CHAPTER 7.7.

~~GUIDELINES ON~~ STRAY DOG POPULATION CONTROL

Preamble: The scope of these recommendations is to deal with stray and feral dogs, which pose serious human health, animal health and welfare problems and have a socio-economic, political~~,~~ and religious problems in many countries. Whilst acknowledging human health is a priority including the prevention of zoonotic diseases notably rabies, the OIE recognises the importance of controlling dog populations without causing unnecessary or avoidable animal suffering. Veterinary Services should play a lead role in preventing zoonotic diseases and ensuring animal welfare and should be involved in dog population control, coordinating their activities with other competent public institutions and/or agencies.

Article 7.7.1.

Guiding principles

The following recommendations are based on those laid down in Chapter 7.1. Some additional principles are relevant to these recommendations:

1. The promotion of Responsible dog ownership can significantly reduce the numbers of stray dogs and the incidence of zoonotic diseases.

2. Because dog ecology is linked with human activities, control of dog populations has to be accompanied by changes in human behaviour to be effective.

Article 7.7.2.

Definitions

Stray dog

means any dog not under direct control by a person or not prevented from roaming.

Types of stray dog:

a) free-roaming owned dog not under direct control or restriction at a particular time;

b) free-roaming dog with no owner;

c) feral dog: domestic dog that has reverted to the wild state and is no longer directly dependent upon humans for successful reproduction.

Owned dog

means a dog with a person that claims responsibility.

Person

this can include more than one individual, and could comprise family/household members or an organisation.

Responsible dog ownership

means the situation whereby a person (as defined above) accepts and commits to perform various duties according to the legislation in place and focused on the satisfaction of the behavioural, environmental and physical needs of a dog and to the prevention of *risks* (aggression, *disease* transmission or injuries) that the dog may pose to the community~~,~~ other animals or the environment.

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Euthanasia
means the act of inducing death in a humane manner.

Dog population control programme
means a programme with the aim of reducing a stray dog population to a particular level and/or maintaining it at that level and/or managing it in order to meet a predetermined objective (see Article 7.7.3).

Carrying capacity
means the upper limit of the dog population density that could be supported by the habitat based on the availability of resources (food, water, shelter), and human acceptance.

Article 7.7.3.

Dog population control programme objectives

The objectives of a programme to control the dog population may include the following:

1. improve health and welfare of owned and stray dog population;
2. reduce numbers of stray dogs to an acceptable level;
3. promote responsible ownership;
4. assist in the creation and maintenance of a rabies immune or rabies-free dog population;
5. reduce the risk of zoonotic diseases other than rabies;
6. manage other risks to human health (e.g. parasites);
7. prevent harm to the environment and other animals;
8. prevent illegal trade and trafficking.

Article 7.7.4.

Responsibilities and competencies

1. Veterinary Authority

   The *Veterinary Authority* is responsible for the implementation of animal health and animal welfare legislation, in coordination with other competent government agencies and institutions. Control of endemic zoonotic diseases such as rabies and parasitic *infections* (e.g. *Echinococcus* spp.) would require technical advice from the *Veterinary Authority*, as animal health and some aspects of public health are within this Authority's competence but organising and/or supervising dog control schemes can be the responsibility of non-governmental organisations and governmental agencies other than the *Veterinary Authority*.

2. Other government agencies

   The responsibilities of other government agencies will depend on the risk being managed and the objective/nature of the dog population control measures employed.

The ministry or other agency responsible for public health would normally play a leadership role and may have legislative authority in dealing with zoonotic diseases. Control of stray dogs with regard to other human health risks (e.g. stray dogs on roads; dog attacks within communities) may fall within the responsibility of the public health agency but is more likely to be the responsibility of the local government authorities or other agencies for public safety/security operating at the state/provincial or municipal level.

Environment protection agencies may take responsibility for control problems associated with stray dogs when they present a hazard to the environment (e.g. control of feral dogs in national parks; prevention of dog attacks on wildlife or transmission of *diseases* to wildlife) or where a lack of environmental controls is giving rise to stray dog populations that threaten human health or access to amenities. For example, environmental protection agencies may regulate and enforce measures to prevent dogs from accessing waste or human sewage.

3. Private sector veterinarians

The private sector veterinarian is responsible for providing advice to dog owners or handlers consulting the veterinarian for advice or treatment of a dog. The private sector veterinarian can play an important role in *disease* surveillance because he/she might be the first to see a dog suffering from a *notifiable disease* such as rabies. It is necessary that the private sector veterinarian follow the procedure established by the *Veterinary Authority* for responding to and reporting a suspected rabies case or a dog that is suffering from any other *notifiable disease*. Private sector veterinarians also play an important role (often in liaison with the police and/or local authorities) in dealing with cases of neglect that can lead to problems with stray and mismanaged dogs.

The private veterinarian has competence and will normally be involved in dog health programmes and population control measures, including health testing, vaccination, identification, kennelling during the absence of the owner, sterilisation and euthanasia. Two-way communication between the private sector veterinarian and *Veterinary Authority*, often via the medium of a veterinary professional organisation, is very important and the *Veterinary Authority* is responsible for setting up appropriate mechanisms for this action.

4. Non governmental organisations (NGOs)

Non governmental organisations (NGOs) are potentially important partners of the *Veterinary Services* in contributing to public awareness and understanding and helping to obtain resources to contribute in a practical way to the design and successful implementation of dog control programmes. NGOs can supply local knowledge on dog populations and features of ownership, as well as expertise in handling and kennelling dogs and the implementation of sterilisation programmes. NGOs can also contribute, together with veterinarians and the authorities in educating the public in responsible dog ownership.

5. Local government authorities

Local government authorities are responsible for many services and programmes that relate to health, safety and public good within their jurisdiction. In many countries the legislative framework gives authority to local government agencies in regard to aspects of public health, environmental health/hygiene and inspection/compliance activities.

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In many countries local government agencies are responsible for the development and enforcement of legislation relating to dog ownership (e.g. registration, microchipping, vaccination, leash laws, abandonment), the control of stray dogs (e.g. dog catching and shelters) and the alleviation of the problems stray dogs cause in their jurisdiction. This would normally be done with advice from a higher level (national or state/provincial) authority with specialised expertise in regard to public health and animal health. Collaboration with the private sector veterinarians (e.g. in programs to sterilise and vaccinate stray dogs) and NGOs is a common feature of dog control programmes. Regardless of the legislative basis, it is essential to have the co-operation of local government authorities in the control of stray dogs.

6. 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 must ensure that the welfare of the dog, including behavioural needs, are respected and the dog is protected, as far as possible, from infectious *diseases* (e.g. through vaccination and parasite control) and from unwanted reproduction (e.g. through contraception or sterilisation). Owners should ensure that the dog's ownership is clearly identified (preferably with permanent identification such as a tattoo or microchip) and, where required by legislation, registered on a centralised database. All reasonable steps should be taken to ensure that the dog does not roam out of control in a manner that would pose a problem to the community and/or the environment.

Article 7.7.5.

In the development of a dog population control programme it is recommended that the authorities establish 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/authorities, environmental control services/authorities, NGOs and the public). The main purpose of this advisory group would be to analyse and quantify the problem, identify the causes, obtain public opinion on dogs and propose the most effective approaches to use in the short and long term.

Important considerations are as follows:

1. Identifying the sources of stray dogs

a) Owned dogs that roam freely

b) Dogs that have been abandoned by their owner, including puppies resulting from uncontrolled breeding of owned dogs.

c) Unowned dogs that reproduce successfully.

2. Estimating the existing number, distribution and ecology

Practical tools that are available include registers of dogs, population estimates, and surveys of dogs~~,~~ owners, dog shelters and veterinarians. The important factors relevant to the dog carrying capacity of the environment include food, shelter, water and human attitudes and behaviour.

A methodology could be established to make an estimate of the total dog population. An overview of appropriate methodologies may be found in Article 7.7.8. The same methodology could be used at appropriate intervals to assess population trends.

3. Regulatory framework

A regulatory framework that would help authorities establish successful dog control programmes could include the following key elements:

a) registration and identification of dogs and licensing of dog breeders;

b) vaccination against rabies and other preventive measures against zoonotic disease, as appropriate;

c) veterinary procedures (e.g. surgical procedures);

d) control of dog movement (national and international);

e) control of dangerous dogs;

f) regulations on the breeding and sale of dogs;

g) environmental controls (e.g. *abattoirs*, rubbish dumps, dead stock facilities);

h) regulations for dog shelters;

i) animal welfare obligations of owners and authorities.

4. Resources available to authorities

a) Human resources;

b) financial resources;

c) technical tools;

d) infrastructure;

e) cooperative activities;

f) public-private-NGO partnerships;

g) central-state or province-local partnerships.

Article 7.7.6.

Control measures

The following control measures could be implemented according to the national context and local circumstances. Measures may be used in combination. Euthanasia of dogs, used alone, is not an effective control measure. If used, it should be done humanely (see point 11 of Article 7.7.6.) and in combination with other measures to achieve effective long term control. It is also important that authorities gain an understanding of people's attitudes towards dog ownership so that they can develop a cooperative approach to the control of dog populations.

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1. Education and legislation for responsible ownership

Encouraging dog owners to be more responsible will reduce the number of dogs allowed to roam, improve the health and welfare of dogs, and minimise the risk that dogs pose to the community. The promotion of responsible dog ownership through legislation and education is a necessary part of a dog population control programme. Collaboration with local government authorities, animal welfare NGOs, kennel clubs, private veterinarians and veterinary organisations will assist *Veterinary Authorities* in establishing and maintaining programmes.

Education on responsible dog ownership (for the currently owned dog and any offspring it produces) should address the following elements:

a) the importance of proper selection and care to ensure the welfare of the dog and any offspring; the latter may include preparing the dog to cope with its environment through attention to socialisation and training;

b) registration and identification of dogs (see point 2 of Article 7.7.6.);

c) disease prevention, in particular zoonotic disease, e.g. through regular vaccination in rabies endemic areas;

d) preventing negative impacts of dogs on the community, via pollution (e.g. faeces and noise), risks to human health through biting or traffic accidents and risks to other dogs, wildlife, livestock and other companion animal species;

e) control of dog reproduction.

In order to achieve a shift towards responsible ownership, a combination of legislation, public awareness, education, and promotion of these elements will be required. It may also be necessary to improve access to resources supporting responsible ownership, such as veterinary care, identification and registration services and measures for control of zoonotic diseases.

2. Registration and identification of dogs (licensing)

A core component of dog population control by the *Competent Authorities* is the registration and identification of owned dogs. This may include granting licences to owners and breeders. Registration and identification may be emphasized as part of responsible dog ownership and are often linked to animal health programs, for example, mandatory rabies vaccination and traceability.

Registration of animals in a centralised database can be used to support the enforcement of legislation and the reuniting of lost animals with owners. The control of dog reproduction by sterilisation can be encouraged through financial incentives presented by differential licensing fees.

3. Reproductive control

Controlling reproduction in dogs prevents the birth of unwanted puppies and can help address the balance between demand for dogs and the size of the population. It is advisable to focus efforts to control reproduction on those individuals or groups in the dog population identified as the most productive and the most likely to be the sources of unwanted and stray dogs, to ensure best use of resources. 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 is essentially the responsibility of owners and can be incorporated into education on responsible ownership (see point 1 of Article 7.7.6.). Methods for controlling reproduction in dogs include:

a) surgical sterilisation;

b) chemical sterilisation;

c) chemical contraception;

d) separation of female dogs during oestrus from unsterilised males.

Surgical sterilisation should be carried out by a veterinarian and include appropriate anaesthesia and pain management.

Any chemicals or drugs used in controlling reproduction should be shown to have appropriate safety, quality and efficacy for the function required and used according to the manufacturer's and *Competent Authority*'s regulations. In the case of chemical sterilants and contraceptives, research and field trials may need to be completed before use.

4. Removal and handling

The *Competent Authority* should collect dogs that are not under direct supervision and verify their ownership. Capture, transport, and holding of the dogs should be done humanely. The *Competent Authority* should develop and implement appropriate legislation and training to regulate these activities. Capture should be achieved with the minimum force required and equipment should be used that supports humane handling. Uncovered wire loops should not be used for capture.

5. Capture and return, rehoming or release

Competent Authorities have the responsibility to develop minimum standards for the housing (physical facilities) and care of these dogs. There should be provision for holding the dogs for a reasonable period of time to allow for reunion with the owner and, as appropriate, for rabies observation.

a) Minimum standards for housing should include the following provisions:

   i) site selection: Access to drainage, water and electricity are essential and environmental factors such as noise and pollution should be taken into account;

   ii) kennel size, design and occupancy taking exercise into account;

   iii) *disease* control measures including isolation and quarantine facilities.

b) Management should address:

   i) adequate fresh water and nutritious food;

   ii) regular hygiene and cleaning;

   iii) routine inspection of the dogs;

   iv) monitoring of health and provision of required veterinary treatments;

   v) policies and procedures for rehoming (adoption), sterilisation and euthanasia;

   vi) training of staff in safe and appropriate handling of dogs;

   vii) record keeping and reporting to authorities.

Dogs that are removed from a community may be reunited with the owner or offered to new owners for rehoming. This provides an opportunity to promote responsible ownership and good animal health care (including rabies vaccination). Prior to rehoming, authorities may consider sterilisation of dogs as a population control measure. The suitability of new owners to adopt dogs should be assessed and owners matched with available animals. The effectiveness of rehoming may be limited due to the suitability and number of dogs.

Dogs that are removed from a community may in some cases be provided with health care (including rabies vaccination), 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 stray dogs is considered to be inevitable and is 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. If the local community has owned dogs, and sterilised dogs are released, consideration should be given to the risk that this could encourage abandonment of unwanted dogs. In the situation where many dogs are owned, a population control 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.

c) If this method is adopted, the following factors should be addressed:

   i) raising awareness of the programme within the local community to ensure understanding and support;

   ii) use of humane methods for catching, transporting and holding dogs;

   iii) correct surgical technique, anaesthesia and analgesia, followed by post-operative care;

   iv) *disease* control may include blanket vaccination (e.g. rabies) and treatments and testing for *diseases* (e.g. leishmaniasis) followed, as appropriate by treatment or euthanasia of the dog;

   v) behavioural observation may be used to assess if dogs are suitable for release; if not suitable for release or rehoming, euthanasia should be considered;

   vi) 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 and identification of a level of 'ownership' by the organisation/authority responsible for carrying out this intervention. A visible identification (e.g. collar) may also be used to prevent unnecessary recapture;

   vii) the dog should be returned to a place that is as near as possible to the place of capture;

   viii) the welfare of dogs after release should be monitored and action taken if required.

Dogs that are removed from a community may be too numerous or may be unsuitable for any rehoming scheme. If euthanasia of these unwanted animals is the only option, the procedure should be conducted in accordance with the regulations of the *Competent Authority* (see point 11 of Article 7.7.6.)

6. Environmental controls

Steps should be taken to exclude dogs from sources of food (e.g. rubbish dumps and *abattoirs*, and installing animal-proof rubbish containers).

This should be linked to a reduction in the dog population by other methods, to avoid animal welfare problems.

7. Control of dog movement – international (export/import)

Chapter 8.10. provides recommendations on the international movement of dogs between rabies free countries and countries considered to be infected with rabies.

8. Control of dog movements – within country (e.g. leash laws, roaming restrictions)

Measures for the control of dog movement in a country are generally invoked for the following reasons:

a) for rabies control when the *disease* is present in a country;

b) for public safety reasons;

c) for the safety of "owned dogs" in an area or locality when a stray dog control programme is in place;

d) to protect wildlife and livestock.

It is necessary to have a regulatory framework and a national or local infrastructure comprising organisation, administration, staff and resources to encourage the finders of stray dogs to report to the *Competent Authority*.

9. Regulation of commercial dog dealers

Dog breeders and dealers should be encouraged to form or join an appropriate association. Such associations should encourage a commitment to the raising and selling of physically and psychologically healthy dogs, as unhealthy dogs may be more likely to be abandoned to become part of the stray population. They should encourage breeders and dealers to provide advice on proper care to all new owners of dogs. Regulations covering commercial dog breeders and dealers should include specific requirements for accommodation, provision of suitable food, drink and bedding, adequate exercise, veterinary care and disease control and may require breeders and dealers to allow regular inspection, including veterinary inspection.

10. Reduction in dog bite incidence

The most effective means of reducing prevalence of dog bites are education and placing responsibility on the owner. Dog owners should be educated in principles of responsible dog ownership as described in point 1 of Article 7.7.6. Legal mechanisms that enable the *Competent Authorities* to impose penalties or otherwise deal with irresponsible owners are necessary. Mandatory registration and identification schemes will facilitate the effective application of such mechanisms. 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. Authorities should seek advice from dog behaviour experts in developing dog safety education programmes.

Annex XVII (contd)

11. Euthanasia

When euthanasia is practised, the general principles in the *Code* should be followed, with the emphasis on using the most practical, rapid and humane methods and ensuring operator safety. Regardless of the method used, it is important to minimise distress, anxiety and pain by ensuring that operators are appropriately trained.

Table 1 shows a Summary analysis ~~List~~ of methods for the euthanasia of dogs.

Annex XVII (contd)

Table 1: Summary analysis ~~List~~ of methods for the euthanasia of dogs

Euthanasia method	Specific method	Animal welfare concerns/ implications	Key animal welfare requirements	Considerations relating to operator security	Advantages	Disadvantages
Chemical -via injection	Barbiturates	Correct restraint is needed. IP is slow and may be irritant. IC injection is a painful procedure.	Recommend to use IV injection. When using IP injection, the solution may be diluted or local anaesthetic agent used in conjunction. IC should only be performed on unconscious animal and by skilled operator.	Correct restraint is needed. Administered under veterinary supervision and requires trained personnel.	Speed of action generally depends on the dose, concentration, route and rate of injection. Barbiturates induce euthanasia smoothly, with minimal discomfort to the animal. Barbiturates are less expensive than many other euthanasia agents.	These drugs persist in the carcass and may cause sedation or death in animals that consume the cadaver.
	Embutramide +Mebezonium +Tetracaine	Muscle paralysis may occur before lost of consciousness if injection given rapidly	Use slow IV injection with sedation to permit slow rate of injection.	Correct restraint is needed. To be administered under veterinary supervision and by trained personnel.	Quite low cost.	Unavailable/unlicensed in some countries
Chemical -via injection (contd)	Anaesthetic agent overdose (thiopentone or propofenol)	Underdosing may lead to recovery	IV injection of a sufficient dose	Correct restraint is needed. To be administered under veterinary supervision and by trained personnel.	Generally quick action and minimal discomfort to animal.	Large volume required (cost implications)
	Potassium chloride (KCl)	K^+ is cardiotoxic and very painful if used without anaesthetic agent.	Only use on anaesthetised animals, IV injection	Requires trained personnel.	Readily available without veterinary control.	Prior need for anaesthetic (cost and availability implications)

Annex XVII (contd)

Table 1: Summary analysis ~~List~~ of methods for the euthanasia of dogs (contd)

Mechanical	Free bullet	Can be inhumane if shot is inaccurate and dog is only wounded; dog may also escape.	Skilled operator essential.	Risk of injury to operators and spectators.	Not necessary to handle or capture dog.	Brain tissue may be unavailable for rabies diagnosis. Risk of injury to bystanders. Legal constraints on use of firearms.
	Penetrating captive bolt followed by pithing where necessary to ensure death	Can be inhumane if shot is inaccurate and dog is only wounded.	Skilled operator essential.	Animal must be restrained. Skilled operator essential.	No risk to operator (cf free bullet) unless risk of dog infected with rabies, due to potential contact with brain tissue	Brain tissue may be unavailable for rabies diagnosis. Legal constraints on use of firearms. May raise aesthetic objections.
	Exsanguination	Onset of hypovolaemia may cause dog to become anxious.	Only use on unconscious animal	Danger to operator through use of sharp instrument.	Material requirements minimal.	Must be done on unconscious animal. Aesthetically objectionable

Table 1: Summary analysis ~~List~~ of methods for the euthanasia of dogs (contd)

Euthanasia method	Specific method	Animal welfare concerns/ implications	Key animal welfare requirements	Considerations relating to operator security	Advantages	Disadvantages
Gaseous	Carbon monoxide (CO)	Inadequate concentration of CO is not lethal and can cause suffering. Signs of distress (convulsions, vocalization and agitation) may occur.	Compressed CO in cylinders must be used to achieve and maintain adequate concentration, which must be monitored. Note: fumes from gasoline engines are an irritant and this source of CO is not recommended.	Very hazardous for operator - gas is odourless and causes toxicity at both acute high levels and chronic low levels	Dog dies quite rapidly if concentration of 4 to 6% used. No odour (therefore no aversive effect). Gas is not flammable or explosive except at concentration greater than 10%.	

Annex XVII (contd)

Table 1: Summary analysis ~~List~~ of methods for the euthanasia of dogs (contd)

Euthanasia method	Specific method	Animal welfare concerns/ implications	Key animal welfare requirements	Considerations relating to operator security	Advantages	Disadvantages
Gaseous	Carbon dioxide (CO_2)	Gas is aversive. Inadequate concentration of CO_2 is not lethal and can cause suffering. CO_2 is heavier than air, so when incomplete filling of the chamber occurs, dogs may raise their head and avoid exposure. Few studies on adequate concentration and animal welfare.	Compressed CO_2 gas chamber is the only acceptable method because the concentration can be monitored and regulated.	Minimal hazard to operator when properly designed equipment used.	Gas is not flammable or explosive and causes quite rapid anaesthesia when correct concentrations used. Low cost. Readily available as compressed gas	Unconsciousness can occur in minutes, but death may take some time. Likelihood of suffering before unconsciousness.
	Inert gas (nitrogen, N_2 argon, Ar)	Loss of consciousness is preceded by hypoxemia and ventilatory stimulation, which may be distressing to the dog. Re-establishing a low concentration of O_2 (i.e. greater than or equal to 6%) in the chamber before death will allow immediate recovery.	Concentration above 98% must be achieved rapidly and maintained. Properly designed equipment must be used	Minimal hazard to operator when properly designed equipment used.	Gas is not flammable or explosive and is odourless. Readily available as compressed gas.	High cost. Little data on animal welfare implications in dogs.

Annex XVII (contd)

Table 1: Summary analysis ~~List~~ of methods for the euthanasia of dogs (contd)

Euthanasia method	Specific method	Animal welfare concerns/ implications	Key animal welfare requirements	Considerations relating to operator security	Advantages	Disadvantages
Gaseous	Anaesthetic gas overdose (halothane or enflurane)	Animal may struggle and become anxious during induction. Vapours may be irritating and can induce excitement.	Supplementation with air or O_2 required to avoid hypoxemia during induction phase.	Some gases may be hazardous, especially for pregnant women. General recommendation: Avoid human exposure to greater than or equal to 2ppm to avoid narcosis.	Gas is not flammable or explosive. Valuable for use with small animals (<7kgs) and animals that are already anesthetised with gas.	High cost. Anaesthetic and euthanasia properties of the gas used must be known. Isoflurane has a pungent odour. Methoxyflurane's action is slow and dog may become agitated.
Electrical	Electrocution	Cardiac fibrillation occurs before onset of unconsciousness, causing severe pain if dog is conscious. Pain can also be caused by violent extension of the limbs, head and neck. Method may not be effective if insufficient current applied.	Dogs must be unconscious before being electrocuted. This can be accomplished by electrical stunning (current through the brain to produce an instantaneous stun) or anaesthesia. Electrodes should span the brain in order that the current passed through the brain in order to achieve an effective stun. Death would result from current passed through the heart of an unconscious animal. Proper equipment and trained operator is essential.	May be hazardous for operator, who should use protective equipment (boots and gloves).	Low cost.	Inhumane if performed on conscious dog. May raise aesthetic objections.

KEY to abbreviations used in Table 1:
IV: intravenous
IP: Intraperioneal
IC: Intracardiac

Annex XVII (contd)

a) Comments on methods for the euthanasia of dogs:

i) 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. Some euthanasia methods must be used in association with sedation or anaesthesia in order to be considered humane.

ii) Special equipment

When special equipment is needed to perform euthanasia (e.g. gas chamber) the system should be designed for the purpose and regularly maintained in order to achieve operator security and animal welfare.

iii) The following methods, procedures and practices are unacceptable on animal welfare grounds:

- Chemical methods:
  - Embutramide +Mebezonium +Tetracaine without sedation or by other than IV injection
  - Chloral hydrate
  - Nitrous oxide: may be used with other inhalants to speed the onset of anaesthesia, but alone it does not induce anaesthesia in dogs
  - Ether
  - Chloroform
  - Cyanide
  - Strychnine
  - Neuromuscular blocking agents (nicotine, magnesium sulphate, potassium chloride, all curariform agents) : when used alone, respiratory arrest occurs before loss of consciousness, so the dog may perceive pain
  - Formalin
  - Household products and solvents.
- Mechanical methods:
  - Air embolism on conscious animal
  - Burning
  - Exsanguination of conscious animal
  - Decompression: expansion of gas trapped in body cavities may be very painful
  - Drowning
  - Hypothermia, rapid freezing
  - Stunning: stunning is not a euthanasia method, it should always be followed by a method which ensures death.
  - Kill-trapping
  - Electrocution of conscious animal.

Because neonatal animals and adults with impaired breathing or low blood pressure are resistant to hypoxia, methods that depend upon achieving a hypoxic state (e.g. CO_2, CO, N_2, Ar) should not be used. These methods should not be used in animals aged less than 2 months, except to produce loss of consciousness and should be followed by another method to cause death. Concussion and cervical dislocation may be used in very small neonatal dogs and only in cases of emergency.

