for at least 48 hours.

Article 11.10.7.

Recommendations for importation of trophies derived from susceptible wild ruminants from countries or zones not free from infection with *Theileria*

Veterinary Authorities should require the presentation of an *international veterinary certificate* attesting that the products have been processed to ensure the destruction of tick *vectors*.

CHAPTER 11.11.

TRICHOMONOSIS

Article 11.11.1.

General provisions

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

Article 11.11.2.

Recommendations for the importation of cattle for breeding

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

- 1) the animals showed no clinical sign of trichomonosis on the day of shipment;
- 2) the animals were kept in a *herd* in which no case of trichomonosis has been reported; and/or
- 3) ~~for females which have been mated, direct microscopic examination and culture of vaginal mucus were negative~~
were subjected to an agent identification test with negative results.

Article 11.11.3.

Recommendations for the importation of bulls for breeding (natural service or artificial insemination)

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

- 1) the animals showed no clinical sign of trichomonosis on the day of shipment;
- 2) the animals were kept in a *herd* in which no case of trichomonosis has been reported; and/or
- 3) the animals have never been used for natural service; or
- 4) the animals have only mated virgin heifers; or
- 5) the animals were subjected to ~~a direct microscopic and cultural examination of preputial specimens~~ an agent identification test with negative results.

Article 11.11.4.

Recommendations for the importation of bovine semen

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

- 1) the donor animals have never been used for natural service; or
- 2) the donor animals have only mated virgin heifers; or
- 3) the donor animals were kept in an *establishment* or *artificial insemination centre* where no case of trichomonosis has been reported;
- 4) the donor animals were subjected to ~~a direct microscopic and cultural examination of preputial specimens~~ an agent identification test with negative results;
- 5) the semen was collected, processed and stored in accordance with Chapter 4.6. and 4.7.

CHAPTER 12.2.

INFECTION WITH *TAYLORELLA EQUIGENITALIS* (CONTAGIOUS EQUINE METRITIS)

Article 12.2.1.

General provisions

This chapter addresses the occurrence of clinical or asymptomatic *infection* of a mare caused by *Taylorella equigenitalis* as well as the presence of *T. equigenitalis* on the genital mucous membrane surface in the male horse.

For the purposes of the *Terrestrial Code*, the following defines *infection* with *T. equigenitalis*:

- 1) *T. equigenitalis* has been isolated and identified from a genital swab sample from a horse;
- 2) antigen or genetic material specific to *T. equigenitalis* has been identified in a sample from a mare showing clinical or pathological signs consistent with *infection* with *T. equigenitalis* or epidemiologically linked to a confirmed or suspected case of *infection* with *T. equigenitalis*;
- 3) genetic material specific to *T. equigenitalis* has been identified in a sample from a male horse.

For the purposes of the *Terrestrial Code*:

- due to long-term persistence of *T. equigenitalis* in horses, the *infective period* shall be lifelong;
- the *incubation period* in mares shall be 14 days.

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

For the purposes of this chapter, a temporary importation refers to the introduction of a horse into a country or *zone*, for competition or cultural events excluding breeding, for a defined period of time, not exceeding 90 days, during which the *risk* of transmission of the *infection* is mitigated through specific measures under the supervision of the *Veterinary Authority*. Temporary imported horses are re-exported at the end of this period. The duration of the temporary importation period and the destination after this period, as well as the conditions required to leave the country or *zone*, should be defined in advance.

When authorising import or transit of the *commodities* listed in this chapter, with the exception of those listed in Article 12.2.2., *Veterinary Authorities* should require the conditions prescribed in this chapter relevant to the *T. equigenitalis* status of the *exporting country, zone or establishment*.

Article 12.2.2.

Safe commodities

When authorising import or transit of the following *commodities*, *Veterinary Authorities* should not require any *T. equigenitalis*-related conditions regardless of the *T. equigenitalis* *infection* status of the *exporting country, zone, or establishment*.