Operators must be well trained in the use of physical techniques to ensure that they are correctly and humanely carried out. The dog must be exsanguinated immediately after concussion or cervical dislocation.

iv) Confirmation of death

For all methods of euthanasia used, death must be confirmed before animals are disposed of or left unattended. If an animal is not dead, another method of euthanasia must be performed.

v) Carcass disposal

Carcasses should be disposed of in a manner that complies with legislation. Attention must be paid to the risk of residues occurring in the carcase. Incineration is generally the safest way of carcass disposal.

Article 7.7.7

Monitoring and evaluation of dog population control programmes

Monitoring and evaluation allows for comparison of important indicators against the baselines measured during initial assessment (see Article 7.7.5.). The three main reasons for carrying out monitoring and evaluation are:

1. to help improve performance, by highlighting both problems and successful elements of interventions;

2. for accountability, to demonstrate that the programme is achieving its aims;

3. assuming methods are standardised, to compare the success of strategies used in different locations and situations.

Monitoring is a continuous process that aims to check the programme progress against targets and allows for regular adjustments. Evaluation is a periodic assessment, usually carried out at particular milestones to check the programme is having the desired and stated impact. These procedures involve the measurement of 'indicators' that are chosen because they reflect important components of the programme at different stages. Selection of suitable indicators requires clear planning of what the programme is aiming to achieve, the best selection of indicators will be one that reflects the interest of all relevant stakeholders. Standardised methodology will facilitate comparison of data from subsequent evaluations and performance between different projects. Indicators can be direct measurements of an area targeted to change (e.g. population of free roaming dogs on public property) or indirect measures that reflect change in a targeted area.

Annex XVII (contd)

4. Elements that should generally be monitored and evaluated include:

   a) dog population size, separated ~~by~~ into sub-populations according to ownership and restriction of movement (i.e. roaming unrestricted or restricted by an owner);

   b) dog welfare, in the target population (e.g. body condition score, skin conditions and injuries or lameness) and as a result of the programme (if interventions involve direct handling of dogs, the welfare of the dogs as result of this handling should be monitored);

   c) prevalence of zoonotic diseases, such as rabies, in both the animal and human population;

   d) responsible animal ownership, including measures of attitudes and understanding of responsible ownership and evidence that this is translating into responsible behaviour.

5. There are many sources of information for monitoring and evaluation purposes, including:

   a) feedback from the local community (e.g. through the use of structured questionnaires, focus groups or 'open format' consultation processes);

   b) records and opinions obtained from relevant professionals (e.g. veterinarians, medical doctors, law enforcement agencies, educators);

   c) animal based measurements (e.g. direct observation surveys of population size and welfare status).

The output of activities against budget should be carefully recorded in order to evaluate the effort (or cost) against the outcomes and impact (or benefit) that are reflected in the results of monitoring and evaluation.

Article 7.7.8.

An overview of appropriate methods for estimating the size of dog populations.

Population estimates are necessary for making realistic plans for dog population management and zoonosis control, and for monitoring the success of such interventions. However, for designing effective management plans, data on population sizes alone are insufficient. Additional information is required, such as degrees of supervision of owned dogs, the origin of ownerless dogs, accessibility, etc.

The term "owned" may be restricted to a dog that is registered with licensing authorities, or it may be expanded to unregistered animals that are somewhat supervised and receive shelter and some form of care in individual households. Owned dogs may be well supervised and restrained at all times, or they may be left without control for various time periods and activities. Dogs without owners that claim responsibility may still be accepted or tolerated in the neighbourhood, and individuals may provide food and protection. Such animals are sometimes called "community owned dogs" or "neighbourhood dogs". For an observer it is frequently impossible to decide if a free roaming dog belongs to someone or not.

The choice of methods for assessing the size of a dog population depends on the ratio of owned versus ownerless dogs, which may not always easy to judge. For populations with a large proportion of owned dogs it may be sufficient to consult dog registration records or to conduct household surveys. These surveys should establish the number of owned dogs and the dog to human ratio in the area. In addition, questions on dog reproduction and demographics, care provided, zoonosis prevention, dog bite incidence, etc. may be asked. Sample questionnaires can be found in the "Guidelines for Dog Population Management" (WHO/WSPA 1990). Standard polling principles must be applied.

If the proportion of ownerless dogs is high or difficult to asses, then one must resort to more experimental approaches. Methods borrowed from wildlife biology can be applied. These methods are described WHO/WSPA's "Guidelines for Dog Population Management" (1990), and in more detail in numerous professional publications and handbooks, such as Bookhout (1994) and Sutherland (2006). Being generally diurnal and tolerant to human proximity, dogs lend themselves to direct observation and the application of mark-recapture techniques. Nevertheless, a number of caveats and limitations have to be taken into account.. Firstly, the risk of zoonotic disease transmission is increased through close physical contact. Also, the methods are relatively labour intensive, they require some understanding of statistics and population biology, and most importantly, they are difficult to apply to very large areas. One must take into account that dog distribution is non-random, that their populations are not static, and that individual dogs are fairly mobile.

Counting of dogs visible in a defined area is the simplest approach to getting information on population size. One has to take into account that the visibility of dogs depends on the physical environment, but also on dog and human activity patterns. The visibility of animals changes with the time of the day and with seasons as a function of food availability, shelter (shade), disturbance, etc. Repeated standardized counting of dogs visible within defined geographical localities (e.g. wards) and specific times will provide indications of population trends. Direct counting is most reliable if it is applied to small and relatively confined dog populations, e.g. in villages, where it might be possible to recognize individual dogs based on their physical appearance.

Methods using mark-recapture procedures are often considered more reliable. However, they also produce trustworthy results only when a number of preconditions are met. Mortality, emigration and recruitment into the population must be minimal during the census period. One may be able to incorporate corrective factors into the calculations.

It is therefore important that the recommended census procedures are applied at times of low dispersal and that one selects study plots of shape and size that minimize the effect of dog movements in and out of the observation area. Census surveys should be completed within a few days to a maximum of two weeks in order to reduce demographic changes. In addition, all individuals in the population must have an equal chance of being counted. This is a highly improbable condition for dogs, whose visibility depends on ownership status and degrees of supervision. It is therefore recommended that the investigator determines what fraction of the total population he/she might cover with an observational method and how much this part overlaps with the owned dog segment that he/she assesses with household surveys.

There are essentially two ways to obtain a population estimate if it is possible, in a defined area and within a few days, to tag a large number of dogs with a visible mark, e.g. a distinctive collar or a paint smudge. The first method requires that the capture (marking) effort remains reasonably constant for the whole length of the study. By plotting the daily number of dogs marked against the accumulated total of marked dogs for each day one can extrapolate the value representing the total number of dogs in the area. More commonly used in wildlife studies are mark recapture methods (Peterson-Jackson, Lincoln indices). Dogs are marked (tagged) and released back into the population. The population is subsequently sampled by direct observation. The number of marked and unmarked dogs is recorded. One multiplies the number of dogs that were initially marked and released by the number of subsequently observed dogs divided by the number of dogs seen as marked during the re-observation to obtain a total population estimate. Examples for the two methods are given in WHO/WSPA's "Guidelines for Dog Population Management" (1990).

Since the dog populations of entire countries, states, provinces or even cities are much too large for complete assessment, it is necessary to apply the methods summarized above to sample areas. These should be selected (using common sense) so that results can be extrapolated to larger areas.

Annex XVII (contd)

Bookhout TA (ed), 1994: *Research and Management Techniques for Wildlife and Habitats*, 5th ed. The Wildlife Society, Bethesda, Maryland, 740p.

Sutherland WJ (ed), 2006: *Ecological Census Techniques* - A Handbook, 2nd ed. Cambridge University Press, Cambridge, 448 p.

WHO/WSPA, 1990: *Guidelines for Dog Population Management*. WHO/ZOON/90.165. WHO, Geneva, 116 p.

Annex XVII (contd)

CHAPTER 7.X.

USE OF ANIMALS IN RESEARCH AND EDUCATION, ~~TESTING OR TEACHING~~

Preamble

The purpose of this chapter is to provide advice and assistance ~~standards~~ for OIE Members to follow when formulating regulatory requirements, or other form of oversight, for the use of live *animals* in research ~~, testing or teaching~~ and education [1]. ~~It is the responsibility of all scientists using animals to ensure that they give due regard to these standards in designing and implementing their research protocols.~~ A system of animal use oversight should be implemented in each country. The system will, in practice, vary from country to country and according to cultural, economic, religious and social factors. However, the OIE recommends that Members address all the essential elements identified in these standards in formulating a regulatory framework that is appropriate to their local conditions. This framework may be delivered through a combination of jurisdictions at the levels of the country, the region and/or the institution and both public sector and private sector responsibilities should be clearly defined.

The OIE recognises the vital role played by the use of live *animals* in research and education. The OIE Guiding Principles for Animal Welfare state that such use makes a major contribution to the wellbeing of people and *animals* and emphasise the importance of the Three Rs of Russell and Burch (1959). Most scientists and members of the public agree that the *animals* should only be used when necessary and ethically justified (thereby avoiding unnecessary duplication of animal based research); that the minimum number of *animals* should be used to achieve the scientific or educational goals; and that such use of *animals* should cause as little pain and/or distress as possible~~, and those animals should only be used when necessary. The OIE also recognises the need for humane treatment of sentient animals and that good quality science depends upon good animal welfare. In keeping with the overall approach to animal welfare, as detailed in the Guiding Principles, the OIE emphasises the importance of standards based on outcomes for the animal.~~

The OIE emphasises the need for humane treatment of sentient *animals* and that good quality science depends upon good *animal welfare*. It is the responsibility of all involved in the use of *animals* to ensure that they give due regard to these recommendations. In keeping with the overall approach to *animal welfare* detailed in the Guiding Principles, the OIE stresses the importance of standards based on outcomes for the *animal*.

The OIE recognises the ~~central~~ significant role of *veterinarians* in animal based research. Given their unique training and skills, they are essential members of a team including scientists and animal care technicians. This team approach is based on the concept that everyone involved in the use of *animals* has an ethical responsibility for the *animals' welfare*. The approach also ensures that animal use leads to high quality scientific and educational outcomes and optimum *welfare* for the *animals* used.

The OIE recommends that records on animal use should be maintained, as appropriate to the institution and project proposals and species used, on a regional or national basis. These records may be used to provide a degree of public transparency, without compromising personnel or animal safety, or releasing proprietary information.

[1] Wherever the term "research" is used, it includes basic and applied research ,testing and the production of biological materials ~~means "research, testing or teaching".~~ ; "education" includes teaching and training.

Annex XVII (contd)

Article 7.X. ~~X~~ 1.

Definitions

~~***Animal Care and Use Committee (ACUC)***~~

~~means a committee responsible for overseeing the care and use of animals within an institution, including ethical considerations. It is also sometimes called Animal Care Committee, Animal Ethics Committee, Ethical Review Committee or Institutional Animal Care and Use Committee.~~

~~***Project Proposal***~~

~~or protocol, means a written description of a study or experiment,, programme of work, or other activities that includes the goals, characterises the use of the animals, and includes ethical considerations. The purpose of the *Project Proposal* is to enable assessment of the quality and integrity of the study, work or activity.~~

~~***Operant (Instrumental) conditioning***~~

~~means the association that an animal makes between a particular response (such as pressing a bar) and a particular reinforcement (for example, a food reward). As a result of this association, the occurrence of a specific behaviour of the animal can be modified (e.g. increased or decreased in frequency or intensity).~~

Biological safety or biosafety

means the application of knowledge, techniques and equipment to prevent personal, laboratory and environmental exposure to potentially infectious agents or biohazards.

Biosecurity

means a continuous process of *risk assessment* and *risk management* designed to minimise or eliminate microbiological *infection* with adventitious organisms that can cause clinical *disease* in the infected *animals* or humans, or make *animals* unsuitable for biomedical research. A comprehensive biosecurity programme not only seeks to prevent contamination but also to minimise the loss of *animals* and scientific data, and to limit the spread of unwanted microorganisms should contamination occur.

Biological containment or biocontainment

means the system and procedures designed to prevent the accidental release of biological material including allergens. The objective of biocontainment is to confine biohazards and to reduce the potential exposure of the laboratory worker, *animals* on other studies, persons outside of the laboratory, and the environment to potentially infectious agents.

Bioexclusion

means the prevention of the unintentional transfer of ~~pathogenic~~ adventitious organisms ~~and~~ with subsequent *infection* of *animals*~~, vermin or other means~~ resulting in adverse effects on their health or suitability for research.

Cloned animal

means a genetic copy of another living or dead *animal* produced by somatic cell nuclear transfer or other reproductive technology.

Distress

means the state of an *animal*, that has been unable to adapt completely to stressors, and that manifests as abnormal physiological or behavioural responses. It can be acute or chronic and may result in pathological conditions.

Environmental enrichment

means increasing the complexity (e.g. with toys, cage furniture, foraging opportunities, social housing, etc.) in a captive *animal*'s environment to foster the expression of non-injurious species-typical behaviours and reduce the expression of maladaptive behaviours, as well as provide cognitive stimulation.

Euthanasia

means the act of inducing *death* using a method that results in rapid loss of consciousness and minimum pain or distress to the *animal.*

Ethical review

means consideration of the validity and justification for using *animals* including: the potential harms for *animals* and likely benefits of the use and how these balance; experimental design; implementation of the Three Rs; animal husbandry and care and other related issues such as staff training. Ethical judgements are influenced by prevailing societal attitudes.

Endangered species

means a population of organisms which is at risk of becoming extinct because it is either few in numbers, or threatened by changing environmental or predation parameters.

Genetically altered animal (GA animal)

means an *animal* that has had a random or targeted change in its nuclear or mitochondrial DNA, or the progeny of such an *animal(s)*, where they have inherited the change, achieved through a deliberate human technological intervention.

Humane endpoint

means the point in time at which an experimental *animal*'s pain and/or distress is avoided, terminated, minimised or reduced, by taking actions such as giving treatment to relieve pain and/or distress, terminating a painful procedure, removing the *animal* from the study, or humanely killing the *animal.* Ideal humane endpoints are those that can be used to end a study before the onset of pain and/or distress, without jeopardising the study's objectives. In consultation with the *veterinarian*, humane endpoints should be described in the Project Proposal and, thus, established prior to commencement of the study. They should form part of the ethical review. Endpoint criteria should be easy to assess over the course of the study. Except in rare cases, *death* (other than euthanasia) as a planned endpoint is considered ethically unacceptable.

Harm-benefit analysis

means the process of weighing the likely adverse effects (harms) to ~~on~~ the *animals* against the benefits likely to accrue as a result of the proposed project. ~~The analysis should require more than just establishing that the benefit is likely to exceed the harms.~~ The benefits should be maximised and the harms, in terms of ~~animal use and suffering~~ pain and distress, should be minimised.

The Three Rs

means the internationally accepted ~~philosophy~~ tenet, first described by ~~of~~ Russell and Burch (1959), for the use of *animals* in research and education. The Three Rs comprise:

- **replacement** which refers to methods that do not require the use of *animals* to achieve the scientific aims;

- **reduction** which refers to methods that enable researchers to obtain comparable levels of information from fewer *animals* or to obtain more information from the same number of *animals*;

- **refinement** which refers to methods that prevent, alleviate or minimise known and potential pain, distress or lasting harm and/or enhance welfare for the *animals* used~~; or which replace higher animals with those of lower neurophysiological sensitivity which have less capacity to experience pain, distress, discomfort or lasting harm~~. Refinement includes the appropriate selection of species with a lesser degree of structural and functional complexity in their nervous systems and a lesser apparent capacity for experiences that derive from this complexity. Opportunities for refinement should be considered and implemented throughout the lifetime of the *animal* and include, for example, housing and transportation as well as procedures and euthanasia.

Operant (Instrumental) conditioning

means the association that an *animal* makes between a particular response (such as pressing a bar) and a particular reinforcement that may be positive (for example, a food reward) or negative (e.g. a mild electric shock). As a result of this association, the occurrence of a specific behaviour of the *animal* can be modified (e.g. increased or decreased in frequency or intensity).

Project Proposal (or Protocol)

means a written description of a study or experiment, programme of work, or other activities that includes the goals of the work, characterises the use of the *animals*, and includes ethical considerations. The purpose of the Project Proposal is to enable assessment of the quality of, and justification for, the study, work or activity.

Pain

means an unpleasant sensory and emotional experience associated with actual or potential tissue damage. It may elicit protective actions, result in learned avoidance and distress and may modify species-specific traits of behaviour, including social behaviour.

Article 7.X.~~X~~ 2.

Scope

These standards apply to *animals* as defined in the ~~Terrestrial Animal Health Code (*Terrestrial Code*)~~ (excluding bees) bred, supplied and/or used in research~~, testing or teaching~~ (including testing) and higher education. *Animals* to be used for production of biologicals and/or humanely killed for harvesting their cells, tissues and organs for scientific purposes are also covered. Members should consider both the species and the developmental stage of the *animal* in implementing these standards.

Article 7.X.~~X~~ 3.

The Oversight Framework

The role of a *Competent Authorities* is to implement a system (governmental or other) for verification of compliance by institutions. This usually involves a system of ~~approval~~ authorisation (such as licensing or registering of institutions, scientists, and/or projects) and compliance may be assessed at the level of the country, the region and/or the institution.

~~The framework for compliance should comprise three key elements:~~

~~1. Project Proposal Review,~~

~~2. Facility Inspections; and~~

~~3. Animal Care and Use Programme (ACUP) Review.~~

~~Different systems of oversight may involve animal welfare officers, regional/local committees, or national bodies. One common system is for each institution using live animals for research to have an Animal Care and Use Committee (ACUC) that is responsible, at the institutional level, for ensuring compliance with applicable requirements regarding the use of live animals as well as cells, tissues and organs derived from live animals. It is important that an ACUC should report to a senior individual within the institution to ensure the committee has an appropriate level of authority and support. An ACUC should undertake periodic review of its own policies, procedures and performance.~~

~~In providing this oversight, the following expertise should be included, as a minimum:~~

A requirement for keeping records on animal use, as appropriate to the institution, project proposal and species, should be included. It may be appropriate to maintain such records on a regional or national basis and to provide some degree of public access without compromising personnel or animal safety, or releasing proprietary information.

The oversight framework encompasses both ethical review of animal use and considerations related to animal care and *welfare*. This may be accomplished by a single body or distributed across different groups. Different systems of oversight may involve *animal welfare* officers, regional/local committees, or national bodies. Typically each institution utilises a local committee (often referred to as Animal Care and Use Committee, Animal Ethics Committee or Animal Care Committee) to deliver this oversight framework. Where the local committee does not perform ethical review, this may be undertaken by regional or national ethical review bodies. It is important that the local committee reports to senior management within the institution to ensure it has appropriate authority, resources and support. Such a committee should undertake periodic review of its own policies, procedures and performance.

In providing this oversight and ensuring the implementation of the Three Rs, the following expertise should be included as a minimum:

- one scientist with experience in animal research, whose role is to ensure that protocols are designed and implemented in accordance with sound science;

- one *veterinarian*, with the necessary expertise to work with research *animals*, whose specific role is to provide advice on the care, use and *welfare* of ~~the~~ such *animals*;

- one public member to represent general community interests who is independent of the institution and is not involved in the use of *animals* in research.

Additional expertise may be sought from the animal care staff, as these professional and technical staff are centrally involved in ensuring the *welfare* of *animals* used. Other participants may include statisticians, information scientists and ethicists and biosafety specialists, as appropriate to the studies conducted. It may be appropriate, in teaching institutions, to involve a student representative.

~~Other participants may include statisticians, information scientists and ethicists and biosafety specialists, as appropriate to the studies conducted.~~

~~It may be appropriate to involve representatives of the community (general public) or, in teaching institutions, a student representative. This increases public confidence in the oversight process.~~

Annex XVII (contd)

Oversight responsibilities include three key elements:

1. Project Proposal Review

Project Proposals, or significant amendments to these, should be reviewed and approved prior to commencement of the work, should identify the person with primarily responsibility for the project and should include a description of the following elements, where relevant:

a) the scientific or educational aims, including consideration of the relevance of the experiment to human or animal health, the environment, or the advancement of biological knowledge;

b) an informative, non-technical (lay) summary may enhance understanding of the project and facilitate the ethical review of the proposal by allowing full and equitable participation of members of the local committee who may be dealing with matters outside their specific field; subject to safeguarding confidential information, such summaries may be made publicly available;

~~b~~c) the experimental design, including ~~statistics where appropriate;~~ justification for choice of species, source and number of *animals*, including any proposed reuse;

~~c~~d) the experimental procedures;

~~d~~e) methods of handling and restraint and consideration of ~~alternative~~ refinements such as animal training and operant conditioning;

~~e) the application of the Three Rs;~~

f) the methods to avoid or minimise pain, discomfort, distress or lasting impairment of physical or physiological function, including the use of anaesthesia and/or analgesia;

g) application of humane endpoints and the final disposition of *animals*, including methods of euthanasia;

h) consideration of the general health, husbandry and care of the species proposed to be used, including environmental enrichment and any special housing requirements;

i) ~~consideration of the relevance of the experiment to human or animal health or the advancement of biologic knowledge;~~ ethical considerations such as the application of the Three Rs and a harm/benefit analysis;

j) an ~~assessment for~~ indication of any ~~occupational~~ special health and safety risks; and

k) resources/infrastructure necessary to support the proposed work (e.g. facilities, equipment, qualified staff).

~~The provision of a non-technical (lay) summary may enhance understanding of the project.~~

The oversight body has a critical responsibility in determining the acceptability of Project Proposals, taking account of the *animal welfare* implications, the advancement of knowledge and scientific merit, as well as the societal benefits, in a risk-based assessment of each project using live *animals*.

Following approval of a Project Proposal, consideration should be given to implementing an oversight method to ensure that animal activities conform with those described in the approved Project Proposal. This process is often referred to as post approval monitoring. Such monitoring may be achieved through animal observations made during the conduct of routine husbandry procedures; observations made by the veterinary staff during their rounds; or by inspections by the local oversight committee, *animal welfare* officer, compliance/quality assurance officer or government inspector.

2. Facility inspection

There should be regular inspections of the facilities, at least annually. These inspections should include the following elements:

a) the *animals* and their records, including cage labels;

b) husbandry practices;

c) maintenance, cleanliness and security of the facility;

d) type and condition of caging and other equipment;

e) environmental conditions of the *animals* at the cage and room level;

f) procedure areas such as surgery; necropsy and animal research laboratories;

g) support areas such as washing equipment; animal feed, bedding and drug storage locations;

h) occupational health and safety concerns.

Principles of *risk management* should be followed when determining the frequency and nature of inspections.

3. Animal ~~C~~care and ~~U~~use ~~P~~programme ~~(ACUP)~~ ~~R~~review

~~Critical elements of t~~The ~~A~~animal ~~C~~care and ~~U~~use ~~P~~programme ~~(ACUP)~~ reflects the policies and practices of the institution. It should include the functioning of the local oversight committee; training and competency of staff; veterinary care; husbandry and operational conditions, including emergency plans; sourcing and final disposition of *animals*; and occupational health and safety. The programme should be reviewed regularly and should be included in relevant regulations to empower the ~~government~~ *Competent Authority* to take appropriate action to ensure compliance. ~~The ACUP should be reviewed regularly to include the following:~~

- ~~training and competency of all staff;~~
- ~~the programme of veterinary care;~~

- husbandry and operational conditions;
- sourcing and final disposition of animals; and
- occupational health and safety programme;

A requirement for keeping records on animal use, as appropriate to the institution, project proposal and species, should be included. It may be appropriate to maintain such records on a regional or national basis and to provide some degree of public access without compromising personnel or animal safety, or releasing proprietary information.

Article 7.X.~~X~~ 4.

Assurance of Training and Competency

An essential component of the ~~ACUP~~ animal care and use programme is the assurance that the personnel working with the *animals* are appropriately trained and qualified to work with the species used and the procedures to be performed, including ethical considerations. A system (at the level of the country, the region and/or the institution) to assure competency should be in place, which includes supervision during the training period. Continuing professional and paraprofessional educational opportunities should be made available to relevant staff. Senior management, given their overarching responsibility for the animal care and use programme, should be knowledgeable about related issues.

1~~a~~) Scientific staff. Researchers using *animals* have a direct ethical and legal responsibility for all matters relating to the *welfare* of the *animals* in their care. Due to the specialised nature of animal research, focused training should be undertaken to supplement educational and experiential backgrounds of scientists (including visiting scientists) before initiating a study. Focused training may include such topics as the national and/or local regulatory framework and institutional policies. The laboratory animal *veterinarian* is often a resource for this and other training. Scientific staff should have demonstrated ~~C~~competency in ~~performance of~~ procedures related to their ~~the scientist's~~ research (e.g. surgery, anaesthesia, sampling and administration, etc.).

2~~b~~) Veterinarians. It is important that *veterinarians* working in an animal research environment have veterinary medical knowledge and experience in the species used, including normal behaviour, and they should understand research methodology. Relevant approvals issued by the *Veterinary statutory body* and appropriate national or regional schemes (where these exist) should be adopted as the reference for veterinary training.

3~~c~~) Animal Care Staff. Animal care staff should receive training that is consistent with the scope of their work responsibilities and ~~their~~ have demonstrated competency in the performance of these tasks ~~should be verified~~.

4~~d~~) Students. ~~Wherever possible s~~Students should learn scientific and ethical principles using nonanimal methods (videos, computer models, etc.) when such methods can effectively reduce or replace the use of *animals* and still meet learning objectives. Wherever it is necessary for students to participate in classroom or research activities involving *animals*, they should receive appropriate supervision in the use of *animals* until such time that they have demonstrated competency in the related procedure(s).

5) Members of the local oversight committee or others involved with oversight. Continuing education about the use of *animals* in research and education, including associated ethics, regulatory requirements and their institutional responsibility, should be provided.