- 1) geldings;
- 2) *milk* and *milk products*;
- 3) *meat* and *meat products*;
- 4) hides and skins;
- 5) hooves;
- 6) gelatine and collagen.

Annex 24 (contd)

Article 12.2.3.

Establishment free from *infection* with *T. equigenitalis*1. Prerequisite

Infection with *T. equigenitalis* has been a *notifiable disease* in the entire country for at least the past two years.

2. Qualification

To qualify as free from *infection* with *T. equigenitalis*, an *establishment* should satisfy the following conditions:

- a) it is under the control of the *Veterinary Authority*;
- b) no *case* has occurred for at least two years;
- c) all horses from the *establishment* have been subjected to *T. equigenitalis* tests, with negative results. These tests should have been carried out on three occasions, within a 12-day period with an interval of no less than three days apart between each test. Horses must have not been treated with antibiotics for at least 21 days before the sampling;
- d) stored semen was subjected to a test to detect *T. equigenitalis* with negative results, carried out on an aliquot of the stored semen.

3. Maintenance of freedom

- a) requirements in points 1 and 2a) and 2b) of Article 12.2.3 are met;
- b) appropriate *surveillance*, capable of detecting *infection* with *T. equigenitalis* even in the absence of clinical signs, is in place; this may be achieved through a *surveillance* programme in accordance with Chapter 1.4. and this chapter;
- c) the introduction of horses and their germplasm into the *establishment* is carried out in accordance with the import conditions for these *commodities* listed in this chapter.

4. Recovery of freedom

When a *case* is detected in a previously free *establishment*, the free status of the *establishment* should be suspended until the following conditions are met in the affected *establishment*.

- a) the *disinfection* of the *establishment* has been applied;
- b) 21 days after the last removal or the last treatment of an infected horse, all horses have been subjected to a *T. equigenitalis* test, with negative results, on three occasions, within a 12-day period with an interval of no less than three days apart between each test;
- c) stored semen was subjected to a test to detect *T. equigenitalis* with negative results, carried out on an aliquot of the stored semen;
- d) the introduction of horses and their germplasm into the *establishment* is carried out in accordance with the import conditions for these *commodities* listed in this chapter.

Article 12.2.4.

Recommendations for importation of stallions or mares

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

Annex 24 (contd)

- 1) mares showed no clinical sign of *infection* with *T. equigenitalis* on the day of shipment;

AND

- 2) horses have been kept in an *establishment*:
 - a) free from *infection* with *T. equigenitalis* since birth or for at least two years prior to shipment;

OR

- b)
 - i) in which no case has been reported during the 60 days prior to shipment;

AND

- ii) were subjected to *T. equigenitalis* tests, with negative results, on three occasions, within a 12-day period with an interval of no less than three days apart between each test, being the last test carried out within the 30 days prior to shipment. Horses must not have been treated with antibiotics for at least 21 days prior to sampling.

Article 12.2.5.

Recommendations for temporary importation of horses

When importing on a temporary basis horses that do not comply with recommendations in Article 12.2.4. for purposes different than breeding and rearing, *Veterinary Authorities* should:

- 1) require:
 - a) the animals be accompanied by a passport in accordance with the model contained in Chapter 5.12. or be individually identified as belonging to a high health status *subpopulation* as defined in Chapter 4.17.;
 - b) the presentation of an *international veterinary certificate* attesting that the mares showed no clinical sign of *infection* with *T. equigenitalis* on the day of shipment;
 - c) the duration of the temporary importation period and the destination after this period, and the conditions required to leave the country or *zone* be defined;
- 2) ensure that during their stay in the country or *zone*, the animals:
 - a) are not used for breeding (including artificial insemination, semen collection, used as teaser stallions) and do not have any sexual contact with other horses;
 - b) do not undergo any genital examinations;
 - c) are kept and transported individually in stalls and *vehicles/vessels* which are subsequently cleaned and disinfected before re-use.

Article 12.2.6.

Recommendations for importation of semen of horses

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

- 1) semen was collected in an *approved* centre and collection, processing and storing was done in accordance with Chapter 4.6; and

Annex 24 (contd)

EITHER

2) the donor stallion was kept in an *establishment* free from *infection* with *T. equigenitalis*;

OR

3)

a) the donor stallion was kept in an *establishment* in which no *case* has been reported during the 60 days prior to semen collection; andb) the donor stallion was subjected to *T. equigenitalis* identification tests, with negative results, on three occasions, within a 12-day period with an interval of no less than three days apart between each test, being the last test carried out within the 30 days prior to shipment. The donor stallion must not have been treated with antibiotics for at least 21 days prior to sampling;

OR

4) aliquots of fresh semen were subjected to culture and a test for detection of genetic material for *T. equigenitalis* with negative results, carried out immediately prior to processing and on an aliquot of semen collected within 15 to 30 days after the first collection of the semen to be exported;

OR

5) aliquots of frozen semen corresponding to the earliest and the most recent collection were subjected to culture and a test for detection of genetic material for *T. equigenitalis* with negative results.

Article 12.2.7.

Recommendations for importation of oocytes or embryos of horses*Veterinary Authorities* should require the presentation of an *international veterinary certificate* attesting that:

- 1) the oocytes and embryos were collected, processed and stored in *approved* centres following the general provisions in accordance with Chapters 4.9. and 4.10.;
- 2) the donor mare showed no clinical signs of *infection* with *T. equigenitalis* on the day of collection;

AND

for the importation of embryos:

- 3) the semen used for embryo production complied with Chapters 4.6. and 4.7.

Article 12.2.8.

Surveillance1. General principles of surveillance*Surveillance* for *infection* with *T. equigenitalis* is relevant for *establishments* seeking to achieve and demonstrate freedom from *infection*, as well as part of an *official control programme* in countries where the disease is endemic.The *surveillance* strategy chosen should be adequate to detect the *infection* with *T. equigenitalis* even in the absence of clinical signs.

Annex 24 (contd)

The *Veterinary Services* should implement programmes to raise awareness among farmers and workers who have day-to-day contact with horses, as well as *veterinarians*, *veterinary paraprofessionals* and diagnosticians, who should report promptly any suspicion of *infection* with *T. equigenitalis* to the *Veterinary Authority*.

Under the responsibility of the *Veterinary Authority*, Member Countries should have in place:

- a) a formal and ongoing system for detecting and investigating cases;
- b) a procedure for the rapid collection and transport of samples from suspected *cases* to a *laboratory* for diagnosis;
- c) a system for recording, managing and analysing diagnostic and *surveillance* data.

2. Clinical surveillance

Clinical *surveillance* aims at detecting clinical signs by close physical examination of horses and based on reproduction performance. However, clinical *surveillance* should be complemented by bacteriological and molecular tests, as asymptomatic carriers play an important role in the maintenance and transmission of the *infection*.

3. Agent surveillance

An active programme of *surveillance* of horses to detect *cases* should be implemented to establish the status of a country, *zone* or *establishment*. Culture for *T. equigenitalis* and molecular testing are the most effective methods of detection of the *case*.

Stored semen should be included in *surveillance* programmes. It represents a valuable source of material and may be very helpful in contributing to retrospective studies, including providing support for claims of freedom from *infection* and may allow certain studies to be conducted more quickly and at lower cost than other approaches. Samples can be gathered through representative sampling or following a *risk*-based approach.

4. Serological surveillance

Serological *surveillance* is not the preferred strategy for detecting *T. equigenitalis*. If used, serology should be used in conjunction with culture in assessing the status of a mare that may have been infected with *T. equigenitalis*. The usefulness of serological tests is further described in the *Terrestrial Manual*.

CHAPTER 12.7.

**EQUINE PIROPLASMOSIS INFECTION WITH
THEILERIA EQUI AND BABESIA CABALLI (EQUINE
PIROPLASMOSIS)**

Article 12.7.1.