Occupational health and safety training for research animal related risks should be provided as part of the assurance of training and competency for personnel. This might include consideration of human infectious *diseases* which may infect research *animals* and thus compromise research results, as well as possible *zoonoses*. Personnel should understand that there are two categories of hazards, those that are intrinsic to working in an animal facility and those associated with the research. Specific training may be required for particular species, for specific procedures, and for the use of appropriate protective measures for personnel who may be exposed to animal allergens. Research materials, such as chemicals of unknown toxicity, biological agents and radiation sources, may present special hazards.

Article 7.X.~~X~~ 5.

Provision of Veterinary Care

Adequate veterinary care includes responsibility for promoting an *animal*'s *welfare* before, during and after research procedures and providing advice and guidance based on best practice. Veterinary care includes attention to the physical and behavioural status of the *animal*. The *veterinarian* must have authority and responsibility for making judgements concerning *animal welfare*. Veterinary advice should be available at all times.

1~~a~~) Clinical Responsibilities. Preventive medicine programmes that include vaccinations, ectoparasite and endoparasite treatments and other *disease* control measures should be initiated according to currently acceptable veterinary medical practices appropriate to the particular animal species and source. *Disease surveillance* is a major responsibility of the *veterinarian* and should include routine monitoring of colony *animals* for the presence of parasitic, bacterial and viral agents that may cause overt or sub clinical *diseases*. The *veterinarian* must have the authority to use appropriate treatment or control measures, including euthanasia if indicated, and access to appropriate resources, following diagnosis of an animal *disease* or injury. Where possible, the *veterinarian* should discuss the situation with the scientist to determine a course of action consistent with experimental goals. ~~The veterinarian has the responsibility to ensure that~~ C~~c~~ontrolled drugs prescribed by the veterinary staff must be ~~are~~ managed in accordance with applicable regulations.

2) Post mortem examinations. In the case of unexpected *disease* or *deaths*, the *veterinarian* should provide advice based on post mortem examination results. As part of health monitoring, a planned programme of post mortem examinations may be considered.

3~~b~~) Veterinary Medical Records. Medical records, including post mortem records, are considered to be a key element of a programme of adequate veterinary care for *animals* used in research and education~~, teaching, and testing~~. Application of performance standards within the medical record programme allows the *veterinarian* to effectively employ professional judgment, ensuring that the *animal* receives the highest level of care available.

4~~c~~) Advice on zoonotic risks and notifiable diseases. The use of some species of *animals* poses a significant risk of the transmission of zoonotic disease (e.g. some nonhuman primates). The *veterinarian* should be consulted to identify sources of *animals* that minimise these risks and to advise on measures that may be taken in the animal facility to minimize the risk of transmission (e.g. personal protective equipment, air pressure differentials in animal holding rooms, etc.). *Animals* brought into the institution may carry *diseases* that require notification to government officials. It is important that the *veterinarian* be aware of, and complies with, these requirements.

5~~d~~) Advice on surgery and postoperative care. A programme of adequate veterinary care includes input into the review and approval process of preoperative, surgical and postoperative procedures by an appropriately qualified *veterinarian*. A *veterinarian*'s inherent responsibility includes providing advice concerning preoperative procedures, aseptic surgical techniques, the ~~qualifications of institutional~~ competence of staff to perform surgery and the provision of postoperative care. Veterinary oversight should include the detection and resolution of emerging patterns of surgical and post procedural complications.

6~~e~~) Advice on analgesia, ~~and~~ anaesthesia and euthanasia. Adequate veterinary care includes providing ~~guidance to animal users and monitoring animal use to ensure that appropriate methods of handling and restraint are being used as well as the~~ advice on the proper use of anaesthetics, analgesics ~~tranquilizers~~, and methods of euthanasia ~~for all species~~.

7~~f~~) Advice on humane endpoints ~~and euthanasia~~. Humane endpoints should be established prior to commencement of a study in consultation with the *veterinarian* who also plays an important role in ensuring that approved humane endpoints are followed during the course of the study. It is essential that the *veterinarian* have the authority to ensure euthanasia is carried out as required to relieve pain and distress unless the Project Proposal approval specifically does not permit such intervention on the basis of the scientific purpose and the ethical evaluation. ~~Endpoints are established for both experimental and humane reasons. An experimental endpoint is chosen to mark the planned end of an experimental manipulation and associated data gathering. In experiments with unrelieved or unanticipated pain/or distress, humane endpoints are criteria that indicate or predict pain, distress, or death and are used as signals to end a study early to avoid or terminate pain and/or distress. Ideal endpoints are those that can be used to end a study before the onset of pain and/or distress without jeopardizing the study's objectives. However, in most cases, humane endpoints are developed and used to reduce the severity and duration of pain and/or distress.~~

~~The veterinarian and the ACUC where applicable, have a key role in ensuring that approved humane endpoints are followed during the course of the study. It is essential that the veterinarian have the responsibility and authority to ensure euthanasia is carried out as required to relieve pain and distress unless the *Project Proposal* approval specifically does not permit such intervention on the basis of the scientific purpose.~~

~~Article 7.X.X.~~

~~**Physical Facility and Environmental Conditions**~~

~~A well-planned, well-designed, well-constructed, and properly maintained facility should include animal holding rooms as well as areas for support services such as for procedures, surgery and necropsy, cage washing and appropriate storage. An animal facility should be designed and constructed in accordance with all applicable building standards. The design and size of an animal facility depend on the scope of institutional research activities, the animals to be housed, the physical relationship to the rest of the institution, and the geographic location. For indoor housing, non-porous, non-toxic and durable materials should be used which can be easily cleaned and sanitised. Animals should normally be housed in facilities dedicated to, or assigned for, that purpose. Security measures (e.g. locks, fences, cameras, etc.) should be in place to protect the animals and prevent their escape. For many species (e.g. rodents), environmental conditions should be controllable to minimise physiological changes which may be potentially confounding scientific variables and of welfare concern.~~

Article 7.X.~~X~~ 6.

Source of animals

Animals to be used for research should be of high quality to ensure the validity of the data.

1~~a~~) Animal procurement. *Animals* ~~should~~ must be acquired legally. It is preferable that *animals* are purchased from recognised sources producing or securing high quality *animals*.

Purpose bred *animals* should be used whenever these are available and *animals* that are not bred for the intended use should be avoided unless scientifically justified or the only available source. ~~The use of non-purpose-bred animals, including farm animals, non-traditional breeds and species, and animals captured in the wild, is sometimes necessary to achieve study goals.~~ In the case of farm *animals*, non traditional breeds and species, and *animals* captured in the wild, non purpose bred *animals* are often used to achieve specific study goals. The use of wild caught nonhuman primates is generally discouraged.

2~~b~~) Documentation. Relevant documentation related to the source of the *animals*, including health ~~certificate~~ and other veterinary certification, breeding records, genetic status and animal identification, should accompany the *animals*.

3~~c~~) Animal health status. The health status of *animals* can have a significant impact on scientific outcomes. There also may be occupational health and safety concerns related to animal health status. *Animals* should have appropriate health profiles for their intended use. The health status of *animals* should be known before initiating research.

4~~d~~) Genetically defined animals. A known genetic profile of the *animals* used in a study can reduce variability in the experimental data resulting from genetic drift and increase the reproducibility of the results. Genetically defined *animals* are used to answer specific research questions and are the product of sophisticated and controlled breeding schemes which must be validated by periodic genetic monitoring, typically using biochemical or immunological markers. Detailed and accurate documentation of the colony breeding records must be maintained.

5~~e~~) Genetically altered or cloned animals. If genetically altered or cloned *animals* are used, such use should be conducted in accordance with relevant regulatory guidance. With such *animals*, as well as harmful mutant lines arising from spontaneous mutations, ~~C~~consideration should be given to addressing and monitoring special husbandry and *welfare* needs associated with abnormal phenotypes. Records should be kept of biocontainment requirements, genetic information, and individual identification, and be communicated by the animal provider to the recipient. Archiving and sharing of genetically altered lines is recommended to facilitate the sourcing of these customised *animals*.

6~~f~~) Animals captured in the wild. If wild *animals* are to be used, the capture technique should be humane and give due regard to human and animal health and safety. ~~Endangered species should only be used in exceptional circumstances where there is strong scientific justification which cannot be achieved with any other species.~~ Field studies have the potential to cause disturbance to the habitat thus adversely affecting both target and non-target species. The potential for such disturbance should be assessed and minimised. The effects of a series of stressors, such as trapping, handling, transportation, sedation, anaesthesia, marking and sampling, can be cumulative, and may produce severe, possibly fatal, consequences. An assessment of the potential sources of stress and management plans to eliminate or minimise distress should form part of the Project Proposal.

7) Endangered species. Endangered species should only be used in exceptional circumstances where there is strong scientific justification that the desired outcomes cannot be achieved using any other species.

8g) Transport, importation and exportation. *Animals* should be transported under conditions that are appropriate to their physiological and behavioural needs and pathogen status, with care to ensure appropriate physical containment of the *animals* as well as exclusion of contaminants. The amount of time *animals* spend on a *journey* should be kept to a minimum. It is important to ensure that relevant documentation accompanies *animals* during transport to avoid unnecessary delays during the *journey* from the sender to the receiving institution.

9h) Risks to Bbiosecurity risks. To reduce risks to biosecurity risks related to *animals*, the pathogen status of *animals* should be confirmed and appropriate biocontainment and bioexclusion measures should be practised. Biosecurity risks to *animals* arising from exposure to humans should also be addressed.

Article 7.X.X.

Husbandry

High standards of care and accommodation enhance the health and welfare of the animals used and contributes to the scientific validity of animal research. Animal care and accommodation should, as a minimum, demonstrably conform to relevant, published national or international animal care, accommodation and husbandry guidelines.

a) Acclimatisation. Newly received animals should be given a period for physiological and behavioural stabilisation before their use. The length of time for stabilisation will depend on the type and duration of animal transportation, the species involved, place of origin, and the intended use of the animals.

b) Normal Behaviour. The housing environment and husbandry practices should take into consideration the normal behaviour of the species and age of the animal and minimise stress to the animal.

c) Enrichment. Animals should be housed with a goal of maximising species-specific behaviours and minimising stress-induced behaviours. One way to achieve this is to enrich the structural and social environment of the research animals and to provide opportunities for physical and cognitive activity. Such provision should not compromise the health and safety of the animals or people, nor significantly interfere with the scientific goals.

Article 7.X.X.

Occupational Health and Safety

Institutional occupational health and safety programmes should be developed and implemented to protect personnel from workplace hazards. National or state legislation requires employers to provide a safe working environment for staff. In addition to national or state legislative requirements, particular precautions need to be in place for those involved in the care and use of animals. These measures should extend to animal users, animal care staff, students, and others who may be exposed to animals or animal by products.

Occupational health and safety training for animal related risks should be provided as part of the assurance of training and competency for personnel. Specific training may be required for particular species, and for specific procedures/studies involving animals.

a) Infectious diseases. To protect personnel, all infectious diseases or potentially infectious diseases within the institution, including zoonoses, should be identified.

i) Biological Hazards

Hazards can arise from pathogens that are endemic to the particular animals as well as from pathogens (bacteria, viruses, parasites, fungi, prions) that have been brought into an institution for research purposes. National or state regulations or guidelines for working with biological hazards (biohazards) must be followed. These should include requirements for biocontainment, laboratory design, personal hygiene and safety. Any biozardous materials should be labelled as such. Necropsy of animals with highly infectious agents should be carried out in certified biological safety cabinets. Animals, animal waste and carcasses should be disposed of appropriately, depending on the pathogenicity of the organisms to which they have been exposed. Material contaminated with highly infectious agents should be decontaminated before disposal.

ii) Zoonoses

The institutional veterinarian(s) should be able to provide input to the occupational health and safety program concerning any zoonoses (infections that are secondarily transmitted from animals to humans) that might be contracted from the species used by the institution. He/she should also be able to provide advice on the measures needed to protect those involved with the animals. These may include personal protective equipment, vaccination, special restrictions for vulnerable employees (e.g. pregnant women). In general, the closer phylogenetically a species is to humans, the greater the likelihood of zoonoses.

Particular precautions should be taken when working with non-human primates

b) Allergies

Individuals exposed to laboratory animals run a risk of developing allergies. Protective measures should be in place for personnel who may be exposed to animal allergens. These should include:

Environmental control and air handling systems to control air flow and contain allergens in the areas where the animals are housed and/or used;

Personal protective equipment such as masks, gloves and clothing dedicated to animal rooms;

Equipment such as filtered bedding disposal units and ventilated hoods for carrying out procedures;

Use of filtered transfer cages when transporting animals.

c) Physical injuries

Injuries that can be incurred as a result of handling animals include: bites, scratches, or being kicked, stepped on or crushed by larger species. These injuries can be minimized by ensuring that all personnel are: competent to handle the animals; aware of the particular hazards associated with each species; familiar with the hazards of the experiment; are provided with a proper working area and protective clothing; and have access to and use the appropriate restraining equipment or drugs. A mechanism should be in place to deal with animal inflicted injury, including referral for further medical treatment. Cuts, bites, scratches or needle punctures acquired while working with non-human primates require particular attention and should be reported to the medical authority designated by the institution.

Other physical injuries can occur as a result of working in a laboratory animal facility (e.g. burns, injuries from lifting animals or heavy equipment, repetitive strain injuries). These should be minimized through the implementation of an occupational health and safety programme, which examines the workplace hazards and ensures that adequate safeguards are in place for personnel.

Annex XVII (contd)

~~d) Chemical injuries~~

~~There are potentially hazardous materials involved in most animal-based studies. These include drugs; cleaning agents and chemical compounds used for research studies. All hazardous substances must be labelled appropriately. The relevant national or state authority should provide licences to veterinarians or scientists requiring access to drugs for animal based studies. Licence holders are thereby responsible and liable for the use of substances purchased by them. Drugs must be handled, stored and used according to the requirements of national or state legislation.~~

~~Material Safety Data Sheets should be made available to personnel who are likely to come into contact with hazardous materials. Personnel should also be trained to use hazardous materials safely.~~

~~e) Radiation~~

~~Where radioactive materials are to be used, the national authority responsible for nuclear safety should be informed. National authorities should require personnel to obtain a licence and should impose restrictions on the use of radioisotopes. A radiation safety officer should be designated within the institution to be responsible for radioactive material use and disposal. Strict measures should be in place to limit and contain radioactive contamination, including appropriate signage and limiting access to rooms containing radioactive material. Strict measures should also be in place to protect personnel working with radioactive animals, and staff in the vicinity, from exposure to the animals, animal wastes and carcasses.~~

Article 7.X.~~X.~~7.

Physical Facility and Environmental Conditions

A well-planned, well-designed, well-constructed, and properly maintained facility should include animal holding rooms as well as areas for support services such as for procedures, surgery and necropsy, cage washing and appropriate storage. An animal facility should be designed and constructed in accordance with all applicable building standards. The design and size of an animal facility depend on the scope of institutional research activities, the *animals* to be housed, the physical relationship to the rest of the institution, and the geographic location. For indoor housing, non-porous, non-toxic and durable materials should be used which can be easily cleaned and sanitised. *Animals* should normally be housed in facilities designed for that purpose. Security measures (e.g. locks, fences, cameras, etc.) should be in place to protect the *animals* and prevent their escape. For many species (e.g. rodents), environmental conditions should be controllable to minimise physiological changes which may be potentially confounding scientific variables and of *welfare* concern.

Important environmental parameters to consider include ventilation, temperature and humidity, lighting and noise:

1) Ventilation. The volume and physical characteristics of the air supplied to a room and its diffusion pattern influence the ventilation of an *animal*'s primary enclosure and are thus important determinants of its microenvironment. Factors to consider when determining the air exchange rate include range of possible heat loads; the species, size, and number of *animals* involved; the type of bedding or frequency of cage changing; the room dimensions; and the efficiency of air distribution from the secondary to the primary enclosure. Control of air pressure differentials is an important tool for biocontainment and bioexclusion.

2) Temperature and humidity. Environmental temperature is a physical factor which has a profound effect on the *welfare of animals*. Typically, animal room temperature should be monitored and controlled. The range of daily fluctuations should be kept to a minimum to avoid repeated large demands on the *animals*' metabolic and behavioural processes to compensate for changes in the thermal environment. Relative humidity may also be controlled, but not nearly as narrowly as temperature.

3) Lighting. Light can affect the physiology, morphology and behaviour of various *animals*. In general, lighting should be diffused throughout an animal holding area and provide appropriate illumination for the *welfare of the animals* while facilitating good husbandry practices, adequate inspection of *animals* and safe working conditions for personnel. It may also be necessary to control the light/dark cycle.

4) Noise. Separation of human and animal areas minimises disturbance to animal occupants of the facility. Noisy *animals*, such as dogs, pigs, goats, and nonhuman primates, should be housed away from quieter *animals*, such as rodents, rabbits, and cats. Consideration should be given to insulating holding rooms and procedure rooms to mitigate the effects of noise sources. Many species are sensitive to high frequency sounds and thus the location of potential sources of ultrasound should be considered.

Article 7.X.~~X~~.8.

Husbandry

Good husbandry practices enhance the health and *welfare of the animals* used and contribute to the scientific validity of animal research. Animal care and accommodation should, as a minimum, demonstrably conform to relevant published animal care, accommodation and husbandry guidelines and regulations.

The housing environment and husbandry practices should take into consideration the normal behaviour of the species, including their social behaviour and age of the *animal*, and should minimise stress to the *animal.* During the conduct of husbandry procedures, personnel should be keenly aware of their potential impact on the *animals' welfare.*

1) Transportation. Transportation is a typically stressful experience for *animals* should be transported. Every precaution should be taken to avoid unnecessary stress through inadequate ventilation, exposure to extreme temperatures, lack of feed and water, long delays, etc. Consignments of *animals* should be accepted into the facility without avoidable delay and, after inspection, should be transferred to clean cages or pens and be supplied with feed and water as appropriate.

2) Acclimatisation. Newly received *animals* should be given a period for physiological and behavioural stabilisation before their use. The length of time for stabilisation will depend on the type and duration of transportation, the age and species involved, place of origin, and the intended use of the *animals.* Facilities should be available to isolate *animals* showing signs of ill health.

3) Cages and pens. Cages and pens should be made out of material that can be readily cleaned and decontaminated. Their design should be such that the *animals* are unlikely to injure themselves. Space allocations should be reviewed and modified as necessary to address individual housing situations and animal needs (for example, for prenatal and postnatal care, obese *animals*, and group or individual housing). Whenever it is appropriate, social *animals* should be housed in pairs or groups, rather than individually, provided that such housing is not contraindicated by the protocol in question and does not pose an undue risk to the *animals.*

Annex XVII (contd)

4) Enrichment. *Animals* should be housed with a goal of maximising species specific behaviours and avoiding or minimising stress induced behaviours. One way to achieve this is to enrich the structural and social environment of the research *animals* and to provide opportunities for physical and cognitive activity. Such provision should not compromise the health and safety of the *animals* or people, nor significantly interfere with the scientific goals.

5) Feeding. Provision should be made for each *animal* to have access to feed to satisfy its physiological needs. Precautions should be taken in packing, transporting and storing feed to avoid chemical, physical and microbiological contamination, deterioration or destruction. Utensils used for feeding should be regularly cleaned and, if necessary, sterilised.

6) Water. Uncontaminated potable drinking water should normally be available at all times. Watering devices, such as drinking tubes and automatic watering systems, should be checked daily to ensure their proper maintenance, cleanliness, and operation.

7) Bedding. Animal bedding is a controllable environmental factor that can influence experimental data and *animal welfare*. Bedding should be dry, absorbent, non-dusty, non-toxic and free from infectious agents, vermin or chemical contamination. Soiled bedding should be removed and replaced with fresh material as often as is necessary to keep the *animals* clean and dry.

8) Hygiene. The successful operation of a facility depends very much on good hygiene. Special care should be taken to avoid spreading *infection* between *animals* through fomites, including through personnel traffic between animal rooms. Adequate routines and facilities for the cleaning, washing, decontamination and, when necessary, sterilisation of cages, cage accessories and other equipment should be established. A very high standard of cleanliness and organisation should also be maintained throughout the facility.

9) Identification. Animal identification is an important component of record keeping. *Animals* may be identified individually or by group. Where it is desirable to individually identify *animals*, this should be done by a reliable and the least painful method.

~~Article 7.X.X.~~

~~**Post Approval Monitoring**~~

~~The institution should ensure that a culture of compliance exists within the animal care and use programme. Key to that compliance is assuring that studies are conducted in accordance with the written description in the project proposals that has been approved by the oversight body (animal care and use committee, government agency, etc.). The focus of post approval monitoring is to determine what happens to the animals after approval of the work has been granted and the study is underway. Such monitoring may be achieved through animal observations made during the conduct of routine husbandry procedures; observations made by the veterinary medical staff during their rounds; or by inspections by an animal care and use committee, animal welfare officer, compliance/quality assurance officer or government inspector.~~

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CHAPTER 7.X.

USE OF ANIMALS IN RESEARCH AND EDUCATION

Preamble

The purpose of this chapter is to provide advice and assistance for OIE Members to follow when formulating regulatory requirements, or other form of oversight, for the use of live *animals* in research ~~,~~and education [2]. A system of animal use oversight should be implemented in each country. The system will, in practice, vary from country to country and according to cultural, economic, religious and social factors. However, the OIE recommends that Members address all the essential elements identified in these standards in formulating a regulatory framework that is appropriate to their local conditions. This framework may be delivered through a combination of jurisdictions at the level of the country, the region and/or the institution and both public sector and private sector responsibilities should be clearly defined.

The OIE recognises the vital role played by the use of live *animals* in research and education. The OIE Guiding Principles for Animal Welfare state that such use makes a major contribution to the wellbeing of people and *animals* and emphasise the importance of the Three Rs of Russell and Burch (1959). Most scientists and members of the public agree that the *animals* should only be used when necessary and ethically justified (thereby avoiding unnecessary duplication of animal based research); that the minimum number of *animals* should be used to achieve the scientific or educational goals; and that such use of *animals* should cause as little pain and/or distress as possible.

The OIE emphasises the need for humane treatment of sentient *animals* and that good quality science depends upon good *animal welfare*. It is the responsibility of all involved in the use of *animals* to ensure that they give due regard to these recommendations. In keeping with the overall approach to *animal welfare* detailed in the Guiding Principles, the OIE stresses the importance of standards based on outcomes for the *animal*.

The OIE recognises the significant role of *veterinarians* in animal based research. Given their unique training and skills, they are essential members of a team including scientists and animal care technicians. This team approach is based on the concept that everyone involved in the use of *animals* has an ethical responsibility for the *animals' welfare*. The approach also ensures that animal use leads to high quality scientific and educational outcomes and optimum *welfare* for the *animals* used.

The OIE recommends that records on animal use should be maintained, as appropriate to the institution and project proposals and species used, on a regional or national basis. These records may be used to provide a degree of public transparency, without compromising personnel or animal safety, or releasing proprietary information.

[2] Wherever the term "research" is used, it includes basic and applied research, testing and the production of biological materials; "education" includes teaching and training.

Article 7.X.1

Definitions

Biological safety or biosafety

means the application of knowledge, techniques and equipment to prevent personal, laboratory and environmental exposure to potentially infectious agents or biohazards.

Biosecurity:

means a continuous process of *risk assessment* and *risk management* designed to minimise or eliminate microbiological *infection* with adventitious organisms that can cause clinical *disease* in the infected *animals* or humans, or make *animals* unsuitable for biomedical research. A comprehensive biosecurity programme not only seeks to prevent contamination but also to minimise the loss of *animals* and scientific data, and to limit the spread of unwanted microorganisms should contamination occur.

Biological containment or biocontainment

means the system and procedures designed to prevent the accidental release of biological material including allergens. The objective of biocontainment is to confine biohazards and to reduce the potential exposure of the laboratory worker, *animals* on other studies, persons outside of the laboratory, and the environment to potentially infectious agents.

Bioexclusion

means the prevention of the unintentional transfer of adventitious organisms with subsequent *infection* of *animals*, resulting in adverse effects on their health or suitability for research.

Cloned animal

means a genetic copy of another living or dead *animal* produced by somatic cell nuclear transfer or other reproductive technology.

Distress

means the state of an *animal*, that has been unable to adapt completely to stressors, and that manifests as abnormal physiological or behavioural responses. It can be acute or chronic and may result in pathological conditions.

Environmental enrichment

means increasing the complexity (e.g. with toys, cage furniture, foraging opportunities, social housing, etc.) in a captive *animal*'s environment to foster the expression of non-injurious species-typical behaviours and reduce the expression of maladaptive behaviours, as well as provide cognitive stimulation.

Euthanasia

means the act of inducing *death* using a method that results in rapid loss of consciousness and minimum pain or distress to the *animal*.

Ethical review

means consideration of the validity and justification for using *animals* including: the potential harms for *animals* and likely benefits of the use and how these balance; experimental design; implementation of the Three Rs; animal husbandry and care and other related issues such as staff training. Ethical judgements are influenced by prevailing societal attitudes.

Endangered species

means a population of organisms which is at risk of becoming extinct because it is either few in numbers, or threatened by changing environmental or predation parameters.

Genetically altered animal (GA animal)

means an *animal* that has had a random or targeted change in its nuclear or mitochondrial DNA, or the progeny of such an *animal(s)*, where they have inherited the change, achieved through a deliberate human technological intervention.

Humane endpoint

means the point in time at which an experimental *animal*'s pain and/or distress is avoided, terminated, minimised or reduced, by taking actions such as giving treatment to relieve pain and/or distress, terminating a painful procedure, removing the *animal* from the study, or humanely killing the *animal.* Ideal humane endpoints are those that can be used to end a study before the onset of pain and/or distress, without jeopardising the study's objectives. In consultation with the *veterinarian*, humane endpoints should be described in the Project Proposal and, thus, established prior to commencement of the study. They should form part of the ethical review. Endpoint criteria should be easy to assess over the course of the study. Except in rare cases, *death* (other than euthanasia) as a planned endpoint is considered ethically unacceptable.