General provisions

The use of the term equine piroplasmosis indicates clinical diseases caused by the transmission of *Theileria equi* (*T. equi*) or *Babesia caballi* (*B. caballi*) through competent ticks or iatrogenic practices. This chapter deals not only with the occurrence of clinical signs caused by infection with *T. equi* or *B. caballi*, but also with the presence of infection with *T. equi* or *B. caballi* in the absence of clinical signs.

Susceptible animals for infection with *T. equi* or *B. caballi* are primarily domestic and wild equids. Although old-world camelids are susceptible to infection and potential reservoirs, they are not found to play a significant role in the epidemiology of the disease.

Equids infected with *T. equi* or *B. caballi* may remain carriers of these blood parasites for long periods, sometimes lifelong and act as sources of infection for competent tick vectors of the genera *Dermacentor*, *Rhipicephalus*, *Hyalomma* and *Amblyomma*.

For the purposes of the *Terrestrial Code*, the following defines infection with *T. equi* or *B. caballi*:

- 1) identification of the parasite by microscopic examination of a sample from an equid showing clinical or pathological signs consistent with infection with *T. equi* or *B. caballi* or epidemiologically linked to a confirmed or suspected case of infection with *T. equi* or *B. caballi*; or
- 2) antigen or genetic material specific for *T. equi* or *B. caballi* has been identified in a sample from an equid showing clinical or pathological signs consistent with infection with *T. equi* or *B. caballi* or epidemiologically linked to a confirmed or suspected case of infection with *T. equi* or *B. caballi*; or
- 3) antibodies specific to *T. equi* or *B. caballi* have been identified in a sample from an equid showing clinical or pathological signs consistent with infection with *T. equi* or *B. caballi* or epidemiologically linked to a confirmed or suspected case of infection with *T. equi* or *B. caballi*.

For the purposes of the *Terrestrial Code*, the incubation period of infection with *T. equi* or *B. caballi* in equids shall be 30 days and the infective period shall be lifelong.

For the purposes of this chapter, a temporary importation refers to the introduction of equids into a country or zone, for a defined period of time, not exceeding 90 days, during which the risk of transmission of the infection is mitigated through specific measures under the supervision of the *Veterinary Authority*. Temporarily imported horses are re-exported or slaughtered at the end of this period. The duration of the temporary importation period and the destination after this period, as well as the conditions required to leave the country or zone, should be defined in advance.

When authorising import or transit of the commodities listed in this chapter, with the exception of those listed in Article 12.7.2, *Veterinary Authorities* should require the conditions prescribed in this chapter relevant to the status of infection with *T. equi* and *B. caballi* of the exporting country or zone.

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

Annex 25 (contd)Article 12.7.2.**Safe commodities**

When authorising import or transit of the following commodities, Veterinary Authorities should not require any conditions related with infection with *T. equi* or *B. caballi*, regardless of the infection status of the exporting country or zone:

- 1) milk and milk products;
- 2) meat and meat products;
- 3) hides and skins;
- 4) hooves;
- 5) gelatine and collagen;
- 6) semen collected;
- 7) sterile filtered horse serum;
- 8) embryos collected, processed and stored in accordance with Chapters 4.9. and 4.10.

Article 12.7.3.**Country or zone free from infection with *T. equi* and *B. caballi***

- 1) Historical freedom as described in Chapter 1.4. does not apply to infection with *T. equi* and *B. caballi*.
- 2) A country or a zone may be considered free from infection with *T. equi* and *B. caballi* when:
 - a) infection with *T. equi* and infection with *B. caballi* have been notifiable diseases in the entire country for at least the past 10 years and, in the country or zone:

EITHER:

 - i) there has been no case of infection with *T. equi* and no case of infection with *B. caballi* during the past six years; and
 - ii) a surveillance programme performed in accordance with Article 12.7.9. has demonstrated no evidence of infection with *T. equi* and no evidence of infection with *B. caballi* in the past six years;

OR

 - iii) an ongoing surveillance programme performed in accordance with Article 12.7.9. has found no competent tick vectors for at least six years;
 - b) imports of equids into the country or zone are carried out in accordance with this chapter. A country or zone free from infection with *T. equi* and *B. caballi* in which ongoing vector surveillance, performed in accordance with Article 12.7.9., has found no competent tick vector will not lose its free status through the introduction of seropositive or infective equids;
 - c) a country or zone free from infection with *T. equi* and *B. caballi* adjacent to an infected country or zone should include a high-risk area in which continuous serological, agent and vector surveillance is conducted in accordance with Article 12.7.9.