Harm-benefit analysis

means the process of weighing the likely adverse effects (harms) to the *animals* against the benefits likely to accrue as a result of the proposed project. The benefits should be maximised and the harms, in terms of pain and distress, should be minimised.

The Three Rs

means the internationally accepted tenet, first described by ~~of~~ Russell and Burch (1959), for the use of *animals* in research and education. The Three Rs comprise:

- **replacement** which refers to methods that do not require the use of *animals* to achieve the scientific aims;

- **reduction** which refers to methods that enable researchers to obtain comparable levels of information from fewer *animals* or to obtain more information from the same number of *animals*;

- **refinement** which refers to methods that prevent, alleviate or minimise known and potential pain, distress or lasting harm and/or enhance *welfare* for the *animals* used. Refinement includes the appropriate selection of species with a lesser degree of structural and functional complexity in their nervous systems and a lesser apparent capacity for experiences that derive from this complexity. Opportunities for refinement should be considered and implemented throughout the lifetime of the *animal* and include, for example, housing and transportation as well as procedures and euthanasia.

Operant (Instrumental) conditioning

means the association that an *animal* makes between a particular response (such as pressing a bar) and a particular reinforcement that may be positive (for example, a food reward) or negative (e.g. a mild electric shock). As a result of this association, the occurrence of a specific behaviour of the *animal* can be modified (e.g. increased or decreased in frequency or intensity).

Annex XVII (contd)

Project Proposal (or Protocol)

means a written description of a study or experiment, programme of work, or other activities that includes the goals of the work, characterises the use of the *animals*, and includes ethical considerations. The purpose of the Project Proposal is to enable assessment of the quality of, and justification for, the study, work or activity.

Pain

Means an unpleasant sensory and emotional experience associated with actual or potential tissue damage. It may elicit protective actions, result in learned avoidance and distress and may modify species-specific traits of behaviour, including social behaviour.

Article 7.X.2.

Scope

These standards apply to *animals* as defined in the *Terrestrial Code* (excluding bees) bred, supplied and/or used in research, (including testing) and higher education. *Animals* to be used for production of biologicals and/or humanely killed for harvesting their cells, tissues and organs for scientific purposes are also covered. Members should consider both the species and the developmental stage of the *animal* in implementing these standards.

Article 7.X.3.

The Oversight Framework

The role of a *Competent Authority* is to implement a system (governmental or other) for verification of compliance by institutions. This usually involves a system of authorisation (such as licensing or registering of institutions, scientists, and/or projects) and compliance may be assessed at the level of the country, the region and/or the institution.

A requirement for keeping records on animal use, as appropriate to the institution, p*roject proposal* and species, should be included. It may be appropriate to maintain such records on a regional or national basis and to provide some degree of public access without compromising personnel or animal safety, or releasing proprietary information.

The oversight framework encompasses both ethical review of animal use and considerations related to animal care and *welfare*. This may be accomplished by a single body or distributed across different groups. Different systems of oversight may involve *animal welfare* officers, regional/local committees, or national bodies. Typically each institution utilises a local committee (often referred to as Animal Care and Use Committee, Animal Ethics Committee or Animal Care Committee) to deliver this oversight framework. Where the local committee does not perform ethical review, this may be undertaken by regional or national ethical review bodies. It is important that the local committee reports to senior management within the institution to ensure it has appropriate authority, resources and support. Such a committee should undertake periodic review of its own policies, procedures and performance.

In providing this oversight and ensuring the implementation of the Three Rs, the following expertise should be included as a minimum:

- one scientist with experience in animal research, whose role is to ensure that protocols are designed and implemented in accordance with sound science;

- one *veterinarian*, with the necessary expertise to work with research *animals*, whose specific role is to provide advice on the care, use and *welfare* of such *animals*.

- one public member to represent general community interests who is independent of the institution and is not involved in the use of *animals* in research.

Additional expertise may be sought from the animal care staff, as these professional and technical staff are centrally involved in ensuring the *welfare of animals* used. Other participants may include statisticians, information scientists and ethicists and biosafety specialists, as appropriate to the studies conducted. It may be appropriate, in teaching institutions, to involve a student representative.

Oversight responsibilities include three key elements:

1. Project Proposal Review

   Project Proposals, or significant amendments to these, should be reviewed and approved prior to commencement of the work, should identify the person with primarily responsibility for the project and should include a description of the following elements, where relevant:

   a) the scientific or educational aims, including consideration of the relevance of the experiment to human or animal health, the environment, or the advancement of biological knowledge;

   b) an informative, non-technical (lay) summary may enhance understanding of the project and facilitate the ethical review of the proposal by allowing full and equitable participation of members of the local committee who may be dealing with matters outside their specific field. Subject to safeguarding confidential information, such summaries may be made publicly available.

   c) the experimental design, including justification for choice of species, source and number of *animals*, including any proposed reuse;

   d) the experimental procedures;

   e) methods of handling and restraint and consideration of refinements such as animal training and operant conditioning;

   f) the methods to avoid or minimise pain, discomfort, distress or lasting impairment of physical or physiological function, including the use of anaesthesia and/or analgesia;

   g) application of humane endpoints and the final disposition of *animals*, including methods of euthanasia;

   h) consideration of the general health, husbandry and care of the species proposed to be used, including environmental enrichment and any special housing requirements;

   i) ethical considerations such as the application of the Three Rs and a harm/benefit analysis;

   j) an indication of any special health and safety risks; and

   k) resources/infrastructure necessary to support the proposed work (e.g. facilities, equipment, qualified staff).

The oversight body has a critical responsibility in determining the acceptability of Project Proposals, taking account of the *animal welfare* implications, the advancement of knowledge and scientific merit, as well as the societal benefits, in a risk-based assessment of each project using live *animals*.

Following approval of a Project Proposal, consideration should be given to implementing an oversight method to ensure that animal activities conform with those described in the approved Project Proposal. This process is often referred to as post approval monitoring. Such monitoring may be achieved through animal observations made during the conduct of routine husbandry procedures; observations made by the veterinary staff during their rounds; or by inspections by the local oversight committee, *animal welfare* officer, compliance/quality assurance officer or government inspector.

2. Facility inspection

There should be regular inspections of the facilities, at least annually. These inspections should include the following elements:

a) the *animals* and their records, including cage labels;

b) husbandry practices;

c) maintenance, cleanliness and security of the facility;

d) type and condition of caging and other equipment;

e) environmental conditions of the *animals* at the cage and room level;

f) procedure areas such as surgery; necropsy and animal research laboratories.

g) support areas such as washing equipment; animal feed, bedding and drug storage locations.

h) occupational health and safety concerns

Principles of *risk management* should be followed when determining the frequency and nature of inspections.

3. Animal care and use programme review

The animal care and use programme reflects the policies and practices of the institution. It should include the functioning of the local oversight committee; training and competency of staff; veterinary care; husbandry and operational conditions, including emergency plans; sourcing and final disposition of *animals*; and occupational health and safety. The programme should be reviewed regularly and should be included in relevant regulations to empower the *Competent Authority* to take appropriate action to ensure compliance.

Article 7.X.4.

Assurance of Training and Competency

An essential component of the animal care and use programme is the assurance that the personnel working with the *animals* are appropriately trained and qualified to work with the species used and the procedures to be performed, including ethical considerations. A system (at the level of the country, the region and/or the institution) to assure competency should be in place, which includes supervision during the training period. Continuing professional and paraprofessional educational opportunities should be made available to relevant staff. Senior management, given their overarching responsibility for the animal care and use programme, should be knowledgeable about related issues.

1. Scientific staff

   Researchers using *animals* have a direct ethical and legal responsibility for all matters relating to the *welfare of the animals* in their care. Due to the specialised nature of animal research, focused training should be undertaken to supplement educational and experiential backgrounds of scientists (including visiting scientists) before initiating a study. Focused training may include such topics as the national and/or local regulatory framework and institutional policies. The laboratory animal *veterinarian* is often a resource for this and other training. Scientific staff should have demonstrated competency in procedures related to their research (e.g. surgery, anaesthesia, sampling and administration, etc.).

2. Veterinarians

   It is important that *veterinarians* working in an animal research environment have veterinary medical knowledge and experience in the species used, including normal behaviour, and they should understand research methodology. Relevant approvals issued by the *Veterinary statutory body* and appropriate national or regional schemes (where these exist) should be adopted as the reference for veterinary training.

3. Animal Care Staff

   Animal care staff should receive training that is consistent with the scope of their work responsibilities and have demonstrated competency in the performance of these tasks.

4. Students

   Students should learn scientific and ethical principles using nonanimal methods (videos, computer models, etc) when such methods can effectively reduce or replace the use of *animals* and still meet learning objectives. Wherever it is necessary for students to participate in classroom or research activities involving *animals*, they should receive appropriate supervision in the use of *animals* until such time that they have demonstrated competency in the related procedure(s).

5. Members of the local oversight committee or others involved with oversight

   Continuing education about the use of *animals* in research and education, including associated ethics, regulatory requirements and their institutional responsibility, should be provided.

Occupational health and safety training for research animal related risks should be provided as part of the assurance of training and competency for personnel. This might include consideration of human infectious *diseases* which may infect research *animals* and thus compromise research results, as well as possible zoonoses. Personnel should understand that there are two categories of hazards, those that are intrinsic to working in an animal facility and those associated with the research. Specific training may be required for particular species, for specific procedures, and for the use of appropriate protective measures for personnel who may be exposed to animal allergens. Research materials, such as chemicals of unknown toxicity, biological agents and radiation sources, may present special hazards

Article 7.X.5.

Provision of Veterinary Care

Adequate veterinary care includes responsibility for promoting an *animal*'s *welfare* before, during and after research procedures and providing advice and guidance based on best practice. Veterinary care includes attention to the physical and behavioural status of the *animal*. The *veterinarian* must have authority and responsibility for making judgements concerning *animal welfare*. Veterinary advice should be available at all times.

1. Clinical Responsibilities

   Preventive medicine programmes that include vaccinations, ectoparasite and endoparasite treatments and other *disease* control measures should be initiated according to currently acceptable veterinary medical practices appropriate to the particular animal species and source. *Disease surveillance* is a major responsibility of the *veterinarian* and should include routine monitoring of colony *animals* for the presence of parasitic, bacterial and viral agents that may cause overt or sub clinical *diseases*. The *veterinarian* must have the authority to use appropriate treatment or control measures, including euthanasia if indicated, and access to appropriate resources, following diagnosis of an *animal disease* or injury. Where possible, the *veterinarian* should discuss the situation with the scientist to determine a course of action consistent with experimental goals. Controlled drugs prescribed by the veterinary staff must be managed in accordance with applicable regulations.

2. Post mortem examinations

   In the case of unexpected *disease* or *deaths*, the *veterinarian* should provide advice based on post mortem examination results. As part of health monitoring, a planned programme of post mortem examinations may be considered.

3. Veterinary Medical Records

   Medical records, including post mortem records, are considered to be a key element of a programme of adequate veterinary care for *animals* used in research and education. Application of performance standards within the medical record programme allows the *veterinarian* to effectively employ professional judgment, ensuring that the *animal* receives the highest level of care available.

4. Advice on zoonotic risks and notifiable diseases

   The use of some species of *animals* poses a significant risk of the transmission of zoonotic disease (e.g. some nonhuman primates). The *veterinarian* should be consulted to identify sources of *animals* that minimise these risks and to advise on measures that may be taken in the animal facility to minimize the risk of transmission (e.g. personal protective equipment, air pressure differentials in animal holding rooms, etc.). *Animals* brought into the institution may carry *diseases* that require notification to government officials. It is important that the *veterinarian* be aware of, and complies with, these requirements.

5. Advice on surgery and postoperative care

A programme of adequate veterinary care includes input into the review and approval process of preoperative, surgical and postoperative procedures by an appropriately qualified *veterinarian*. A *veterinarian*'s inherent responsibility includes providing advice concerning preoperative procedures, aseptic surgical techniques, the competence of staff to perform surgery and the provision of postoperative care. Veterinary oversight should include the detection and resolution of emerging patterns of surgical and post procedural complications.

6. Advice on analgesia, anaesthesia and euthanasia

Adequate veterinary care includes providing advice on the proper use of anaesthetics, analgesics, and methods of euthanasia.

7. Advice on humane endpoints

Humane endpoints should be established prior to commencement of a study in consultation with the *veterinarian* who also plays an important role in ensuring that approved humane endpoints are followed during the course of the study. It is essential that the *veterinarian* have the authority to ensure euthanasia is carried out as required to relieve pain and distress unless the Project Proposal approval specifically does not permit such intervention on the basis of the scientific purpose and the ethical evaluation.

Article 7.X.6.

Source of animals

Animals to be used for research should be of high quality to ensure the validity of the data.

1. Animal procurement

Animals must be acquired legally. It is preferable that *animals* are purchased from recognised sources producing or securing high quality *animals*.

Purpose bred *animals* should be used whenever these are available and *animals* that are not bred for the intended use should be avoided unless scientifically justified or the only available source.-In the case of farm *animals*, non traditional breeds and species, and *animals* captured in the wild, non purpose bred *animals* are often used to achieve specific study goals. The use of wild caught nonhuman primates is generally discouraged.

2. Documentation

Relevant documentation related to the source of the *animals*, including health and other veterinary certification, breeding records, genetic status and animal identification, should accompany the *animals*.

3. Animal health status

The health status of *animals* can have a significant impact on scientific outcomes. There also may be occupational health and safety concerns related to animal health status. *Animals* should have appropriate health profiles for their intended use. The health status of *animals* should be known before initiating research.

4. Genetically defined animals

A known genetic profile of the *animals* used in a study can reduce variability in the experimental data resulting from genetic drift and increase the reproducibility of the results. Genetically defined *animals* are used to answer specific research questions and are the product of sophisticated and controlled breeding schemes which must be validated by periodic genetic monitoring, typically using biochemical or immunological markers. Detailed and accurate documentation of the colony breeding records must be maintained

5. Genetically altered or cloned animals

If genetically altered or cloned *animals* are used, such use should be conducted in accordance with relevant regulatory guidance. With such *animals*, as well as harmful mutant lines arising from spontaneous mutations, consideration should be given to addressing and monitoring special husbandry and *welfare* needs associated with abnormal phenotypes. Records should be kept of biocontainment requirements, genetic information, and individual identification, and be communicated by the animal provider to the recipient. Archiving and sharing of genetically altered lines is recommended to facilitate the sourcing of these customised *animals*.

6. Animals captured in the wild

If wild *animals* are to be used, the capture technique should be humane and give due regard to human and animal health and safety. Field studies have the potential to cause disturbance to the habitat thus adversely affecting both target and non-target species. The potential for such disturbance should be assessed and minimised. The effects of a series of stressors, such as trapping, handling, transportation, sedation, anaesthesia, marking and sampling, can be cumulative, and may produce severe, possibly fatal, consequences. An assessment of the potential sources of stress and management plans to eliminate or minimise distress should form part of the Project Proposal.

7. Endangered species

Endangered species should only be used in exceptional circumstances where there is strong scientific justification that the desired outcomes cannot be achieved using any other species.

8. Transport, importation and exportation

Animals should be transported under conditions that are appropriate to their physiological and behavioural needs and pathogen status, with care to ensure appropriate physical containment of the *animals* as well as exclusion of contaminants. The amount of time *animals* spend on a *journey* should be kept to a minimum. It is important to ensure that relevant documentation accompanies *animals* during transport to avoid unnecessary delays during the *journey* from the sender to the receiving institution.

9. Risks to biosecurity

To reduce risks to biosecurity related to *animals*, the pathogen status of *animals* should be confirmed and appropriate biocontainment and bioexclusion measures should be practised. Biosecurity risks to *animals* arising from exposure to humans should also be addressed.

Article 7.X.7.

Physical Facility and Environmental Conditions

A well-planned, well-designed, well-constructed, and properly maintained facility should include animal holding rooms as well as areas for support services such as for procedures, surgery and necropsy, cage washing and appropriate storage. An animal facility should be designed and constructed in accordance with all applicable building standards. The design and size of an animal facility depend on the scope of institutional research activities, the *animals* to be housed, the physical relationship to the rest of the institution, and the geographic location. For indoor housing, non-porous, non-toxic and durable materials should be used which can be easily cleaned and sanitised. *Animals* should normally be housed in facilities designed for that purpose. Security measures (e.g. locks, fences, cameras, etc.) should be in place to protect the *animals* and prevent their escape. For many species (e.g. rodents), environmental conditions should be controllable to minimise physiological changes which may be potentially confounding scientific variables and of *welfare* concern.

Important environmental parameters to consider include ventilation, temperature and humidity, lighting and noise:

1. Ventilation

   The volume and physical characteristics of the air supplied to a room and its diffusion pattern influence the ventilation of an *animal*'s primary enclosure and are thus important determinants of its microenvironment. Factors to consider when determining the air exchange rate include range of possible heat loads; the species, size, and number of *animals* involved; the type of bedding or frequency of cage changing; the room dimensions; and the efficiency of air distribution from the secondary to the primary enclosure. Control of air pressure differentials is an important tool for biocontainment and bioexclusion.

2. Temperature and humidity

   Environmental temperature is a physical factor which has a profound effect on the *welfare* of *animals*. Typically, animal room temperature should be monitored and controlled. The range of daily fluctuations should be kept to a minimum to avoid repeated large demands on the *animals*' metabolic and behavioural processes to compensate for changes in the thermal environment. Relative humidity may also be controlled, but not nearly as narrowly as temperature.

3. Lighting

   Light can affect the physiology, morphology and behaviour of various *animals*. In general, lighting should be diffused throughout an animal holding area and provide appropriate illumination for the *welfare* of the *animals* while facilitating good husbandry practices, adequate inspection of *animals* and safe working conditions for personnel. It may also be necessary to control the light/dark cycle.

4. Noise

   Separation of human and animal areas minimises disturbance to animal occupants of the facility. Noisy *animals*, such as dogs, pigs, goats, and nonhuman primates, should be housed away from quieter *animals*, such as rodents, rabbits, and cats. Consideration should be given to insulating holding rooms and procedure rooms to mitigate the effects of noise sources. Many species are sensitive to high frequency sounds and thus the location of potential sources of ultrasound should be considered.

Article 7.X.8.

Husbandry

Good husbandry practices enhance the health and *welfare* of the *animals* used and contribute to the scientific validity of animal research. Animal care and accommodation should, as a minimum, demonstrably conform to relevant published animal care, accommodation and husbandry guidelines and regulations.

The housing environment and husbandry practices should take into consideration the normal behaviour of the species, including their social behaviour and age of the *animal*, and should minimise stress to the *animal*. During the conduct of husbandry procedures, personnel should be keenly aware of their potential impact on the *animals*' *welfare*.

1. Transportation

Transportation is a typically stressful experience for *animals* should be transported. Every precaution should be taken to avoid unnecessary stress through inadequate ventilation, exposure to extreme temperatures, lack of feed and water, long delays, etc. Consignments of *animals* should be accepted into the facility without avoidable delay and, after inspection, should be transferred to clean cages or pens and be supplied with feed and water as appropriate.

2. Acclimatisation

Newly received *animals* should be given a period for physiological and behavioural stabilisation before their use. The length of time for stabilisation will depend on the type and duration of transportation, the age and species involved, place of origin, and the intended use of the *animals*. Facilities should be available to isolate *animals* showing signs of ill health.

3. Cages and pens

Cages and pens should be made out of material that can be readily cleaned and decontaminated. Their design should be such that the *animals* are unlikely to injure themselves. Space allocations should be reviewed and modified as necessary to address individual housing situations and animal needs (for example, for prenatal and postnatal care, obese *animals*, and group or individual housing). Whenever it is appropriate, social *animals* should be housed in pairs or groups, rather than individually, provided that such housing is not contraindicated by the protocol in question and does not pose an undue risk to the *animals*.

4. Enrichment

Animals should be housed with a goal of maximising species specific behaviours and avoiding or minimising stress induced behaviours. One way to achieve this is to enrich the structural and social environment of the research *animals* and to provide opportunities for physical and cognitive activity. Such provision should not compromise the health and safety of the *animals* or people, nor significantly interfere with the scientific goals.

5. Feeding

Provision should be made for each *animal* to have access to feed to satisfy its physiological needs. Precautions should be taken in packing, transporting and storing feed to avoid chemical, physical and microbiological contamination, deterioration or destruction. Utensils used for feeding should be regularly cleaned and, if necessary, sterilised.

6. Water

Uncontaminated potable drinking water should normally be available at all times. Watering devices, such as drinking tubes and automatic watering systems, should be checked daily to ensure their proper maintenance, cleanliness, and operation.

7. Bedding

Animal bedding is a controllable environmental factor that can influence experimental data and *animal welfare*. Bedding should be dry, absorbent, non-dusty, non-toxic and free from infectious agents, vermin or chemical contamination. Soiled bedding should be removed and replaced with fresh material as often as is necessary to keep the *animals* clean and dry.

8. Hygiene

The successful operation of a facility depends very much on good hygiene. Special care should be taken to avoid spreading *infection* between *animals* through fomites, including through personnel traffic between animal rooms. Adequate routines and facilities for the cleaning, washing, decontamination and, when necessary, sterilisation of cages, cage accessories and other equipment should be established. A very high standard of cleanliness and organisation should also be maintained throughout the facility.

9. Identification

Animal identification is an important component of record keeping. *Animals* may be identified individually or by group. Where it is desirable to individually identify *animals*, this should be done by a reliable and the least painful method.

DRAFT CHAPTER X.X.X.

ANIMAL WELFARE AND BROILER CHICKEN PRODUCTION

Article X.X.1.

Definitions

Broiler

Birds of the species *Gallus gallus* kept primarily for commercial meat production.

Cage housing system

In a cage housing system the caretaker accesses the birds from outside the enclosure in which the birds are kept.

Deep litter housing system

In a deep litter housing system the birds are kept on floors that are is covered with bedding material.

Slatted floor housing system

In a slatted floor housing system the birds are kept on raised floors, on which droppings don't accumulate but fall through.

Article X.X. 2.

Scope

These recommendations cover the production period from arrival of the chick on the farm to harvesting the broiler in commercial production systems. Backyard flocks are not included even if the animals or products are traded locally.

Note 1: Welfare of the broiler during transport to the abattoir is covered in Chapters 7.2., 7.3. and 7.4.

Note 2: Recommendations on the management of the breeding flock and hatchery and for the period between hatching and arrival on the farm to be developed.

Article X.X.3.

Commercial broiler production systems

Commercial broiler production systems include:

1. Intensive systems

   Birds are completely confined in a roofed structure, with or without environmental control and usually at a higher stocking density than in other production systems. Birds may be kept in cages (e.g. wire or plastic floor or deep litter floor) or on deep litter, slatted floor or a combination

2. Semi intensive systems

   Birds are confined in a roofed structure but provided with an access to a restricted outdoor area. They may be kept in cages (e.g. wire or plastic floor or deep litter floor) or on deep litter, a slatted floor or a combination of the two.

3. Extensive systems

   Birds are not confined in a roofed structure and are usually kept at a lower stocking density than in intensive or semi intensive systems.

Article X.X.4.

Criteria or measurables for the welfare of broilers

The following outcome (animal) based measurables can be useful indicators of welfare:

1) Mortality rate (dead, culled)
2) Gait
3) Contact dermatitis
4) Feather condition
5) Disease incidence / morbidity rates
6) Ascites / sudden death syndrome (SDS)
7) Respiratory disease
8) Parasitic diseases
9) Carcass and meat quality (condemnations)
10) Behaviour: fear, thermal distress, illness
    a) Human avoidance behaviour
    b) Spatial distribution:
    c) Panting and wing spreading.
    d) Dust bathing
    e) Feather pecking
    f) Cannibalism
    g) Feeding and drinking
11) Water consumption
12) Growth rate

13) Feed conversion

14) Injury rate

15) Eye condition.

Article X.X.5.

Recommendations

1. Biosecurity and animal health

a) Biosecurity and Disease Prevention

Biosecurity means a set of measures designed to protect a flock from the entry of infectious agents.

Biosecurity programmes should be implemented, commensurate with the risk of disease and in accordance with relevant recommendations found in *Terrestrial Code* chapters on OIE listed diseases.

These programmes should address the control of the major routes for disease and pathogen transmission:

i) poultry

ii) other animals

iii) people

iv) equipment

v) vehicles

vi) air

vii) water supply

viii) feed.

Outcome based measurables: disease incidence, mortality, growth rate and feed conversion.

b) Animal Health Management / Preventive Medicine / Veterinary Treatment

Animal health management means a system designed to prevent diseases occurring in a flock and provide treatment if disease occurs in order to optimise the health and welfare of the flock.

Those responsible for the care of birds should be aware of the signs of ill-health or distress, such as reduced food and water intake, reduced growth, changes in behaviour, abnormal conditions of their feathers or droppings, or other physical features.

If persons in charge are not able to identify the causes of ill-health or distress or to correct these or suspect the presence of a listed reportable disease, they should seek advice from those having training and experience, such as poultry veterinarians or other qualified advisers. Veterinary treatments should be prescribed by a qualified veterinarian.

There should be an effective programme for the prevention and treatment of diseases consistent with the programs established by the Veterinary Services as appropriate.

Vaccinations and other treatments administered to chickens should be undertaken with consideration of the welfare of the birds by people skilled in the procedures.

Culling of sick or injured birds should be done in a humane manner as soon as possible. Similarly, killing birds as may be required for diagnostic purposes should be done in a humane manner.

Outcome based measurables: disease incidence, mortality and poor performance.

2. Environment

a) Thermal environment

In intensive and semi intensive production systems every attempt should be made to keep thermal conditions within the recommended range.

A table of recommended ranges will be included

In extensive production systems appropriate management to mitigate the effects of extreme thermal conditions should be implemented.

Outcome based measurables: rates of mortality, rate of contact dermatitis, water consumption, feed consumption, growth rate, feed conversion and behaviour.

b) Lighting

There should be an adequate period of continuous darkness during each 24 hour period to allow the birds to rest.

The light intensity during the light period should be sufficient and homogeneously distributed to allow the chicks to find feed and water in the first few days after they are placed in the house, to stimulate bird activity, and to allow inspection of the birds.

Birds should be gradually adjusted to lighting changes.

Outcome based measurables: lameness, feed and water consumption, behavior and injuries.

c) Air quality

Adequate ventilation is required at all times to provide fresh air and is one means of controlling temperature and humidity.

Ammonia concentration should not routinely exceed 25 ppm at bird level.

Dust levels should be kept to a minimum. Methods for doing that can include: maintaining appropriate ventilation and optimal relative humidity levels (50% - 80%).

Outcome based measurables: incidence of respiratory diseases, behaviour (panting, huddling), condition of the eyes, growth rate, feed conversion, contact dermatitis, distribution of the birds.

d) Acoustic environment

Exposure of birds to sudden or loud noises should be minimized where possible to prevent stress and fear reactions (e.g. piling).

Note: location of farms should, where possible, take into account existing environmental conditions.

Outcome based measurables: daily mortality rate, growth rate, food conversion, injuries, fearfulness and behaviour.

e) Nutrition

Birds should be fed a diet containing adequate nutrients to meet their requirements for good health.

Feed and water should be palatable and free from contaminants potentially hazardous to bird health.

Cleaning the water system should be done regularly.

Birds must be provided with adequate accessibility to feed on a daily basis. Water should be available continuously.

Special provisions should be made to enable young chicks to access feed and water.

Outcome based measurables: feed and water consumption, growth rate, food conversion, behaviour, lameness, disease incidence, mortality, morbidity and carcass and meat quality.

f) Flooring, bedding, resting surfaces (litter quality)

The floor of a poultry building should be easy to clean and disinfect.

If litter is recycled it should be managed to minimize any detrimental effects on welfare and health. Litter should be replaced when required to control a disease outbreak in the next flock.

Day old chicks should be housed on a floor suitable for their size.

If housed on litter based systems, before the one day old chicks enter the building the floor should have a bedding of uncontaminated new substrate (e.g. wood shavings, straw, shredded paper) of sufficient depth to elicit normal behaviour and to protect them from the floor.

Litter quality is partly related to the type of substrate used and partly to different management practices. The type of substrate should be chosen carefully. Litter should be maintained so that it is friable and not dusty, caked or wet.

The floors of cages and slatted systems should be designed, constructed and maintained to adequately support the birds and prevent injuries and to ensure that manure can be adequately removed.

Outcome based measurables: contact dermatitis, breast blisters, feather condition, ascites, lameness, behaviour, eye condition, respiratory disease and growth rate.

g) Social environment

Management methods (e.g. reducing light intensity, providing foraging materials, nutritional modifications, reducing stocking density) should be implemented to reduce feather pecking and cannibalism in growing systems where these behaviors are a potential problem.

If these management strategies fail, therapeutic beak trimming should be considered.

Outcome based measurables: injuries, behaviour, feather condition, mortality, carcass - and meat quality.

h) Stocking density

Broiler chickens should be housed in an acceptable stocking density.

To determine the appropriate stocking density, the following factors should be taken into account: ambient conditions, housing systems, productions systems, litter quality, biosecurity strategy, selection of genetic stocks, and market age of birds should be taken into account so that the floor space provided will ensure good welfare (comfort, ability to express normal postural adjustments and to access feed and water).

Outcome based measurables: rates of injuries, rates of contact dermatitis, rates of mortality, behaviour, growth rate, feed conversion, plumage condition and carcass quality.

i) Outdoor areas

Management of outdoor areas is important in extensive and semi-intensive production systems.

Land (pasture) management measures should be taken to reduce the risk of birds being infected by parasites transmitted. This might include limiting the stocking density and / or using several pieces of land consecutively (rotation).

Outdoor areas should be managed appropriately to minimize swampy conditions and mud.

Outdoor areas should be managed appropriately to ensure that they are free of poisonous plants and other contaminants.

Particularly in extensive systems where birds do not have access to an indoor area, protection from adverse climatic conditions (e.g. heat, cold, rain) should be provided

Outcome based measurables: incidence of parasitic diseases, growth rate, feather condition and mortality rate.

j) Protection from predators

Broilers should be protected from predators.

Outcome based measurables: mortality and injuries.

3. Management

a) Genetic selection

Welfare and health considerations, in addition to productivity, should be taken into account when choosing a strain for a particular location or production system.

Outcome based measurables: lameness, ascites, sudden death syndrome (SDS), mortality, feed conversion and growth rate.

b) Painful interventions

Commercial broiler chickens are not typically subjected to management practices that cause pain. However, prophylactic beak-trimming may be required in case of outbreaks of feather pecking and cannibalism, as described earlier. Guidelines for beak-trimming to minimize negative impacts on bird health and performance are presented in Glatz and Miao (2005). Only the minimum amount of beak needed to prevent beak re-growth before market age (ideally, only the hook at the end of the upper beak) should be removed, and the trim should be performed so as to prevent subsequent distortion or deformation of the beak. The beak should be cauterized after cutting to minimise bleeding. Trimming at an early age (before 10 days of age; Hester and Shea-Moore, 2003) is preferred to prevent long-term pain, but since feather pecking and cannibalism develop when the birds are somewhat older prophylactic trimming will likely occur after this time.

There is a small specialty market for capons (castrated male broilers). Because the testes of male chickens are located inside the abdominal cavity, this procedure is a major surgery (Jacob and Mather, 2000) that should be performed only by skilled individuals and with measures to minimize pain, injury, and bleeding. The procedure is described in Jacob and Mather (2000).

Painful interventions (e.g. beak trimming, toe trimming, dubbing) should not be routinely practiced on broilers.

If therapeutic beak trimming is required, it should be carried out by trained and skilled personnel and care should be taken to remove the minimum amount of beak necessary using a method which minimizes pain and controls bleeding.

Surgical caponisation should not be performed without adequate pain and infection control methods and should only be performed by trained and skilled personnel under veterinary supervision.

c) Handling and inspection

Broilers should be inspected every day. This inspection should have three main objectives: to pick up dead birds; to identify sick or injured birds to treat or cull them, and to detect and correct any welfare or health problem in the flock (e.g. related to the supply of feed and water, thermal conditions, ventilation, litter quality).

Inspection should be done in such a way that birds are not unnecessarily disturbed, for example personnel should move quietly and slowly through the flock.

When birds are handled they should not be injured or unnecessarily frightened or stressed.

Birds which have an incurable sickness, significant deformity or injury should be removed from the flock and humanely killed as soon as possible.

Cervical dislocation is an acceptable method for killing small numbers of birds if carried out competently. For a complete description of killing methods see Chapter 7.6.17. of the *Terrestrial Code*.

Outcome based measurables: fear, performance, injuries, mortality and morbidity.

d) Personnel training

All people responsible for the broilers should be competent according to their responsibilities and should have sufficient knowledge of broiler behaviour, biosecurity, general signs of disease, and indicators of poor animal welfare such as stress, pain and fatigue, and their alleviation.

e) Emergency Plans

Poultry producers should have emergency plans to minimize and mitigate the consequences of: natural disasters, disease outbreaks and the failure of mechanical equipment. Planning may include the provision of fail safe alarm devices to detect malfunctions, back up generators, access to maintenance providers, alternative heating arrangements, ability to store water on farm, access to water cartage services, adequate on farm storage of feed and alternative feed supply and emergency ventilation.

An emergency plan for animal health should be developed consistent with national programs established or recommended by Veterinary Services as appropriate.

f) Location, construction and equipment of farms

The location of poultry farms should be chosen to be safe from the effects of fires and floods and other natural disasters to the extent practical. In addition farms should be sited to avoid or minimize biosecurity risks, exposure of birds to chemical and physical contaminants, noise and adverse climatic conditions.

Housing and equipment to which poultry have access should be designed and maintained to avoid injury or pain to the birds.

Buildings should be constructed and electrical and fuel installations should be fitted to minimise the risk of fire and other hazards.

Poultry producers should have a maintenance programme in place for all equipment that, in case of failure, can jeopardize broiler welfare.

g) On farm harvesting

Feed should be removed at a suitable time prior to catching.

Water should be available for as long as possible.

Injured and sick birds should be culled or separated prior to harvesting.

Catching should be done by skilled workers and every attempt should be made to minimize stress and fear reactions, and injury.

The broilers should not be picked up by their neck or wings.

The broilers should be put in the transport container carefully.

Mechanical catchers should be designed, operated and maintained to minimize injury, stress and fear to the birds. Contingency plan is advisable in case of mechanical failure.

Catching should preferably be carried out under dim or blue light to calm the birds.

Catching should be scheduled to minimize the time to slaughter as well as climatic stress during catching, transport and holding.

Stocking density in transport containers should suit climatic conditions and maintain comfort.

Containers should be clean and disinfected and designed and maintained to avoid injury to the birds.

Outcome based measurables: incidence of injuries, mortality rate and carcass quality.

h) Humane killing

Injured and sick birds should be killed humanely.

Cervical dislocation is considered a humane method for killing small numbers of birds.

For a description of other methods for the humane killing of broilers see Chapter 7.6.5. of the *Terrestrial Code*.

DRAFT CHAPTER 7.X.X.

ANIMAL WELFARE AND BEEF CATTLE PRODUCTION SYSTEMS

Article 7.X.1

Definitions

The *ad hoc* Group discussed the application of the OIE recommendations and decided that these should be designed with application to commercial beef production. Beef cattle production systems are defined as all commercial cattle productions systems where the purpose of the operation includes some or all of the breeding, rearing and finishing of cattle intended for beef consumption.

Article 7.X. 2

Scope

The first priority is to address the on farm aspects of the production systems, from birth through to finishing. The areas of emphasis are cow- calf, stockers and finishing beef production.

Article 7.X.3

Commercial beef cattle production systems

Commercial beef cattle production systems include:

1. Intensive (stocker and finishing)

   Would include cattle that are place on confinement. Animals are depending on the daily animal husbandry for provision of feed, shelter and water.

2. Extensive (all areas)

   Would include from a wide range grazing habitat

3. Semi Intensive (mixed)

   Would include a combination of intensive and extensive systems

Article 7.X.4

Criteria or measurables for the welfare of beef cattle

The following outcome (animal) based measurables can be useful indicators of welfare

1. behaviour
2. morbidity rates
3. mortality rates

4. weight gain and body condition score
5. reproductive rates
6. physical appearance
7. handling responses
8. rate of post-procedures complications
9. post-mortem pathology
10. survivability.

Article 7.X.5

Recommendations

1. Biosecurity and Animal Health

   a) Biosecurity and disease prevention

      Biosecurity means a set of measures designed to protect a herd from the entry of infectious agents.

      Biosecurity programmes should be implemented, commensurate with the risk of disease and in accordance with relevant recommendations found in Terrestrial Code chapters on OIE listed diseases.

      These programmes should address the control of the major routes for disease and pathogen transmission:

      i) cattle
      ii) other animals
      iii) people
      iv) equipment
      v) vehicles
      vi) air
      vii) water supply
      viii) feed.

      Outcome based measurables: morbidity rate, mortality rate, reproductive efficiency.

   b) Animal health management

      Animal health management is a mean to prevent diseases occurring in cattle herds and also providing treatments for animals when disease occurs. There should be an effective programme for the prevention and treatment of diseases consistent with the programs established by the Veterinary Services as appropriate.

Those responsible for the care of cattle should be aware of the signs of ill-health, such as reduced food and water intake, weight gain and body condition, changes in behaviour or abnormal physical appearance.

Cattle with higher risk for disease will require more frequent inspection by animal *animal handlers*. If a*nimal handlers* are not able to determine the causes of ill-health or distress or to correct these or suspect the presence of a listed reportable disease. they should seek advice from those having training and experience, such as bovine veterinarians or other qualified advisers. Veterinary treatments should be prescribed by a qualified veterinarian.

Vaccinations and other treatments administered to cattle should be undertaken by people skilled in the procedures and on the basis of veterinary or other expert advice.

Animal handlers should have experience in caring for downer cattle. They should also have experience in managing chronically ill or injured animals. Euthanasia on non-responding cattle should be done as soon as recovery is deemed not possible.

Outcome based measurables: morbidity rate, mortality rate, reproductive efficiency, behaviour, physical appearance and body condition score.

2. Environment

a) Thermal environment

Although cattle can adapt to a wide range of thermal environment particularly if appropriate breeds are used for the anticipated conditions, sudden fluctuations in weather can cause heat or cold stress.

i) Heat stress

The Thermal Heat Index (THI) is influenced by air temperature, relative humidity and wind speed. As the THI increases the risk of hyperthermia increases. Also as cattle are fed longer and become fatter are more susceptible to heat stress.

Animal handlers should be aware of the critical THI threshold for their animals. When the THI is expected to reach this threshold routine daily processes that include cattle movement should cease. As the THI moves into emergency levels the *animal handlers* should institute an emergency action plan that could include shade, drinking water, sprinkling water to penetrate the hair coat.

ii) Cold stress

Protection from wind and rain should be provided where possible, particularly for young stock outdoors for the first time. This could be provided by natural or man made shelter structures.

Animal handlers should also ensure that cattle have access to adequate feed and water during cold stress. During time of heavy snow fall or blizzard animal handlers should institute an emergency action plan to provide cattle with shelter, feed and water.

Outcome based measurables : Mortality rates, physical appearance, behaviour

b) Lighting

Confined cattle that do not have access to natural light should be provided with sufficient supplementary lighting for their health and welfare, to facilitate natural behaviour patterns and to allow adequate inspection of the animals.

Outcome based measurables: Behaviour, morbidity, physical appearance

c) Air quality

Good air quality is an important factor for the health and welfare of cattle in intensive and confined production systems. It is a composite variable of air constituents such as gases, dust and micro-organisms that is strongly influenced by the management of the beef producer. The air composition is influenced by the stocking density, the size of the cattle, flooring, bedding, waste management, building design and ventilation system.

Proper ventilation is important for effective heat dissipation in cattle and preventing the build up of CO_2, NH_3 and effluent gases in the confinement unit. Poor air quality and ventilation are risk factors for respiratory diseases.

Outcome based measurables: Morbidity rate, behaviour, mortality rate, weight gain, post-mortem pathologies

d) Acoustic environment

Cattle are adaptable to different acoustics environments. However, exposure of cattle to sudden or loud noises should be minimized where possible to prevent stress and fear reactions (e.g. stampede). Ventilation fans, feeding machinery or other equipment should be constructed, placed, operated and maintained in such a way that they cause the least possible amount of noise.

Outcome based measurables: Behaviour.

e) Nutrition

The nutrient requirements of beef cattle have been well defined. Energy, protein, amino acid, mineral and vitamin contents of the diet are major factors determining the growth, feed efficiency, reproductive efficiency, and body composition.

Animal handlers should provide cattle a level of nutrition that meets or exceeds their maintenance requirements from the previously reference materials. It should be noted that cattle in certain climates and production systems may experience short term periods of below maintenance nutrition without compromise their welfare. Animal handlers should have adequate knowledge of appropriate body condition score for their cattle and should not allow body condition score to drop below these critical thresholds. In times of severe drought steps should be taken to avoid starvation of animals wherever possible.

In intensive production systems cattle should have access to adequate feed and water supply to meet their physiological needs.

Feedstuffs and feed ingredients should be of satisfactory quality to meet nutritional need and under certain circumstances (e.g., drought, frost, and flood), should be tested for the presence of substances (e.g. mycotoxins and nitrates) that can be detrimental to cattle health and welfare.

Cattle in intensive production systems typically consume diets that contain a high proportion of grain(s) (corn, milo, barley, grain by-products) and a smaller proportion of roughages (hay, straw, silage, hulls, etc.). As the proportion of grain increases in the diet, the relative risk of digestive upset in cattle increase. Animal handlers should understand the impact of cattle size, age, weather patterns, diet composition and sudden diet changes in respect to digestive upsets and their sequelae (acidosis, bloat, liver abscess, laminitis). Where appropriate beef producers should consult a nutritionist (private consultant, university or feed company employee) for advice on ration formulation and feeding programs.

Beef producers should become familiar with potential micronutrient deficiencies or excesses for intensive and extensive production systems in their respective geographical areas and use appropriately formulated supplements where necessary.

The water quality and the method of supply can affect welfare. All cattle need adequate supply and access to palatable water that also meets their physiological requirements and free from contaminants potentially hazardous to cattle health.

Outcome based measurables: Mortality rates, morbidity rates, behaviour, weight gain, body condition scoring, reproductive rates.

f) Flooring, bedding, resting surfaces (litter quality)

In all production systems cattle need a comfortable place to rest.

Pen floor management in intensive production systems can have a significant impact on cattle welfare.

Mud depth should not consistently be deeper than the ankles of cattle in pens.

Slopes of pens should be maintained to allow water to run off away from the feed bunks and not pool excessively in the pens.

If slope is not sufficient to allow for proper drainage, a mound should be constructed in each pen to allow cattle to have a dry place to lie down.

Pens should be thoroughly cleaned after each production cycle as conditions warrant.

If animals are housed in a slatted floor shed, the slat width should be appropriate to the hoof size of the animals to prevent injuries.

In straw or other bedding systems the bedding shoud be maintained to allow animals a dry and comfortable place in which to lie.

Outcome based measurables: Morbidity rates (lameness), behaviour, weight gain, physical appearance.

g) Social environment

Management of cattle in outdoor and indoor intensive production systems methods should take into account the social environment of cattle as it relates to animal welfare. Problem areas include: buller activity, mixing of heifers and steers, feeding cattle of different size and age in same pens, insufficient space at the feeder, insufficient water access and mixing of bulls.

In the case of buller animals, they should be identified and removed from the pen immediately. Beef producers should utilize management practices to reintroduce these animals. If reintroduction fails these animals will have to housed separately from the pen mates. Animal handlers should work to feed cattle of the same size and age in the same pens. Depending on feeding systems, health status of the animals and size of the animals beef producer will need to allow adequate feeder space and water access for the cattle.

Adequate fencing should be provided to minimize any animal welfare problems that may be caused by mixing of inappropriate groups of cattle.

Outcome based measurables: Behavior, physical appearance, weight gain, morbidity and mortality rate

h) Stocking density

High stocking densities may have an adverse effect on growth rate, feed efficiency, survivability, carcass quality and behavior (locomotion, resting, feeding and drinking).

In extensive outdoors systems stocking density should be managed to ensure an adequate feed supply for the cattle.

Stocking density should be managed such that crowding does not adverse impact key components of normal behavior of cattle. These include the ability to lie down freely without the risk of injuries, move freely around the pen and access feed and water. Stocking density should also be managed such that weight gain is not adversely affected by crowding. Excessive tongue rolling can be associated with overcrowding of confined cattle.

Outcome based measurables: Behavior, Morbidity rate, mortality rate, weight gain, physical appearance.

i) Outdoor areas

Not applicable.

j) Protection from predators

Where practical, cattle should be protected from predators.

Outcome based measurables: Mortality, behaviour, physical appearance.

3. Management

a) Genetic selection

Welfare and health considerations, in addition to productivity, should be taken into account when choosing a breed for a particular location or production system. Examples of these include nutritional maintenance requirement, ectoparasite resistance and heat tolerance.

Individual animals within breed can be genetically selected to propagate offspring that exhibit the following traits beneficial to animal health and welfare: Maternal ability, birth weight, milking ability, body conformation and temperament.

Outcome based measurables: Morbidity rate, mortality rate, behaviour, physical appearance, reproductive efficiency.

b) Weaning

Weaning for the purposes of this document is the term to describe transfer of the calf to a fibrous diet from nursing the dam or being fed with milk or milk replacer. In beef cattle production systems, weaning can be a stressful time in the calf's life.

Calves should be weaned only when their ruminant digestive systems have developed sufficiently to enable them to maintain growth and welfare.

The practice of creep feeding is sometimes utilised prior to weaning to help the calf more easily adapt to a solid diet.

There are different weaning strategies utilised in the beef cattle production systems. These could include abrupt separation, fence line separation and the use of devices placed in the nose of the calf to discourage suckling.

Special care should be taken if abrupt weaning is immediately followed by transportation off farm as research has shown that calves are at risk of increased morbidity under these circumstances.

Beef cattle producers should seek expert advice on the most appropriate time and method of weaning for their type of cattle and production system.

Outcome based measurables: Morbidity rate, mortality rate, behaviour, physical appearance, weight gain.

c) Painful husbandry procedures

Surgical husbandry practices that have the potential to cause pain are routinely practiced on cattle for reasons of production efficiency, animal health and welfare and human safety. Where possible, these procedures should be performed in such a way as to minimize any pain and stress on the animal. Options to consider including the performing the procedure at as early an age as possible or where appropriate use of analgesia.

Future options for enhancing animal welfare in relation to these procedures include: 1) ceasing the procedure and addressing the current need for the operation through management strategies; 2) breeding animals that do not require the procedure; 3) replacing the current procedure with a non-surgical alternative that has been shown to enhance animal welfare; or 4) performing the procedure in a way that minimises pain.

Example of such interventions include: castration, dehorning, (spaying), tail docking, identification.

i) Castration

Castration of beef cattle is performed in many production systems to reduce inter-animal aggression, improve human safety, remove the risk of unwanted pregnancies in the herd, and enhance production efficiency by producing beef that better meets market requirements.

Where it is necessary to castrate beef cattle, producers should seek guidance from veterinarians as to the optimum method and timing for their type of cattle and production system.

Methods of castration used in beef cattle include surgical (knife) removal of the testes, ischaemic methods (banding or ringing), and crushing of the spermatic cord (burdizzo operation).

Where practical, cattle should be castrated before the age of 3 months, or at the first available handling opportunity beyond this age.

Producers should seek guidance from veterinarians on the availability and advisability of analgesia/anaesthesia for castration of beef cattle, particularly in older animals.

Operators performing castration of beef cattle should be trained and competent in the procedure used, and be able to recognise the signs of complications.

ii) Dehorning

Beef cattle which are naturally horned are commonly dehorned in order to reduce animal injuries and hide damage, improve human safety, and facilitate transport and handling. Where practical and appropriate for the production system, the selection of polled cattle can remove the need for dehorning.

Where it is necessary to dehorn beef cattle, producers should seek guidance from veterinary advisers as to the optimum method and timing for their type of cattle and production system.

Where practical, cattle should be dehorned while horn development is still at the horn bud stage, or at the first available handling opportunity beyond this age. This is because the procedure involves less tissue trauma when horn development is still at the horn bud stage, and there is no attachment of horn to the skull of the animal.

Methods of dehorning at the horn bud stage include removal of the horn buds with a knife, thermal cautery of the horn buds, or the application of chemical paste to cauterise the horn buds. Methods of dehorning when horn development has commenced involve the removal through of the horn cutting or sawing at the base of the horn close to the skull.

Producers should seek guidance from veterinarians on the availability and advisability of analgesia/anaesthesia for dehorning of beef cattle, particularly in older animals.

Operators performing dehorning of beef cattle should be trained and competent in the procedure used, and be able to recognise the signs of complications.

iii) Spaying (ovariectomy)

Spaying of heifers is sometimes required for international trade or to prevent unwanted pregnancies under extensive rangeland conditions. Surgical spaying should be performed by veterinarians or by highly trained operators. Producers should seek guidance from veterinarians on the availability and advisability of analgesia/anaesthesia for spaying of beef cattle.

iv) Tail docking

Tail docking has been performed in beef cattle to prevent tail tip necrosis in confinement operations. Research shows that increasing space per animal and proper bedding are effectives means in preventing tail tip necrosis. Therefore it is not recommended for producers to dock the tails of beef cattle.

v) Identification

Ear-tagging, ear-notching, tattooing, freeze branding and radio frequency identification devices (RFID) are preferred methods of permanently identifying beef cattle from an animal welfare stand point. In some situations however hot iron branding may be required or be the only practical method of permanent identifying beef cattle. If cattle are branded, it should be accomplished quickly, expertly and with the proper equipment. Identification systems should be established also according to the Chapter 4.1. of the *Terrestrial Code* on General principles on identification and traceability of live animals.

Outcome based measures: Rate of post-procedures complications, mortality rate, behaviour, physical appearance, weight gain.

d) Handling and inspection

Beef cattle should be inspected at intervals appropriate to the production systems and the risks to the health and welfare of the animals.

Some animals may benefit from more frequent inspection for example: neonatal calves, cows in late gestation, newly weaned calves, and cattle experiencing environmental stress and after painful husbandry or veterinary surgical procedures.

Animal handlers need to be competent in recognising the clinical signs of health, disease and welfare of beef cattle.

Beef cattle identified as sick or injured should be given appropriate treatment at the first available opportunity. If animal handlers are unable to provide appropriate treatment, then the service of veterinarians should be enlisted.

If prognosis of the animal condition is poor with little chance of recovery, humane euthanasia of the animal should be considered. For a description of methods for the humane killing of beef cattle see chapter 7.6.5 of the OIE *Terrestrial Code*

Recommendations on the handling of cattle are also found in Chapter 7.5., Articles 7.5.1 and 7.5.2 of the OIE T*errestrial Code.*

Where beef cattle are herded into a handling facility from extensive conditions, they should be moved quietly. Weather conditions should be taken into account and cattle should not be herded in excessively hot or cold conditions. Cattle should not be driven to the point of collapse. Properly trained dogs can be effective tools for cattle herding.