Article 12.7.4.**Recovery of a free status**

When infection with *T. equi* or *B. caballi* is detected in a previously free country or zone, Article 12.7.3. applies.

Article 12.7.25.**Recommendations for the importation of equines ~~equids~~**

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

- 1) ~~the animals~~ showed no clinical signs ~~equine piroplasmosis~~ of infection with *T. equi* or *B. caballi* on the day of shipment, ~~and~~
- 2) EITHER:
 - a) the animals were kept in a country or zone free from infection with *T. equi* and *B. caballi* since birth;
 - OR
 - 2) were subjected to diagnostic tests for equine piroplasmosis (*Theiloriaequi* and *Babesia caballi*) with negative results during the 30 days prior to shipment;
 - b) i) were subjected to a serological or agent identification test with molecular techniques for the detection of *T. equi* and *B. caballi* with negative results carried out on a blood sample taken within the 14 days prior to shipment; and
- 3) ~~were maintained free from ticks, by preventive treatment when necessary, during the 30 days prior to shipment.~~
 - ii) were maintained free from competent ticks in accordance with Article 12.7.7. during the 30 days prior to sampling and after sampling until shipment and throughout the transport to the destination country or zone.

Article 12.7.36.**Recommendations for the temporary importation of equids of competition horses on a temporary basis**

~~Veterinary Authorities of importing countries should consider the possibility of importing competition horses on a temporary basis and which are positive to the testing procedure referred to in point 2) of Article 12.7.2. under the following safeguards:~~

If the importation of equids on a temporary basis does not comply with the recommendations in Article 12.7.5., Veterinary Authorities of importing countries should:

4. —

1) require that:

- a) ~~the horses are~~ the animals be accompanied by a passport in accordance with the model contained in Chapter 5.12. or be individually identified as belonging to a high health status subpopulation as defined in Chapter 4.17.;
- 2.) ~~the Veterinary Authorities of importing countries require~~ the presentation of an *international veterinary certificate* attesting that the animals:
 - a.i) showed no clinical sign of ~~equine piroplasmosis~~ infection with *T. equi* or *B. caballi* on the day of shipment;

Annex 25 (contd)

- b) were treated against ticks within the seven days prior to shipment;
 - ii) were maintained free from ticks in accordance with Article 12.7.7. during the 30 days prior to shipment and during transport;
 - c) the duration of the temporary importation period and the destination after this period, as well as the conditions required to leave the country or zone, be defined;
- 3) the horses are kept in an area where necessary precautions are taken to control ticks and that is under the direct supervision of the Veterinary Authority;
- 4) the horses are regularly examined for the presence of ticks under the direct supervision of the Veterinary Authority.
- 2) ensure that during their stay in the country or zone:
- a) the animals are protected from ticks in accordance with Article 12.7.7.;
 - b) equids are examined daily for the presence of ticks of the genera *Dermacentor*, *Rhipicephalus*, *Hyalomma* and *Amblyomma* with particular attention to the ears, false nostrils, inter-mandibular space, mane, lower body areas, including the axillae, and inguinal region, and the perineum and tail, with negative results;
 - c) the animals are not subjected to any practice that may represent a risk of iatrogenic transmission of infection with *T. equi* or *B. caballi*.

Article 12.7.7.**Protecting equids from ticks**

Under the direct supervision of the Veterinary Authority:

- 1) equids are kept in tick-protected facilities and transported in protected vehicles according to Article 12.7.8.;
- 2) equids have been preventively treated according to the manufacturer's recommendations with an acaricide effective against the competent ticks.