Outcome based measurables: Handling response, morbidity rate, mortality rate, behaviour, reproductive efficiency, weight gain.

e) Personnel training

All people responsible for beef cattle should be competent according to their responsibilities and should understand cattle husbandry, behaviour, biosecurity, general signs of disease, and indicators of poor animal welfare such as stress, pain and discomfort, and their alleviation.

Competence may be gained through formal training and/or practical experience.

Outcome based measurables: Handling response, morbidity rate, mortality rate, behaviour, reproductive efficiency, weight gain.

f) Emergency plans

Beef producers should have contingency plans to cover the failure of power, water and feed supply. These plans may include the provision of fail safe alarm devices to detect malfunctions, back up generators, access to maintenance providers, ability to store water on farm, access to water cartage services, adequate on farm storage of feed and alternative feed supply.

Plans should be in place to minimise and mitigate the effects of natural disasters or extreme climatic conditions e.g., heat stress, drought, blizzard and flooding. Emergency plans should also cover the management of the farm in the face of an emergency disease outbreak, consistent with national programs and recommendations of *Veterinary Services* as appropriate.

g) Location, construction and equipment of farms

Farms for beef cattle should be situated in an appropriate geographical location for the health, welfare and productivity of the animals while considering environmental sustainability.

All facilities for beef cattle should be constructed, maintained and operated to minimise the risk to the welfare of the animals and human safety.

Equipment for handling and restraining beef cattle should only be used in a way that minimises the risk of injury, pain or distress.

Cattle in intensive or extensive production systems must be offered adequate space for comfort, socialization and environmental management.

In intensive production systems the feeder should be sufficiently large so that animals have adequate access to feed and they should be clean and free of spoiled, moldy, sour, packed or unpalatable feed. Also cattle should have access to clean and clear water at all times.

Floors in housing facilities should be properly drained, and barns and handling alleys should provide traction to prevent injuries to animals and handlers.

Handling alleys and housing pens must be free of sharp edges and protrusions to prevent injury to animals and handlers.

Design and operate alleys and gates to avoid impeding cattle movement. Avoid slippery surfaces, especially where cattle enter a single file alley leading to a chute or where they exit the chute. Grooved concrete, metal grating (not sharp), rubber mats or deep sand can be used to minimize slipping and falling. Quiet handling is essential to minimize slipping. When operating gates and catches, reduce excessive noise, which may cause distress to the animals.

Adjust hydraulic or manual restraining chutes to the appropriate size of cattle to be handled. Regular cleaning and maintenance of working parts is imperative to ensure the system functions properly and is safe for the cattle and handlers.

Mechanical and electrical devices used in housing facilities must be safe for animals and humans.

Dipping baths are sometimes used in beef cattle production for ectoparasite control. Where these are used, they should be design and operated to minimise the risk of crowding, injury or drowning.

The loading of the animals at the farms should be conducting accordingly to Chapters 7.2., 7.3. and 7.4. (Transport of animals by sea, land and air respectively)

Outcome based measurables: Handling response, morbidity rate, mortality rate, behaviour, weight gain, physical appearance, lameness.

h) On farm harvesting

Refer to Section 5.3.3.

i) Humane killing

A prompt diagnosis should be made to determine whether the animal should be humanely killed or receive additional care.

Animal handlers should provide feed and water to non-ambulatory cattle at least once daily.

Non-ambulatory animals should be moved very carefully and dragging non-ambulatory animals is unacceptable.

Likewise, animals should not be lifted with chains onto transportation conveyances. Acceptable methods of transporting non-ambulatory animals include a sled, low-boy trailer or in the bucket of a loader.

When treatment is attempted, cattle that are unable to sit up unaided and refuse to eat or drink should be humanely euthanized as soon as recovery is deemed not possible.

Cattle that are non-ambulatory must not be sent to a livestock market or to a processing facility.

Humane killing should occur without pain or suffering.

The decision to humanely kill an animal and the procedure itself should be undertaken by a competent person.

Reasons for euthanasia may include:

i) severe emaciation, weak cattle that are non-ambulatory or at risk of becoming downers;

ii) non-ambulatory cattle that will not sit up, refuse to eat or drink, have not responded to therapy;

iii) rapid deterioration of a medical condition for which therapies have been unsuccessful;

iv) severe, debilitating pain;

v) compound (open) fracture;

vi) spinal injury;

vii) central nervous system disease; and

viii) multiple joint infections with chronic weight loss.

For a description of other methods for the humane killing of beef cattle see Chapter 7.6.5. of the *Terrestrial Code*.

Annex XVIII

CHAPTER 8.1

ANTHRAX

Article 8.1.1.

General provisions

This chapter is intended to manage the human and animal health risks associated with the presence of *Bacillus anthracis* in *commodities* and the environment.

There is no evidence that anthrax is transmitted by animals before the onset of clinical and pathological signs. Early detection of *outbreaks*, quarantine of affected premises, destruction of diseased animals and fomites, and implementation of appropriate sanitary procedures at *abattoirs* and dairy factories will ensure the safety of products of animal origin intended for human consumption.

For the purposes of the *Terrestrial Code*, the *incubation period* for anthrax shall be 20 days.

Anthrax should be notifiable in the whole country.

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

When authorising import or transit of *commodities* listed in this chapter, *Veterinary Authorities* should require the conditions prescribed below.

Article 8.1.1.bis

Safe commodities

When authorising import or transit of the following *commodities*, *Veterinary Authorities* should not require any anthrax related conditions for semen and *in vivo* derived cattle embryos collected and handled in accordance with Chapters 4.5.,4.6., and 4.7., as relevant.

Article 8.1.2.

Recommendations for the importation of ruminants, equines and pigs

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

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

AND

2. were kept for the 20 days prior to shipment in an *establishment* where no *case* of anthrax was officially declared during that period; or

3. were vaccinated, not less than 20 days and not more than 6 months prior to shipment in accordance with the *Terrestrial Manual*.

Annex XVIII (contd)

~~Article 8.1.3.~~

~~**Recommendations for the importation of products of animal origin (from ruminants, equines and pigs) intended for agricultural or industrial use**~~

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

~~1. originate from animals not showing clinical signs of anthrax; or~~

~~2. have been processed to ensure the destruction of both bacillary and spore forms of *Bacillus anthracis*, in conformity with one of the procedures referred to in Chapter X.X. (under study).~~

Article 8.1.4.

Recommendations for the importation of fresh meat and meat products destined for human consumption

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

1. have shown no sign of anthrax during ante-mortem and post-mortem inspections; and

2. were not immunised against anthrax using live vaccine during the 21 days prior to *slaughter*; and

~~2~~3. come from *establishments* which are not placed under quarantine on account of anthrax control and in which~~:~~

   ~~a)~~ there has been no *case* of anthrax during the 20 days prior to *slaughter*~~;~~

   ~~b) no vaccination against anthrax has been carried out during the 42 days prior to *slaughter*~~.

Article 8.1.5.

Recommendations for the importation of hides, skins and hair (from ruminants, equines and pigs)

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

1. have shown no sign of anthrax during ante-mortem and post-mortem inspections; and

2. come from *establishments* which are not placed under quarantine on account of anthrax control.

Article 8.1.6.

Recommendations for the importation of wool

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

~~1. originate from animals showing no clinical signs of anthrax at the time of shearing; and~~

~~2~~1. originate from *establishments* where no *case* of anthrax has been reported since the previous shearing of all animals;

OR

~~3~~2. have been treated in accordance with the recommendations in Article 8.1.11.

Article 8.1.7.

Recommendations for the importation of milk and milk products intended for human consumption

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

1. originate from animals showing no clinical signs of anthrax at the time of milking; or

2. were processed using a heat treatment of 120 °C for 1~~0~~6 seconds ~~at least equivalent to pasteurisation (under study)~~.

Reference

SA XU, THEODORE P. LABUZA & FRANCISCO DIEZ-GONZALEZ (2006). Thermal Inactivation of *Bacillus anthracis* in Cow's Milk. *Applied and Environmental Microbiology*, juin 2006, Vol 72, N°6, pp. 4479-4483.

Article 8.1.8.

Recommendations for the importation of bristles (from pigs)

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

1. have shown no sign of anthrax during ante-mortem and post-mortem inspections; and

2. come from *establishments* which are not placed under quarantine on account of anthrax control;

OR

3. have been processed to ensure the destruction of *B. anthracis* by:

   a) boiling for 60 minutes; and

   b) drying in hot air.

   ~~c) immersion for 24 hours in a 2% solution of formaldehyde at >20 °C.~~

Annex XVIII (contd)

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REINHARD BÖHM. Institut fur Umwelt-und Tierhygiene Sowie Tiermedizin mit Tierklinik, Universität Hohenheim. Communication personnelle au Dr Wolf-Arno Valder, Commission des normes sanitaires pour les animaux terrestres de l'OIE.

E.A. SPOTTS WHITNEY, M.E. BEATTY, T.H. R.J. TAYLOR, R. WEYANT, J. SOBEL, M.J. ARDUINO & D.A. ASHFORD. (2003). Inactivation of *Bacillus anthracis* spores. *Emerging Infectious Diseases*, 9 (6), 623–627.

Article 8.1.9.

~~Recommendations for importation of~~ Procedures for the inactivation of *B. anthracis* spores in skins and trophies from wild animals

~~*Veterinary Authorities* should require the presentation of an *international veterinary certificate* attesting that these products have been processed to ensure the destruction of *B. anthracis* by one of the following methods:~~

In situations in which skins and trophies from wild animals may be contaminated with *B. anthracis* spores, the following *disinfection* procedure is recommended:

1. fumigation with ethylene oxide 500 mg/L, at relative humidity 20-40%, at 55 °C for 30 minutes; or

2. fumigation with formaldehyde 400 mg/m^3, at relative humidity 30%, at >15 °C for 4 hours; or

3. fumigation with methylene bromide 3.4-3.9 g/L, in the presence of moisture, at room temperature for 24 hours; or

4. gamma irradiation with a dose of 40 kGy.

References

REINHARD BÖHM. Institut fur Umwelt-und Tierhygiene Sowie Tiermedizin mit Tierklinik, Universität Hohenheim. Communication personnelle au Dr Wolf-Arno Valder, Commission des normes sanitaires pour les animaux terrestres de l'OIE.

P. TURNBULL P. & O. COSIVI. (2008). Anthrax in humans and animals, 4th Edition, WHO/FAO/OIE

E.A. SPOTTS WHITNEY, M.E. BEATTY, T.H. R.J. TAYLOR, R. WEYANT, J. SOBEL, M.J. ARDUINO & D.A. ASHFORD. (2003). Inactivation of *Bacillus anthracis* spores. *Emerging Infectious Diseases*, 9 (6), 623–627.

Article 8.1.10.

Procedures for the inactivation of *B. anthracis* spores in bone-meal and meat-and-bone meal

The following procedure should be used to inactivate any *B. anthracis* spores which may be present during the production of bone-meal or meat-and-bone meal from ruminants, equines and pigs:

1. the raw material should be reduced to a maximum particle size of 50 mm before heating; and

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.

References

REINHARD BÖHM. Institut fur Umwelt-und Tierhygiene Sowie Tiermedizin mit Tierklinik, Universität Hohenheim. Communication personnelle au Dr Wolf-Arno Valder, Commission des normes sanitaires pour les animaux terrestres de l'OIE.

P. TURNBULL P. & O. COSIVI. (2008). Anthrax in humans and animals, 4th Edition, WHO/FAO/OIE

Article 8.1.11.

Procedures for the inactivation of *B. anthracis* spores in wool and hair

In situations in which wool or hair may be contaminated with *B. anthracis* spores, the following five-step *disinfection* procedure is recommended:

1. immersion in 0.25-0.3% soda liquor for 10 minutes at 450.5 °C;
2. immersion in soap liquor for 10 minutes at 450.5 °C;
3. immersion in 2% formaldehyde solution for 10 minutes at 450.5 °C;
4. a second immersion in 2% formaldehyde solution for 10 minutes at 450.5 °C;
5. rinsing on cold water followed by drying in hot air.

References

REINHARD BÖHM. Institut fur Umwelt-und Tierhygiene Sowie Tiermedizin mit Tierklinik, Universität Hohenheim. Communication personnelle au Dr Wolf-Arno Valder, Commission des normes sanitaires pour les animaux terrestres de l'OIE.

P. TURNBULL P. & O. COSIVI. (2008). Anthrax in humans and animals, 4th Edition, WHO/FAO/OIE

Article 8.1.12.

Procedures for the inactivation of *B. anthracis* spores in manure, dung and bedding

In situations in which manure, dung or bedding may be contaminated with *B. anthracis* spores, the following are recommended:

1. small volumes by incineration; or
2. chemothermal treatment by composting with quicklime as follows:
   a) mix the manure with granulated quicklime at a rate of 100 kg quicklime per m^3 and spray with water;
   b) turn the material after 5 weeks;
   c) leave for a further 5 weeks.

Note: spontaneous combustion of the composting pile is possible.

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References

REINHARD BÖHM. Institut fur Umwelt-und Tierhygiene Sowie Tiermedizin mit Tierklinik, Universität Hohenheim. Communication personnelle au Dr Wolf-Arno Valder, Commission des normes sanitaires pour les animaux terrestres de l'OIE.

Article 8.1.13.

Procedures for the inactivation of *B. anthracis* spores in liquid manure (slurry)

In situations in which liquid manure (slurry) may be contaminated with *B. anthracis* spores, the following is recommended:

1. *disinfection* with formalin (35% aqueous solution of formaldehyde) with stirring one hour stirring daily;

   a) for slurry up to 5% dry matter, 50 kg formalin per m^3 for 4 days;

   b) for slurry >5% and <10% dry matter, 100 kg formalin per m^3 for 4 days.

References

REINHARD BÖHM. Institut fur Umwelt-und Tierhygiene Sowie Tiermedizin mit Tierklinik, Universität Hohenheim. Communication personnelle au Dr Wolf-Arno Valder, Commission des normes sanitaires pour les animaux terrestres de l'OIE.

P. TURNBULL P. & O. COSIVI. (2008). Anthrax in humans and animals, 4th Edition, WHO/FAO/OIE.

Article 8.1.14.

Procedures for the disinfection of surfaces in animal houses, buildings contaminated with *B. anthracis*

In situations in which surfaces in animal houses, stables, *vehicles*, etc. may be contaminated with *B. anthracis* spores, the following three-step approach is recommended:

1. a preliminary *disinfection* should be carried out using one of the following disinfectants at a rate of 1-1.5 L/m^3 for 2 hours;

   a) 10% formaldehyde (approximately 30% formalin); or

   b) 4% glutaraldehyde (pH 8.0-8.5);

2. all surfaces should be washed and scrubbed using ample hot water and, when cleaned and waste water is free from dirt particles, dried;

3. a final *disinfection* step should be carried out using one of the following disinfectants applied at a rate of 0.4 L/m^3 for 2 hours;

   a) 10% formaldehyde (approximately 30% formalin), repeated after one hour; or

   b) 4% glutaraldehyde (pH 8.0-8.5), repeated after one hour; or

c) 3% hydrogen peroxide; or

d) 1% peracetic acid, repeated after one hour.

Note: Formaldehyde and glutaraldehyde should not be used at temperatures below 10 °C. Hydrogen peroxide and peracetic acid are not suitable in the presence of blood.

References

P. TURNBULL P. & O. COSIVI. (2008). Anthrax in humans and animals, 4th Edition, WHO/FAO/OIE.

E.A. SPOTTS WHITNEY, M.E. BEATTY, T.H. R.J. TAYLOR, R. WEYANT, J. SOBEL, M.J. ARDUINO & D.A. ASHFORD. (2003). Inactivation of *Bacillus anthracis* spores. *Emerging Infectious Diseases*, 9 (6), 623–627.

Article 8.1.15.

Procedures for the fumigation of rooms contaminated with *B. anthracis*

Contaminated rooms which cannot be cleared before cleaning and *disinfection* can be fumigated to eliminate *B. anthracis* spores. The following procedure is recommended:

1. all windows, doors and vents to the outside should be sealed with heavy adhesive tape; and

2. for rooms up to 30 m^3, 4 L of water containing 400 ml of concentrated formalin (37% w/v formaldehyde) in an electric kettle (with a timing switch to turn it off) should be boiled away and the room left overnight. Room temperature should be >15 °C.

Note: Formaldehyde fumigation is hazardous and proper respirators should be on hand for operator safety. The effectiveness of the fumigation process should be verified by exposing dried discs of filter paper which have been dipped in a suspension of spores of *B. subtilis* var *globigii* or *B. cereus* or Sterne vaccine strain of *B. anthracis* and placed in the room before fumigation is started. At the end of fumigation, the discs should be placed on nutrient agar plates containing 0.1% histidine and incubated overnight at 37 °C. If fumigation has been effective, there will be no bacterial growth.

References

P. TURNBULL P. & O. COSIVI. (2008). Anthrax in humans and animals, 4th Edition, WHO/FAO/OIE

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Annex XIX

CHAPTER 8.3.

BLUETONGUE

Article 8.3.1.

General provisions

For the purposes of the *Terrestrial Code*, the *infective period* for bluetongue virus (BTV) shall be 60 days.

Historically, t~~T~~he global BTV distribution ~~is~~ has been confined ~~currently~~ between the latitudes of approximately 53°N and north of 34°S with a recent extension in Northern Europe.

In the absence of clinical *disease* in a country or *zone* within this part of the world, its BTV status should be determined by an ongoing *surveillance* programme (in accordance with Articles 8.3.16. to 8.3.21.). The programme may need to be adapted to target parts of the country or *zone* at a higher risk due to historical, geographical and climatic factors, ruminant population data and *Culicoides* ecology, or proximity to enzootic or incursional zones as described in Articles 8.3.16. to 8.3.21.

All countries or *zones* adjacent to a country or *zone* not having free status should be subjected to similar *surveillance*. The *surveillance* should be carried out over a distance of at least 100 kilometres from the border with that country or *zone*, but a lesser distance could be acceptable if there are relevant ecological or geographical features likely to interrupt the transmission of BTV or a bluetongue *surveillance* programme (in accordance with Articles 8.3.16. to 8.3.21.) in the country or *zone* not having free status supports a lesser distance.

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

When authorising import or transit of the *commodities* covered in the chapter, *Veterinary Authorities* should require the conditions prescribed in this chapter relevant to the BTV status of the ruminant population of the *exporting country* or *zone*.

Article 8.3.2.

~~Trade in~~ Safe commodities

When authorising import or transit of the following *commodities*, *Veterinary Authorities* should not require any BTV related conditions regardless of the BTV status of the ruminant population of the *exporting country* or *zone*:

1. *milk* and *milk products*;
2. *meat* and *meat products*;
3. hides and skins;
4. wool and fiber;
5. *in vivo* derived bovine embryos and oocytes collected, processed and stored in conformity with the provisions of Chapters 4.7., except for BTV8 (under study)

~~When authorising import or transit of other *commodities* listed in this chapter, *Veterinary Authorities* should require the conditions prescribed in this chapter relevant to the BTV status of the ruminant population of the *exporting country* or *zone*.~~

Article 8.3.3.

BTV free country or zone

1. A country or a *zone* may be considered free from BTV when bluetongue is notifiable in the whole country and either:

   a) the country or *zone* lies wholly north of 53°N or south of 34°S, and is not adjacent to a country or *zone* not having a free status; or

   b) a *surveillance* programme in accordance with Articles 8.3.16. to 8.3.21. has demonstrated no evidence of BTV in the country or *zone* during the past 2 years; or

   c) a *surveillance* programme has demonstrated no evidence of *Culicoides* likely to be competent BTV vectors in the country or *zone*.

2. A BTV free country or *zone* in which ongoing vector *surveillance*, performed according to point 5 of Article 8.3.19., has found no evidence ~~that~~ of *Culicoides* ~~likely to be competent BTV vectors are present~~ will not lose its free status through the importation of vaccinated, seropositive or infective animals, or semen or embryos/ova from infected countries or *infected zones*.

3. A BTV free country or *zone* in which *surveillance* has found evidence that *Culicoides* likely to be competent BTV vectors are present will not lose its free status through the importation of vaccinated or seropositive animals from infected countries or *infected zones*, provided:

   a) the animals have been vaccinated, at least 60 days prior to dispatch, in accordance with the *Terrestrial Manual* with a vaccine which covers all serotypes whose presence has been demonstrated in the source population through a *surveillance* programme in accordance with Articles 8.3.16. to 8.3.21., and the animals are identified in the accompanying certification as having been vaccinated; or

   b) the animals are not vaccinated and ~~a *surveillance* programme in accordance with Articles 8.3.16. to 8.3.21. has been in place in the source population for a period of~~, at least 60 days ~~immediately~~ prior to dispatch~~, and no evidence of BTV transmission has been detected~~ are demonstrated to have specific antibodies against the bluetongue virus serotypes whose presence has been demonstrated in the *exporting country* or *zone*.

4. A BTV free country or *zone* adjacent to an infected country or *infected zone* should include a *zone* as described in Article 8.3.1. in which *surveillance* is conducted in accordance with Articles 8.3.16. to 8.3.21. Animals within this *zone* must be subjected to continuing *surveillance*. The boundaries of this *zone* must be clearly defined, and must take account of geographical and epidemiological factors that are relevant to BTV transmission.

Article 8.3.4.

BTV seasonally free zone

A BTV seasonally free *zone* is a part of an infected country or an *infected zone* for which for part of a year, *surveillance* demonstrates no evidence either of BTV transmission or of adult *Culicoides* likely to be competent BTV vectors.

For the application of Articles 8.3.7., 8.3.10. and 8.3.13., the seasonally free period is taken to commence the day following the last evidence of BTV transmission (as demonstrated by the *surveillance* programme), and of the cessation of activity of adult *Culicoides* likely to be competent BTV vectors.

For the application of Articles 8.3.7., 8.3.10. and 8.3.13., the seasonally free period is taken to conclude either:

1. at least 28 days before the earliest date that historical data show bluetongue virus activity has recommenced; or

2. immediately if current climatic data or data from a *surveillance* programme indicate an earlier resurgence of activity of adult *Culicoides* likely to be competent BTV vectors.

A BTV seasonally free *zone* in which *surveillance* has found no evidence that *Culicoides* likely to be competent BTV vectors are present will not lose its free status through the importation of vaccinated, seropositive or infective animals, or semen or embryos/ova from infected countries or *infected zones*.

Article 8.3.5.

BTV infected country or zone

A BTV infected country or *infected zone* is a clearly defined area where evidence of BTV has been reported during the past 2 years.

Article 8.3.6.

Recommendations for importation from BTV free countries or zones

for ruminants and other BTV susceptible herbivores

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

1. the animals were kept in a BTV free country or *zone* since birth or for at least 60 days prior to shipment; or

2. the animals were kept in a BTV free country or *zone* for at least 28 days, then were subjected, with negative results, to a serological test to detect antibody to the BTV group according to the *Terrestrial Manual* and remained in the BTV free country or *zone* until shipment; or

3. the animals were kept in a BTV free country or *zone* for at least 7 days, then were subjected, with negative results, to an agent identification test according to the *Terrestrial Manual*, and remained in the BTV free country or *zone* until shipment; or

4. the animals:
   a) were kept in a BTV free country or *zone* for at least 7 days;
   b) were vaccinated, at least 60 days before the introduction into the free country or *zone*, in accordance with the *Terrestrial Manual* against all serotypes whose presence has been demonstrated in the source population through a *surveillance* programme as described in Articles 8.3.16. to 8.3.21.;
   c) were identified as having been vaccinated; and
   d) remained in the BTV free country or *zone* until shipment;

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AND

5. if the animals were exported from a free *zone*, either:

   a) did not transit through an *infected zone* during transportation to the *place of shipment*; or

   b) were protected from attack from *Culicoides* likely to be competent BTV vectors at all times when transiting through an *infected zone*; or

   c) had been vaccinated in accordance with point 4 above.

Article 8.3.7.

Recommendations for importation from BTV seasonally free zones

for ruminants and other BTV susceptible herbivores

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

1. were kept during the seasonally free period in a BTV seasonally free *zone* since birth or for at least 60 days prior to shipment; or

2. were kept during the BTV seasonally free period in a BTV seasonally free *zone* for at least 28 days prior to shipment, and were subjected during the residence period in the *zone* to a serological test to detect antibody to the BTV group according to the *Terrestrial Manual*, with negative results, carried out at least 28 days after the commencement of the residence period; or

3. were kept during the BTV seasonally free period in a BTV seasonally free *zone* for at least 14 days prior to shipment, and were subjected during the residence period in the *zone* to an agent identification test according to the *Terrestrial Manual*, with negative results, carried out at least 14 days after the commencement of the residence period; or

4. were kept during the seasonally free period in a BTV seasonally free *zone* and were vaccinated, at least 60 days before the introduction into the free country or *zone*, in accordance with the *Terrestrial Manual* against all serotypes whose presence has been demonstrated in the source population through a *surveillance* programme in accordance with Articles 8.3.16. to 8.3.21. and were identified as having been vaccinated and remained in the BTV free country or *zone* until shipment;

AND

5. if the animals were exported from a free *zone*, either:

   a) did not transit through an *infected zone* during transportation to the *place of shipment*; or

   b) were protected from attack from *Culicoides* likely to be competent BTV vectors at all times when transiting through an *infected zone*; or

   c) were vaccinated in accordance with point 4 above.

Article 8.3.8.