Article 12.7.8.**Protecting facilities and transports from ticks**

The establishment or facility should be approved by the Veterinary Authority and the means of protection should at least comprise the following:

- 1) measures to limit or eliminate habitats for competent tick vectors should be implemented for an appropriate time and over an appropriate distance in the vicinity of the area where equids are kept;
- 2) the facility and immediate surroundings of the stables and exercise or competition areas should be treated with an effective acaricide before the arrival of equids;
- 3) when transporting animals through infected countries or zones:
 - a) the vehicle should be treated with an effective acaricide before transporting the animals;
 - b) preventive treatment with an acaricide with an extended residual effect that lasts at least for the duration of any stopover during the trip should be conducted.

Article 12.7.9.**Surveillance strategies****1. General principles of surveillance**

A Member Country should justify the surveillance strategy chosen as being adequate to detect the presence of infection with *T. equi* and the presence of infection with *B. caballi*, even in the absence of clinical signs, given the prevailing epidemiological situation in accordance with Chapter 1.4. and Chapter 1.5. and under the responsibility of the Veterinary Authority.

An active programme of surveillance of equids to detect evidence of infection with *T. equi* and evidence of infection with *B. caballi* by serological or agent identification molecular testing is required to establish the status of a country or zone considering that asymptomatic carriers play an important role in the maintenance and transmission of the infection.

The Veterinary Services should implement programmes to raise awareness among veterinarians, horse owners, riders and workers who have day-to-day contact with equids, as well as veterinary paraprofessionals and diagnosticians, who should report promptly any suspicion of infection with *T. equi* and any suspicion of infection with *B. caballi* to the Veterinary Authority.

Under the responsibility of the Veterinary Authority, Member Countries should have in place:

- = a formal and ongoing system for detecting and investigating cases;
- = a procedure for the rapid collection and transport of samples from suspected cases of infection with *T. equi* or *B. caballi* to a laboratory for diagnosis;
- = a system for recording, managing and analysing diagnostic and surveillance data.

2. Clinical surveillance

Clinical surveillance aims at detecting clinical signs by close physical examination of equids.

3. Serological and agent surveillance

An active programme of surveillance of equids to detect evidence of infection with *T. equi* and evidence of infection with *B. caballi* by serological or agent identification test with molecular techniques is required to establish the status of a country or zone considering that asymptomatic carriers play an important role in the maintenance and transmission of the infection.

The study population used for a serological survey should be representative of the population at risk in the country or zone.

4. Surveillance in high-risk areas

Disease-specific enhanced surveillance in a free country or zone should be carried out over an appropriate distance from the border with an infected country or zone, based upon geography, climate, history of infection and other relevant factors. The surveillance should be carried out particularly over the border with that country or zone unless there are relevant ecological or geographical features likely to limit the spatial distribution and thereby prevent the infestation of equids from competent ticks and interrupt the transmission of infection with *T. equi* or *B. caballi*.

5. Vector surveillance

Infection with *T. equi* or *B. caballi* is transmitted between equine hosts by species of Ixodid ticks in the genera *Dermacentor*, *Rhipicephalus*, *Hyalomma*, and *Amblyomma*.

Annex 25 (contd)

Vector surveillance is aimed at demonstrating the absence of tick vectors or defining high, medium and low-risk areas and local details of seasonality by determining the various species present in an area, their respective seasonal occurrence, and abundance. Vector surveillance has particular relevance to potential areas of spread. Long term surveillance can also be used to assess vector abatement measures or to confirm the continued absence of vectors.

Vector surveillance sampling should be scientifically based. The choice of the number and types of traps to be used in vector surveillance and the frequency of their use should consider the size and ecological characteristics of the area to be surveyed as well as the biology and behavioural characteristics of the local vector species of Ixodid ticks.

The use of a vector surveillance system to detect the presence of circulating *T. equi* or *B. caballi* is not recommended as a routine procedure. Animal-based surveillance strategies are preferred to detect *T. equi* or *B. caballi* transmission than entomological surveillance.