Recommendations for importation from BTV infected countries or zones

for ruminants and other BTV susceptible herbivores

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

1. were protected from attack from *Culicoides* likely to be competent BTV vectors in an insect proof *establishment* for at least 60 days prior to shipment and during transportation to the *place of shipment*; or

2. were protected from attack from *Culicoides* likely to be competent BTV vectors in an insect proof *establishment* for at least 28 days prior to shipment and during transportation to the *place of shipment*, and were subjected during that period to a serological test according to the *Terrestrial Manual* to detect antibody to the BTV group, with negative results, carried out at least 28 days after introduction into the ~~*quarantine station*~~ insect proof *establishment*; or

3. were protected from attack from *Culicoides* likely to be competent BTV vectors in an insect proof *establishment* for at least 14 days prior to shipment and during transportation to the *place of shipment*, and were subjected during that period to an agent identification test according to the *Terrestrial Manual*, with negative results, carried out at least 14 days after introduction into the ~~*quarantine station*~~ insect proof *establishment*; or

4. were vaccinated, at least 60 days before shipment, in accordance with the *Terrestrial Manual* against all serotypes whose presence has been demonstrated in the source population through a *surveillance* programme in accordance with Articles 8.3.16. to 8.3.21., and were identified in the accompanying certification as having been vaccinated or,

5. ~~if animals~~ demonstrated to have antibodies for at least 60 days prior to dispatch against all serotypes whose presence has been demonstrated in the source population through a *surveillance* programme in accordance with Articles 8.3.16. to 8.3.21.~~, have been protected from vectors for at least 60 days prior to shipment; or~~

~~5. are not vaccinated, a *surveillance* programme in accordance with Articles 8.3.16. to 8.3.21. has been in place in the source population for a period of at least 60 days immediately prior to shipment, and no evidence of BTV transmission has been detected and were protected from attack from *Culicoides* likely to be competent BTV vectors during transportation to the *place of shipment*.~~

Article 8.3.9.

Recommendations for importation from BTV free countries or zones

for semen of ruminants and other BTV susceptible herbivores

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

1. the donor animals:

   a) were kept in a BTV free country or *zone* for at least 60 days before commencement of, and during, collection of the semen; or

b) were subjected to a serological test according to the *Terrestrial Manual* to detect antibody to the BTV group, between 21 and 60 days after the last collection for this consignment, with negative results; or

c) were subjected to an agent identification test according to the *Terrestrial Manual* on blood samples collected at commencement and conclusion of, and at least every 7 days (virus isolation test) or at least every 28 days (PCR test) during, semen collection for this consignment, with negative results;

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

Article 8.3.10.

Recommendations for importation from BTV seasonally free zones

for semen of ruminants and other BTV susceptible herbivores

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

1. the donor animals:

   a) were kept during the BTV seasonally free period in a seasonally free *zone* for at least 60 days before commencement of, and during, collection of the semen; or

   b) were subjected to a serological test according to the *Terrestrial Manual* to detect antibody to the BTV group, with negative results, at least every 60 days throughout the collection period and between 21 and 60 days after the final collection for this consignment; or

   c) were subjected to an agent identification test according to the *Terrestrial Manual* on blood samples collected at commencement and conclusion of, and at least every 7 days (virus isolation test) or at least every 28 days (PCR test) during, semen collection for this consignment, with negative results;

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

Article 8.3.11.

Recommendations for importation from BTV infected countries or zones

for semen of ruminants and other BTV susceptible herbivores

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

1. the donor animals:

   a) were protected from attack from *Culicoides* likely to be competent BTV vectors for at least 60 days before commencement of, and during, collection of the semen; or

   b) were subjected to a serological test according to the *Terrestrial Manual* to detect antibody to the BTV group, with negative results, at least every 60 days throughout the collection period and between 21 and 60 days after the final collection for this consignment; or

c) were subjected to an agent identification test according to the *Terrestrial Manual* on blood samples collected at commencement and conclusion of, and at least every 7 days (virus isolation test) or at least every 28 days (PCR test) during, semen collection for this consignment, with negative results;

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

Article 8.3.12.

Recommendations for importation from BTV free countries or zones

for *in vivo* derived embryos of ruminants (other than bovines) and other BTV susceptible herbivores and for *in vitro* produced bovine embryos

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

1. the donor females:

   a) were kept in a BTV free country or *zone* for at least the 60 days prior to, and at the time of, collection of the embryos; or

   b) were subjected to a serological test according to the *Terrestrial Manual* to detect antibody to the BTV group, between 21 and 60 days after collection, with negative results; or

   c) were subjected to an agent identification test according to the *Terrestrial Manual* on a blood sample taken on the day of collection, with negative results;

2. the embryos were collected, processed and stored in conformity with the provisions of Chapter 4.7., Chapter 4.8. and Chapter 4.9., as relevant.

Article 8.3.13.

Recommendations for importation from BTV seasonally free zones

for *in vivo* derived embryos/oocytes of ruminants (other than bovines) and other BTV susceptible herbivores and for *in vitro* produced bovine embryos

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

1. the donor females:

   a) were kept during the seasonally free period in a seasonally free *zone* for at least 60 days before commencement of, and during, collection of the embryos/oocytes; or

   b) were subjected to a serological test according to the *Terrestrial Manual* to detect antibody to the BTV group, between 21 and 60 days after collection, with negative results; or

   c) were subjected to an agent identification test according to the *Terrestrial Manual* on a blood sample taken on the day of collection, with negative results;

2. the embryos/oocytes were collected, processed and stored in conformity with the provisions of Chapter 4.7., Chapter 4.8. and Chapter 4.9., as relevant.

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Article 8.3.14.

Recommendations for importation from BTV infected countries or zones

for *in vivo* derived embryos/oocytes of ruminants (other than bovines) and other BTV susceptible herbivores and for *in vitro* produced bovine embryos

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

1. the donor females:

    a) were protected from attack from *Culicoides* likely to be competent BTV vectors for at least 60 days before commencement of, and during, collection of the embryos/oocytes; or

    b) were subjected to a serological test according to the *Terrestrial Manual* to detect antibody to the BTV group, between 21 and 60 days after collection, with negative results; or

    c) were subjected to an agent identification test according to the *Terrestrial Manual* on a blood sample taken on the day of collection, with negative results;

2. the embryos/oocytes were collected, processed and stored in conformity with the provisions of Chapter 4.7., Chapter4.8. and Chapter 4.9., as relevant.

Article 8.3.15.

Protecting animals from *Culicoides* attack

When transporting animals through BTV infected countries or *infected zones*, *Veterinary Authorities* should require strategies to protect animals from attack from *Culicoides* likely to be competent BTV vectors during transport, taking into account the local ecology of the vector.

Potential *risk management* strategies include:

1. treating animals with insect repellents prior to and during transportation;

2. *loading*, transporting and *unloading* animals at times of low vector activity (i.e. bright sunshine, low temperature);

3. ensuring *vehicles* do not stop en route during dawn or dusk, or overnight, unless the animals are held behind insect proof netting;

4. darkening the interior of the *vehicle*, for example by covering the roof and/or sides of *vehicles* with shadecloth;

5. *surveillance* for vectors at common stopping and offloading points to gain information on seasonal variations;

6. using historical information ~~, ongoing~~ and/or ~~BTV modelling~~ information from appropriately verified and validated BTV epidemiological models to identify low risk ports and transport routes.

Article 8.3.16.

Surveillance: introduction

Articles 8.3.16. to 8.3.21. define the principles and provide a guide on the *surveillance* for BT complementary to Chapter 1.4., applicable to Members seeking to determine their BT status. This may be for the entire country or *zone*. Guidance for Members seeking free status following an *outbreak* and for the maintenance of BT status is also provided.

BT is a vector-borne infection transmitted by different species of *Culicoides* insects in a range of ecosystems. An important component of BT epidemiology is vectorial capacity which provides a measure of *disease risk* that incorporates vector competence, abundance, biting rates, survival rates and extrinsic *incubation period*. However, methods and tools for measuring some of these vector factors remain to be developed, particularly in a field context. Therefore, *surveillance* for BT should focus on transmission in domestic ruminants.

Susceptible wild ruminant populations should be included in *surveillance* when these animals are intended for trade.

The impact and epidemiology of BT differ widely in different regions of the world and therefore it is impossible to provide specific recommendations for all situations. It is incumbent upon Members to provide scientific data that explain the epidemiology of BT in the region concerned and adapt the *surveillance* strategies for defining their infection status (free, seasonally free or infected country or *zone*) to the local conditions. There is considerable latitude available to Members to justify their infection status at an acceptable level of confidence.

Surveillance for BT should be in the form of a continuing programme.

Article 8.3.17.

Surveillance: case definition

For the purposes of *surveillance*, a *case* refers to an animal infected with BT virus (BTV).

For the purposes of *international trade*, a distinction must be made between a *case* as defined below and an animal that is potentially infectious to vectors. The conditions for trade are defined in Articles 8.3.1. to 8.3.15. of this chapter.

The purpose of *surveillance* is the detection of virus circulation in a country or *zone* and not determination of the status of an individual animal or *herds*. *Surveillance* deals not only with the occurrence of clinical signs caused by BTV, but also with the evidence of *infection* with BTV in the absence of clinical signs.

The following defines the occurrence of BTV infection:

1. BTV has been isolated and identified as such from an animal or a product derived from that animal, or

2. viral antigen or viral ribonucleic acid (RNA) specific to one or more of the serotypes of BTV has been identified in samples from one or more animals showing clinical signs consistent with BT, or epidemiologically linked to a confirmed or suspected *case*, or giving cause for suspicion of previous association or contact with BTV, or

3. antibodies to structural or nonstructural proteins of BTV that are not a consequence of vaccination have been identified in one or more animals that either show clinical signs consistent with BT, or epidemiologically linked to a confirmed or suspected *case*, or give cause for suspicion of previous association or contact with BTV.

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Article 8.3.18.

Surveillance: general conditions and methods

1. A *surveillance* system in accordance with Chapter 1.4. should be under the responsibility of the *Veterinary Authority*. In particular:

   a) a formal and ongoing system for detecting and investigating *outbreaks of disease* should be in place;

   b) a procedure should be in place for the rapid collection and transport of samples from suspect *cases* of BT to a *laboratory* for BT diagnosis as described in the *Terrestrial Manual*;

   c) a system for recording, managing and analysing diagnostic and *surveillance* data should be in place.

2. The BT *surveillance* programme should:

   a) in a country/*zone* free or seasonally free, include an early warning system for reporting suspicious *cases*. Farmers and workers, who have ~~day-to-day~~ regular contact with domestic ruminants, as well as diagnosticians, should report promptly any suspicion of BT to the *Veterinary Authority*. They should be supported directly or indirectly (e.g. through private *veterinarians* or *Veterinary para-professionals*) by government information programmes and the *Veterinary Authority*. An effective *surveillance* system will periodically identify suspicious *cases* that require follow-up and investigation to confirm or exclude that the cause of the condition is BTV. The rate at which such suspicious *cases* are likely to occur will differ between epidemiological situations and cannot therefore be predicted reliably. All suspected *cases* of BT should be investigated immediately and samples should be taken and submitted to a *laboratory*. This requires that sampling kits and other equipment are available for those responsible for *surveillance*;

   b) conduct random or targeted serological and virological *surveillance* appropriate to the infection status of the country or *zone*.

Generally, the conditions to prevent exposure of susceptible animals to BTV infected vectors will be difficult to apply. However, under specific situations, in establishments such as *artificial insemination centres* or *quarantine stations* exposure to vectors may be preventable. The testing requirements for animals kept in these facilities are described in Articles 8.3.11. and 8.3.14.

Article 8.3.19.

Surveillance strategies

The target population for *surveillance* aimed at identification of *disease* and/or *infection* should cover susceptible domestic ruminants within the country or *zone*. Active and passive *surveillance* for BTV infection should be ongoing. *Surveillance* should be composed of random or targeted approaches using virological, serological and clinical methods appropriate for the infection status of the country or *zone*.

The strategy employed may be based on *surveillance* using randomised sampling that would demonstrate the absence of BTV infection at an acceptable level of confidence. The frequency of sampling should be dependent on the epidemiological situation. Random *surveillance* is conducted using serological tests described in the *Terrestrial Manual*. Positive serological results may be followed up with virological methods as appropriate.

Targeted *surveillance* (e.g. based on the increased likelihood of *infection* in particular localities or species) may be an appropriate strategy. Virological and serological methods may be used concurrently to define the BTV status of targeted populations.

A Member should justify the *surveillance* strategy chosen as being adequate to detect the presence of BTV infection in accordance with Chapter 1.4. and the prevailing epidemiological situation. It may, for example, be appropriate to target clinical *surveillance* at particular species likely to exhibit clinical signs (e.g. sheep). Similarly, virological and serological testing may be targeted to species that rarely show clinical signs (e.g. cattle).

In vaccinated populations, serological and virological *surveillance* is necessary to detect the BTV types circulating to ensure that all circulating types are included in the vaccination programme.

If a Member wishes to declare freedom from BTV infection in a specific *zone*, the design of the *surveillance* strategy would need to be aimed at the population within the *zone*.

For random surveys, the design of the sampling strategy will need to incorporate epidemiologically appropriate design prevalence. The sample size selected for testing will need to be large enough to detect evidence of *infection* if it were to occur at a predetermined minimum rate. The sample size and expected prevalence determine the level of confidence in the results of the survey. The Member must justify the choice of design prevalence and confidence level based on the objectives of *surveillance* and the epidemiological situation, in accordance with Chapter 1.4. Selection of the design prevalence in particular needs to be based on the prevailing or historical epidemiological situation.

Irrespective of the survey approach selected, the sensitivity and specificity of the diagnostic tests employed are key factors in the design, sample size determination and interpretation of the results obtained. Ideally, the sensitivity and specificity of the tests used should be validated for the vaccination/*infection* history and the different species in the target population.

Irrespective of the testing system employed, *surveillance* system 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 needs to be an effective procedure for following up positives to ultimately determine with a high level of confidence, whether they are indicative of *infection* or not. This should involve both supplementary tests and follow-up investigation to collect diagnostic material from the original sampling unit as well as those which may be epidemiologically linked to it.

The principles involved in *surveillance* for *disease*/*infection* are technically well defined. The design of *surveillance* programmes to prove the absence of BTV *infection*/circulation needs to be carefully followed to avoid producing results that are either insufficiently reliable to be accepted by international trading partners, or excessively costly and logistically complicated. The design of any *surveillance* programme, therefore, requires inputs from professionals competent and experienced in this field.

1. Clinical surveillance

   Clinical *surveillance* aims at the detection of clinical signs of BT at the *flock*/*herd* level. Whereas significant emphasis is placed on the diagnostic value of mass serological screening, *surveillance* based on clinical inspection should not be underrated, particularly during a newly introduced *infection*. In sheep and occasionally goats, clinical signs may include oedema, hyperaemia of mucosal membranes, coronitis and cyanotic tongue.

   BT suspects detected by clinical *surveillance* should always be confirmed by *laboratory* testing.

2. Serological surveillance

An active programme of *surveillance* of host populations to detect evidence of BTV transmission is essential to establish BTV status in a country or *zone*. Serological testing of ruminants is one of the most effective methods of detecting the presence of BTV. The species tested depends on the epidemiology of BTV infection, and the species available, in the local area. Cattle are usually the most sensitive indicator species. Management variables that may influence likelihood of *infection*, such as the use of insecticides and animal housing, should be considered.

Surveillance may include serological surveys, for example *abattoir* surveys, the use of cattle as sentinel animals (which must be individually identifiable), or a combination of methods. *Surveillance* may also be conducted by sampling and testing of bulk milk using an ELISA, as prescribed in the *Terrestrial Manual*.

The objective of serological *surveillance* is to detect evidence of BTV circulation. Samples should be examined for antibodies against BTV using tests prescribed in the *Terrestrial Manual*. Positive BTV antibody tests results can have four possible causes:

a natural *infection* with BTV,

b vaccination against BTV,

c) maternal antibodies,

d) positive results due to the lack of specificity of the test.

It may be possible to use sera collected for other survey purposes for BTV *surveillance*. However, the principles of survey design described in these recommendations and the requirements for a statistically valid survey for the presence of BTV infection should not be compromised.

The results of random or targeted serological surveys are important in providing reliable evidence that no BTV infection is present in a country or *zone*. It is, therefore, essential that the survey is thoroughly documented. It is critical to interpret the results in light of the movement history of the animals being sampled.

Serological *surveillance* in a free *zone* should target those areas that are at highest risk of BTV transmission, based on the results of previous *surveillance* and other information. This will usually be towards the boundaries of the free *zone*. In view of the epidemiology of BTV infection, either random or targeted sampling is suitable to select *herds* and/or animals for testing.

A *protection zone* within a free country or *zone* should separate it from a potentially infected country or *infected zone*. Serological *surveillance* in a free country or *zone* should be carried out over an appropriate distance from the border with a potentially infected country or *infected zone*, based upon geography, climate, history of *infection* and other relevant factors.

Serological *surveillance* in *infected zones* will identify changes in the boundary of the zone, and can also be used to identify the BTV types circulating. In view of the epidemiology of BTV infection, either random or targeted sampling is suitable.

3. Virological surveillance

Isolation and genetic analysis of BTV from a proportion of infected animals is beneficial in terms of providing information on serotype and genetic characteristics of the viruses concerned.

Virological *surveillance* using tests described in the *Terrestrial Manual* can be conducted:

a) to identify virus circulation in at risk populations,

b) to confirm clinically suspect *cases*,

c) to follow up positive serological results,

d) to better characterize the genotype of circulating virus in a country or *zone*.

4. Sentinel animals

Sentinel animals are a form of targeted *surveillance* with a prospective study design. They are the preferred strategy for BTV *surveillance*. They comprise groups of unexposed animals managed at fixed locations and sampled regularly to detect new BTV *infections*.

The primary purpose of a sentinel animal programme is to detect BTV infections occurring at a particular place, for instance sentinel groups may be located on the usual boundaries of *infected zones* to detect changes in distribution of BTV. In addition, sentinel animal programmes allow the timing and dynamics of *infections* to be observed.

A sentinel animal programme should use animals of known source and history of exposure, control management variables such as use of insecticides and animal housing (depending on the epidemiology of BTV in the area under consideration), and be flexible in its design in terms of sampling frequency and choice of tests.

Care is necessary in choosing the sites for the sentinel groups. The aim is to maximise the chance of detecting BTV activity at the geographical location for which the sentinel site acts as a sampling point. The effect of secondary factors that may influence events at each location, such as climate, may also be analysed. To avoid bias, sentinel groups should comprise animals selected to be of similar age and susceptibility to BTV infection. Cattle are the most appropriate sentinels but other domestic ruminant species may be used. The only feature distinguishing groups of sentinels should be their geographical location.

Sera from sentinel animal programmes should be stored methodically in a serum bank to allow retrospective studies to be conducted in the event of new serotypes being isolated.

The frequency of sampling will depend on the reason for choosing the sampling site. In endemic areas, virus isolation will allow monitoring of the serotypes and genotypes of BTV circulating during each time period. The borders between infected and non infected areas can be defined by serological detection of *infective period*. Monthly sampling intervals are frequently used. Sentinels in declared free *zones* add to confidence that BTV *infections* are not occurring unobserved. In such cases, sampling prior to and after the possible period of transmission is sufficient.

Definitive information on BTVs circulating in a country or *zone* is provided by isolation and identification of the viruses. If virus isolation is required, sentinels should be sampled at sufficiently frequent intervals to ensure that samples are collected during the period of viraemia.

5. Vector surveillance

BTV is transmitted between ruminant hosts by species of *Culicoides* which vary across the world. It is therefore important to be able to identify potential vector species accurately although many such species are closely related and difficult to differentiate with certainty.

The main purpose of vector *surveillance* is to determine areas of different levels of risk ~~define high, medium and low-risk areas~~ and local details of seasonality by determining the various vector 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 suppression measures.

The most effective way of gathering this information should take account of the biology and behavioural characteristics of the local vector species of *Culicoides* and may include the use of Onderstepoort-type light traps or similar, operated from dusk to dawn in locations adjacent to domestic ruminants, or the use of drop traps over ruminant animals.

Vector *surveillance* should be based on scientific sampling techniques. The choice of the number and type of traps to be used in vector *surveillance* and the frequency of their use should take into account the size and ecological characteristics of the area to be surveyed.

The operation of vector *surveillance* sites at the same locations as sentinel animals is advisable.

The use of a vector *surveillance* system to detect the presence of circulating virus is not recommended as a routine procedure as the typically low vector infection rates mean that such detections can be rare. Other *surveillance* strategies (e.g. the use of sentinel animals of domestic ruminants) are preferred to detect virus circulation.

Article 8.3.20.

Documentation of BTV infection free status

1. Members declaring freedom from BTV infection for the country or zone: additional surveillance procedures

In addition to the general conditions described in the above-mentioned articles, a Member declaring freedom from BTV infection for the entire country or a *zone* should provide evidence for the existence of an effective *surveillance* programme. The strategy and design of the *surveillance* programme will depend on the prevailing epidemiological circumstances and should be planned and implemented according to general conditions and methods described in this chapter, to demonstrate absence of BTV infection during the preceding 24 months in susceptible domestic ruminant populations. This requires the support of a *laboratory* able to undertake identification of BTV infection through virus detection and antibody tests described in the *Terrestrial Manual*. This *surveillance* should be targeted to non-vaccinated animals. Clinical *surveillance* may be effective in sheep while serological *surveillance* is more appropriate in cattle.

2. Additional requirements for countries or zones that practise vaccination

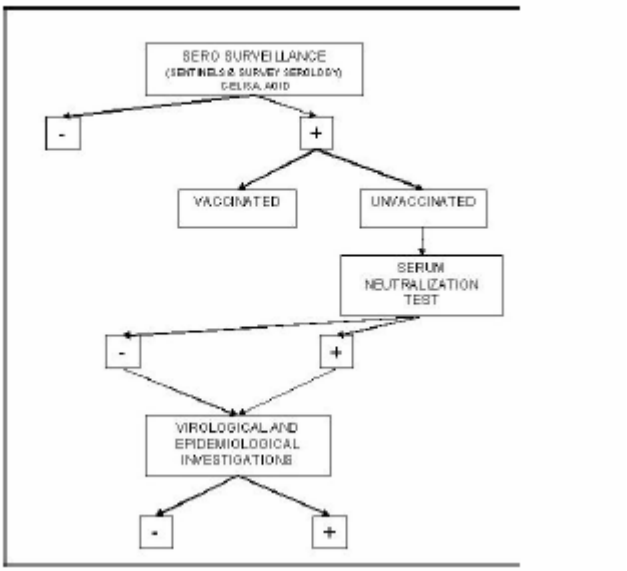
Vaccination to prevent the transmission of BTV may be part of a disease control programme. The level of *flock* or *herd* immunity required to prevent transmission will depend on the *flock* or *herd* size, composition (e.g. species) and density of the susceptible population. It is therefore impossible to be prescriptive. The vaccine must also comply with the provisions stipulated for BTV vaccines in the *Terrestrial Manual*. Based on the epidemiology of BTV *infection* in the country or *zone*, it may be that a decision is reached to vaccinate only certain species or other subpopulations.

In countries or *zones* that practise vaccination, there is a need to perform virological and serological tests to ensure the absence of virus circulation. These tests should be performed on non-vaccinated subpopulations or on sentinels. The tests have to be repeated at appropriate intervals according to the purpose of the *surveillance* programme. For example, longer intervals may be adequate to confirm endemicity, while shorter intervals may allow on-going demonstration of absence of transmission.

Article 8.3.21.

The use and interpretation of serological and virus detection tests

Fig. 1. Application of laboratory tests in serological surveillance



1. Serological testing

Ruminants infected with BTV produce antibodies to structural and non-structural viral proteins, as do animals vaccinated with current modified live virus vaccines. Antibodies to the BTV serogroup antigen are detected with high sensitivity and specificity by competitive ELISA (c-ELISA) and to a lesser extent by AGID as described in the *Terrestrial Manual*. Positive c-ELISA results can be confirmed by neutralization assay to identify the infecting serotype(s); however, BTV infected ruminants can produce neutralizing antibodies to serotypes of BTV other than those to which they were exposed (false positive results), especially if they have been infected with multiple serotypes.

2. Virus detection

The presence of BTV in ruminant blood and tissues can be detected by virus isolation or polymerase chain reaction (PCR) as described in the *Terrestrial Manual*.

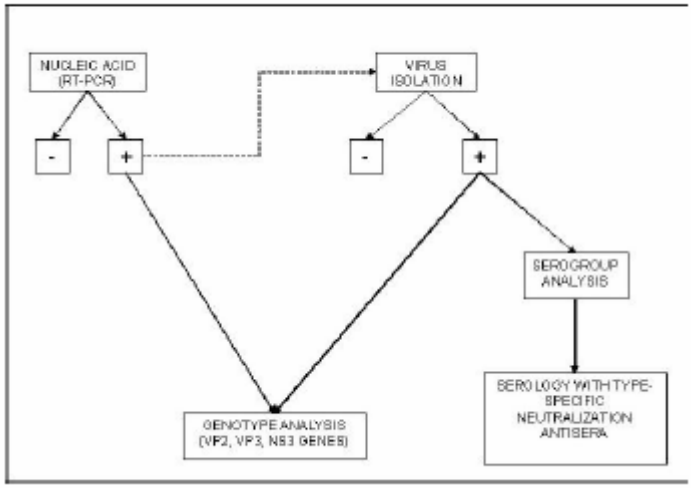
Interpretation of positive and negative results (both true and false) differs markedly between these tests because they detect different aspects of BTV *infection*, specifically (1) infectious BTV (virus isolation) and (2) nucleic acid (PCR). The following are especially relevant to interpretation of PCR assays:

a) The nested PCR assay detects BTV nucleic acid in ruminants long after the clearance of infectious virus. Thus positive PCR results do not necessarily coincide with active *infection* of ruminants. Furthermore, the nested PCR assay is especially prone to template contamination, thus there is considerable risk of false positive results.

b) PCR procedures other than real time PCR allow sequence analysis of viral amplicons from ruminant tissues, insect vectors or virus isolates. These sequence data are useful for creating data bases to facilitate important epidemiological studies, including the possible distinction of field and vaccine virus strains of BTV, genotype characterization of field strains of BTV, and potential genetic divergence of BTV relevant to vaccine and diagnostic testing strategies.

It is essential that BTV isolates are sent regularly to the OIE Reference Laboratories for genetic and antigenic characterization.

Fig. 2. Application of laboratory tests in virological surveillance



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Annex XX

CHAPTER 8.5.

FOOT AND MOUTH DISEASE

Article 8.5.1.

Introduction

For the purposes of the *Terrestrial Code*, the *incubation period* for foot and mouth disease (FMD) shall be 14 days.

For the purposes of this Chapter, ruminants include animals of the family of Camelidae (except *Camelus dromedarius*).

For the purposes of this Chapter, a *case* includes an animal infected with FMD virus (FMDV).

For the purposes of *international trade*, this Chapter deals not only with the occurrence of clinical signs caused by FMDV, but also with the presence of infection with FMDV in the absence of clinical signs.

The following defines the occurrence of FMDV infection:

1. FMDV has been isolated and identified as such from an animal or a product derived from that animal; or

2. viral antigen or viral ribonucleic acid (RNA) specific to one or more of the serotypes of FMDV has been identified in samples from one or more animals, whether showing clinical signs consistent with FMD or not, or epidemiologically linked to a confirmed or suspected *outbreak* of FMD, or giving cause for suspicion of previous association or contact with FMDV; or

3. antibodies to structural or nonstructural proteins of FMDV that are not a consequence of vaccination, have been identified in one or more animals showing clinical signs consistent with FMD, or epidemiologically linked to a confirmed or suspected *outbreak* of FMD, or giving cause for suspicion of previous association or contact with FMDV.

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

Article 8.5.2.

FMD free country where vaccination is not practised

Susceptible animals in the FMD free country where vaccination is not practised should be protected from neighbouring infected countries by the application of animal health measures that effectively prevent the entry of the virus, taking into consideration physical or geographical barriers. These measures may include a *protection zone*.

To qualify for inclusion in the existing list of FMD free countries where vaccination is not practised, a Member should:

1. have a record of regular and prompt animal disease reporting;

2. send a declaration to the OIE stating that:

   a) there has been no *outbreak* of FMD during the past 12 months;

   b) no evidence of FMDV infection has been found during the past 12 months;

   c) no vaccination against FMD has been carried out during the past 12 months;

   d) no vaccinated animal has been introduced since the cessation of vaccination;

3. supply documented evidence that:

   a) *surveillance* for ~~both~~ FMD and FMDV infection in accordance with Articles 8.5.40. to 8.5.46. is in operation;

   b) regulatory measures for the early detection, prevention and control of FMD have been implemented.

4. describe in detail the boundaries and measures of a *protection zone*, if applicable.

The Member will be included in the list only after the submitted evidence has been accepted by the OIE. Retention on the list requires that the information in points 2, ~~3b)~~ 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 according to the requirements in Chapter 1.1.

Article 8.5.3.

FMD free country where vaccination is practised

Susceptible animals in the FMD free country where vaccination is practised should be protected from neighbouring infected countries by the application of animal health measures that effectively prevent the entry of the virus, taking into consideration physical or geographical barriers. These measures may include a *protection zone*.

To qualify for inclusion in the list of FMD free countries where vaccination is practised, a Member should:

1. have a record of regular and prompt animal disease reporting;

2. send a declaration to the OIE stating that ~~there has been no *outbreak* of FMD for the past 2 years and no evidence of FMDV circulation for the past 12 months, with documented evidence that~~:

   a) there has been no *outbreak* of FMD during the past 2 years;

   b) no evidence of FMDV circulation has been found during the past 12 months;

3. supply documented evidence that:

   a) *surveillance* for FMD and FMDV circulation in accordance with Articles 8.5.40. to 8.5.46. is in operation~~, and that regulatory measures for the prevention and control of FMD have been implemented~~;

   b) regulatory measures for the early detection, prevention and control of FMD have been implemented;

~~b~~c) routine vaccination is carried out for the purpose of the prevention of FMD;

~~c~~d) the vaccine used complies with the standards described in the *Terrestrial Manual*.

4. describe in detail the boundaries and measures of a *protection zone*, if applicable.

The Member will be included in the list only after the submitted evidence has been accepted by the OIE. Retention on the list requires that the information in point 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 according to the requirements in Chapter 1.1.

If a Member that meets the requirements of a FMD free country where vaccination is practised wishes to change its status to FMD free country where vaccination is not practised, the status of this country remains unchanged for a period of at least 12 months after vaccination has ceased. Evidence should also be provided showing that FMDV infection has not occurred during that period.

Article 8.5.4.

FMD free zone where vaccination is not practised

A FMD free zone where vaccination is not practised can be established in either a FMD free country where vaccination is practised or in a country of which parts are infected. In defining such *zones* the principles of Chapter 4.3. should be followed. Susceptible animals in the FMD free zone should be protected from the rest of the country and from neighbouring countries if they are of a different *animal health status* by the application of animal health measures that effectively prevent the entry of the virus, taking into consideration physical or geographical barriers. These measures may include a *protection zone*.

To qualify for inclusion in the list of FMD free zones where vaccination is not practised, a Member should:

1. have a record of regular and prompt animal disease reporting;

2. send a declaration to the OIE stating that ~~it wishes to establish a FMD free zone where vaccination is not practised, and that~~ within the proposed FMD free zone:

   a) there has been no *outbreak* of FMD during the past 12 months;

   b) no evidence of FMDV infection has been found during the past 12 months;

   c) no vaccination against FMD has been carried out during the past 12 months;

   d) no vaccinated animal has been introduced into the zone since the cessation of vaccination, except in accordance with Article 8.5.9.;

   ~~e) documented evidence shows that *surveillance* in accordance with Articles 8.5.40. to 8.5.46. is in operation for both FMD and FMDV infection;~~

3. supply documented evidence that:

   a) *surveillance* for FMD and FMDV infection in accordance with Articles 8.5.40. to 8.5.46. is in operation;

   b) regulatory measures for the early detection, prevention and control of FMD have been implemented;

Annex XX (contd)

~~3~~4. describe in detail:

~~a)~~ ~~regulatory measures for the prevention and control of both FMD and FMDV infection,~~

~~b~~a) the boundaries of the proposed FMD free zone ~~and, if applicable, the *protection zone* or physical or geographical barriers,~~

b) the boundaries and measures of a *protection zone*, if applicable,

c) the system for preventing the entry of the virus (including the control of the movement of susceptible animals) into the proposed FMDV free zone (in particular if the procedure described in Article 8.5.9. is implemented),

and supply documented evidence that these are properly implemented and supervised.

The proposed free zone will be included in the list of FMD free zones where vaccination is not practised only after the submitted evidence has been accepted by the OIE.

The information required in points 2, 3 and ~~3~~4 b-c) above should be re-submitted annually and changes in the epidemiological situation or other significant events including those relevant to points 3~~a~~b) and ~~3~~4b) should be reported to the OIE according to the requirements in Chapter 1.1.

Article 8.5.5.

FMD free zone where vaccination is practised

A FMD free zone where vaccination is practised can be established in either a FMD free country where vaccination is not practised or in a country of which parts are infected. In defining such *zones* the principles of Chapter 4.3. should be followed. Susceptible animals in the FMD free zone where vaccination is practised should be protected from neighbouring countries or *zones* if they are of a lesser *animal health status*, by the application of animal health measures that effectively prevent the entry of the virus, taking into consideration physical or geographical barriers. These measures may include a *protection zone*.

To qualify for inclusion in the list of FMD free zones where vaccination is practised, a Member should:

1. have a record of regular and prompt animal disease reporting;

2. send a declaration to the OIE stating that ~~it wishes to establish a FMD free zone where vaccination is practised and that~~ within the proposed FMD free zone;

   a) there has been no *outbreak* of FMD for the past 2 years;

   b) no evidence of FMDV circulation ~~for~~ has been found during the past 12 months;

   ~~c) documented evidence shows that *surveillance* in accordance with Articles 8.5.40. to 8.5.46. is in operation for FMD and FMDV circulation;~~

3. supply documented evidence that:

   a) *surveillance* for FMD and FMDV infection in accordance with Articles 8.5.40. to 8.5.46. is in operation;

   b) regulatory measures for the early detection, prevention and control of FMD have been implemented;

   c) routine vaccination is carried out for the purpose of the prevention of FMD;

   d) the vaccine used complies with the standards described in the *Terrestrial Manual*;

~~3. supply documented evidence that the vaccine used complies with the standards described in the *Terrestrial Manual*;~~

4. describe in detail:

   ~~a) regulatory measures for the prevention and control of both FMD and FMDV circulation,~~

   ~~b~~a) the boundaries of the proposed FMD free zone ~~where vaccination is practised and, if applicable, the *protection zone* or physical or geographical barriers~~,

   b) the boundaries and measures of a *protection zone*, if applicable,

   c) the system for preventing the entry of the virus (including the control of the movement of susceptible animals) into the proposed FMD free zone (in particular if the procedure described in Article 8.5.9. is implemented),

   and supply documented evidence that these are properly implemented and supervised.

The proposed free zone will be included in the list of FMD free zones where vaccination is practised only after the submitted evidence has been accepted by the OIE. The information required in points 2, 3 and 4 b-c) above should be re-submitted annually and changes in the epidemiological situation or other significant events including those relevant to points ~~4a~~3b) and 4b) should be reported to the OIE according to the requirements in Chapter 1.1.

If a Member that has a *zone* which meets the requirements of a FMD free zone where vaccination is practised wishes to change the status of the *zone* to FMD free zone where vaccination is not practised, the status of this *zone* remains unchanged for a period of at least 12 months after vaccination has ceased. Evidence should also be provided showing that FMDV infection has not occurred in the said *zone* during that period.

Article 8.5.5.bis

FMD free compartment

A FMD free *compartment* can be established in either a FMD free country or *zone* ~~where vaccination is practised~~ or in an infected country or *zone*. In defining such a *compartment* the principles of Chapters 4.3. and 4.4. should be followed. Susceptible animals in the FMD free *compartment* should be separated from any other susceptible animals ~~subpopulations~~ by the application of an effective biosecurity management system.

Annex XX (contd)

A Member wishing to establish a FMD free *compartment* should:

1. have a record of regular and prompt animal disease reporting and if not FMD free, have a *surveillance* system for FMD in place according to Articles 8.5.40. to 8.5.42. that allows an accurate knowledge of the prevalence of FMD in the country or *zone*;

2. declare for the FMD free *compartment* that:

   a) there has been no *outbreak* of FMD during the past 12 months;

   b) no evidence of FMDV infection has been found 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 and embryos should only enter the *compartment* in accordance with relevant Articles in this chapter;

   ~~e~~f) documented evidence shows that *surveillance* in accordance with Articles 8.5.40. to 8.5.46. is in operation for ~~both~~ FMD and FMDV infection;

   ~~f~~g) an *animal identification* and *traceability* system in accordance with Chapters 4.1 and 4.2. is in place;

3. describe in detail the animal subpopulation in the *compartment* ~~in detail~~ and the *biosecurity plan* ~~management system~~ for ~~prevention and control of both~~ FMD and FMDV infection~~, including the system for preventing the entry of the virus and its implementation and supervision~~.

Article 8.5.6.

FMD infected country or zone

A FMD infected country is a country that does not fulfil the requirements to qualify as either a FMD free country where vaccination is not practised or a FMD free country where vaccination is practised.

A FMD infected zone is a *zone* that does not fulfil the requirements to qualify as either a FMD free zone where vaccination is not practised or a FMD free zone where vaccination is practised.

Article 8.5.7.

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

In the event of limited *outbreaks* within a FMD free country or zone, including within a *protection zone*, with or without vaccination, a single *containment zone*, which includes all *cases*, can be established for the purpose of minimizing the impact on the entire country or *zone*.

For this to be achieved, the *Veterinary Authority* should provide documented evidence that:

1. the *outbreaks* are limited based on the following factors:

   a) immediately on suspicion, a rapid response including notification has been made;

   b) standstill of animal movements has been imposed, and effective controls on the movement of other *commodities* mentioned in this Chapter are in place;

c) epidemiological investigation (trace-back, trace-forward) has been completed;

d) the *infection* has been confirmed;

e) the primary *outbreak* and likely source of the *outbreak* has been identified;

f) all *cases* have been shown to be epidemiologically linked;

g) no new *cases* have been found in the *containment zone* within a minimum of two *incubation periods* as defined in Article 8.5.1. after the stamping-out of the last detected *case* is completed;

2. a *stamping-out policy* has been applied;

3. the susceptible animal population within the *containment zones* should be clearly identifiable as belonging to the *containment zone*;

4. increased passive and targeted *surveillance* in accordance with Articles 8.5.40. to 8.5.46. in the rest of the country or *zone* has been carried out and has not detected any evidence of *infection*;

5. animal health measures that effectively prevent the spread of the FMDV to the rest of the country or *zone*, taking into consideration physical and geographical barriers, are in place;

6. ongoing *surveillance* in the *containment zone* is in place;

The free status of the areas outside the *containment zone* would be suspended pending the establishment of the *containment zone*. The free status of these areas could be reinstated irrespective of the provisions of Article 8.5.8., once the *containment zone* is clearly established, by complying with points 1 to 6 above. The *containment zone* should be managed in such a way that it can be demonstrated that *commodities* for international trade can be shown to have originated outside the *containment zone*.

The recovery of the FMD free status of the *containment zone* should follow the provisions of Article 8.5.8.

Article 8.5.8.

Recovery of free status

1. When a FMD *outbreak* or FMDV *infection* occurs in a FMD free country or zone where vaccination is not practised, one of the following waiting periods is required to regain the status of FMD free country or zone where vaccination is not practised:

   a) 3 months after the last *case* where a *stamping-out policy* and serological *surveillance* are applied in accordance with Articles 8.5.40. to 8.5.46.; or

   b) 3 months after the *slaughter* of all vaccinated animals where a *stamping-out policy*, emergency vaccination and serological *surveillance* are applied in accordance with Articles 8.5.40. to 8.5.46.; or

   c) 6 months after the last *case* or the last vaccination (according to the event that occurs the latest), where a *stamping-out policy*, emergency vaccination not followed by the slaughtering of all vaccinated animals, and serological *surveillance* are applied in accordance with Articles 8.5.40. to 8.5.46., provided that a serological survey based on the detection of antibodies to nonstructural proteins of FMDV demonstrates the absence of *infection* in the remaining vaccinated population.

   Where a *stamping-out policy* is not practised, the above waiting periods do not apply, and Article 8.5.2. or 8.5.4. applies.

Annex XX (contd)

2. When a FMD *outbreak* or FMDV *infection* occurs in a FMD free country or zone where vaccination is practised, one of the following waiting periods is required to regain the status of FMD free country or zone where vaccination is practised:

   a) 6 months after the last *case* where a *stamping-out policy*, emergency vaccination and serological *surveillance* in accordance with Articles 8.5.40. to 8.5.46. are applied, provided that the serological *surveillance* based on the detection of antibodies to nonstructural proteins of FMDV demonstrates the absence of virus circulation; or

   b) 18 months after the last *case* where a *stamping-out policy* is not applied, but emergency vaccination and serological *surveillance* in accordance with Articles 8.5.40. to 8.5.46. are applied, provided that the serological *surveillance* based on the detection of antibodies to nonstructural proteins of FMDV demonstrates the absence of virus circulation.

3. When a FMD *outbreak* or FMDV *infection* occurs in a FMD free *compartment*, Article 8.5.5.bis. applies.

Article 8.5.9.

Transfer directly to slaughter of FMD susceptible animals from an infected zone to a free zone (where vaccination either is or is not practised) within a country

In order not to jeopardise the status of a free *zone*, FMD susceptible animals should only leave the *infected zone* if moved by mechanised transport directly to *slaughter* in the nearest designated *abattoir* located in a ~~*protection zone* directly to *slaughter*~~.

~~In the absence of an *abattoir* in a *protection zone*, live FMD susceptible animals can be transported to the nearest *abattoir* in a~~ free *zone* ~~directly to *slaughter* only~~ under the following conditions:

1. 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;

2. the animals were kept in the *establishment* of origin for at least 3 months prior to movement;

3. FMD has not occurred within a 10-kilometre radius of the *establishment* of origin for at least 3 months prior to movement;

4. the animals must be 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 *abattoir* without coming into contact with other susceptible animals;

5. such an *abattoir* is not approved for the export of *fresh meat* during the time it is handling the *meat* of animals from the *infected zone*;

6. *vehicles* and the *abattoir* must be subjected to thorough cleansing and *disinfection* immediately after use.

All products obtained from the animals and any products coming into contact with them must be considered infected, and treated in such a way as to destroy any residual virus in accordance with Articles 8.5.32. to 8.5.39.

Animals moved into a free zone for other purposes must be moved under the supervision of the *Veterinary Authority* and comply with the conditions in Article 8.5.12.

Article 8.5.10.

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

for FMD susceptible animals

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 3 months in a FMD free country or zone where vaccination is not practised or a FMD free *compartment*;

3. have not been vaccinated;

4. if transiting an *infected zone*, were not exposed to any source of FMD *infection* during transportation to the *place of shipment*.

Article 8.5.11.

Recommendations for importation from FMD free countries or zones 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 in a FMD free country or zone since birth or for at least the past 3 months; and

3. have not been vaccinated and were subjected, with negative results, to tests for antibodies against FMD virus, when destined to a FMD free country or zone where vaccination is not practised;

4. if transiting an *infected zone*, were not exposed to any source of FMD *infection* during transportation to the *place of shipment*.

Article 8.5.12.

Recommendations for importation from FMD infected countries or zones

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 in the *establishment* of origin since birth, or

   a) for the past 30 days, if a *stamping-out policy* is in force in the *exporting country*, or

   b) for the past 3 months, if a *stamping-out policy* is not in force in the *exporting country*, and that FMD has not occurred within a ten-kilometre radius of the *establishment* of origin for the relevant period as defined in points a) and b) above; and

3. were isolated in an *establishment* for the 30 days prior to shipment, and all animals in isolation were subjected to diagnostic tests (probang and serology) for evidence of FMDV *infection* with negative results at the end of that period, and that FMD did not occur within a ten-kilometre radius of the *establishment* during that period; or

4. were kept in a *quarantine station* for the 30 days prior to shipment, all animals in quarantine were subjected to diagnostic tests (probang and serology) for evidence of FMDV *infection* with negative results at the end of that period, and that FMD did not occur within a ten-kilometre radius of the *quarantine station* during that period;

5. were not exposed to any source of FMD *infection* during their transportation from the *quarantine station* to the *place of shipment*.

Article 8.5.13.

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

for fresh semen of domestic ruminants and pigs

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

1. the donor animals:

   a) showed no clinical sign of FMD on the day of collection of the semen;

   b) were kept for at least 3 months prior to collection in a FMD free country or zone where vaccination is not practised or a FMD free *compartment*;

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

Article 8.5.14.

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

for frozen semen of domestic ruminants and pigs

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

1. the donor animals:

   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 3 months prior to collection in a FMD free country or zone where vaccination is not practised or a FMD free *compartment* ~~for at least 3 months prior to collection~~;

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

Article 8.5.15.

Recommendations for importation from FMD free countries or zones where vaccination is practised

for semen of domestic ruminants and pigs

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

1. the donor animals:

   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 3 months prior to collection in a FMD free country or *zone* ~~free from FMD~~;

   c) if destined to a FMD free country or zone where vaccination is not practised:

      i) have not been vaccinated and were subjected, not less than 21 days after collection of the semen, to tests for antibodies against FMD virus, with negative results; or

      ii) had been vaccinated at least twice, with the last vaccination not more than 12 and not less than one month prior to collection;

2. no other animal present in the *artificial insemination centre* has been vaccinated within the month prior to collection;

3. the semen:

   a) was collected, processed and stored in conformity with the provisions of Chapter 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 were kept showed any sign of FMD.

Article 8.5.16.

Recommendations for importation from FMD infected countries or zones

for semen of domestic ruminants and pigs

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

1. the donor animals:

   a) showed no clinical sign of FMD on the day of collection of the semen;

b) were kept in an *establishment* where no animal had been added in the 30 days before collection, and that FMD has not occurred within 10 kilometres for the 30 days before and after collection;

c) have not been vaccinated and were subjected, not less than 21 days after collection of the semen, to tests for antibodies against FMD virus, with negative results; or

d) had been vaccinated at least twice, with the last vaccination not more than 12 and not less than one month prior to collection;

2. no other animal present in the *artificial insemination centre* has been vaccinated within the month prior to collection;

3. the semen:

a) was collected, processed and stored in conformity with the provisions of Chapter 4.5. and 4.6.;

b) was subjected, with negative results, to a test for FMDV *infection* if the donor animal 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 during this period no animal on the *establishment* where the donor animals were kept showed any sign of FMD.

Article 8.5.17.

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

Irrespective of the FMD status of the *exporting country* ~~or,~~ 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 cattle subject to the presentation of an *international veterinary certificate* attesting that the embryos were collected, processed and stored in conformity with the provisions of Chapter 4.7.or Chapter 4.9.

Article 8.5.18.

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

for *in vitro* produced embryos of 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 at the time of collection in a FMD free country or zone where vaccination is not practised or a FMD free *compartment*;

2. fertilisation was achieved with semen meeting the conditions referred to in Articles 8.5.13., 8.5.14., 8.5.15. or 8.5.16., as relevant;

3. the oocytes were collected, and the embryos were processed and stored in conformity with the provisions of Chapter 4.8. or Chapter 4.9., as relevant.

Article 8.5.19.

Recommendations for importation from FMD free countries or zones where vaccination is practised

for *in vitro* produced embryos of 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 3 months prior to collection in a FMD free country or zone where vaccination is practised;

   c) if destined for a FMD free country or zone where vaccination is not practised or a FMD free *compartment*:

      i) have not been vaccinated and were subjected, with negative results, to tests for antibodies against FMD virus; or

      ii) had been vaccinated at least twice, with the last vaccination not less than one month and not more than 12 months prior to collection;

2. no other animal present in the *establishment* has been vaccinated within the month prior to collection;

3. fertilization was achieved with semen meeting the conditions referred to in Articles 8.5.13., 8.5.14., 8.5.15. or 8.5.16., as relevant;

4. the oocytes were collected, and the embryos were processed and stored in conformity with the provisions of Chapter 4.8. or Chapter 4.9., as relevant.

Article 8.5.20.

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

for *fresh meat* 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 the FMD free country or zone where vaccination is not practised or in a FMD free *compartment* ~~since birth~~, or which have been imported in accordance with Article 8.5.10., Article 8.5.11. or Article 8.5.12.;

2. have been slaughtered in an approved *abattoir* and have been subjected to ante-mortem and post-mortem inspections for FMD with favourable results.

Article 8.5.21.

Recommendations for importation from FMD free countries or zones where vaccination is practised

Annex XX (contd)

for *fresh meat* of cattle and 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 comes from animals which:

1. have been kept in the FMD free country or zone where vaccination is practised ~~since birth~~, or which have been imported in accordance with Article 8.5.10., Article 8.5.11. or Article 8.5.12.;

2. have been slaughtered in an approved *abattoir* and have been subjected to ante-mortem and post-mortem inspections for FMD with favourable results.

Article 8.5.22.

Recommendations for importation from FMD free countries or zones where vaccination is practised

for *fresh meat* or *meat products* of pigs and ruminants other than cattle and buffaloes

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 the FMD free country or zone where vaccination is practised ~~since birth~~, or which have been imported in accordance with Article 8.5.10., Article 8.5.11. or Article 8.5.12.;

2. have been slaughtered in an approved *abattoir* and have been subjected to ante-mortem and post-mortem inspections for FMD with favourable results.

Article 8.5.23.

Recommendations for importation from FMD infected countries or zones, where an official control programme exists, involving compulsory systematic vaccination of cattle

for *fresh meat* of cattle and 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 in the *exporting country* for at least 3 months prior to *slaughter*;

    b) have remained, during this period, in a part of the country where cattle are regularly vaccinated against FMD and where official controls are in operation;

    c) have been vaccinated at least twice with the last vaccination not more than 12 months and not less than one month prior to *slaughter*;

    d) were kept for the past 30 days in an *establishment*, and that FMD has not occurred within a ten-kilometre radius of the *establishment* during that period;

    e) have been transported, in a *vehicle* which was cleansed and disinfected before the cattle were loaded, directly from the *establishment* of origin to the approved *abattoir* without coming into contact with other animals which do not fulfil the required conditions for export;

f) have been slaughtered in an approved *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;

g) have been subjected to ante-mortem and post-mortem inspections for FMD with favourable results within 24 hours before and after *slaughter*;

2. comes from deboned carcasses:

a) from which the major lymphatic nodes have been removed;

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

Article 8.5.24.

Recommendations for importation from FMD infected countries or zones

for *meat products* of domestic ruminants and pigs

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

1. the entire consignment of *meat* comes from animals which have been slaughtered in an approved *abattoir* and have been subjected to ante-mortem and post-mortem inspections for FMD with favourable results;

2. the *meat* has been processed to ensure the destruction of the FMD virus in conformity with one of the procedures referred to in Article 8.5.32.;

3. the necessary precautions were taken after processing to avoid contact of the *meat products* with any potential source of FMD virus.

Article 8.5.25.

Recommendations for importation from FMD free countries or zones (where vaccination either is or is not practised) or FMD free compartments

for *milk* and *milk products* 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

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 ~~or,~~ zone or *compartment* ~~since birth~~, or which have been imported in accordance with Article 8.5.10., Article 8.5.11. or Article 8.5.12.

Article 8.5.26.

Recommendations for importation from FMD infected countries or zones where an official control programme exists

Annex XX (contd)

for *milk*, cream, milk powder and *milk products*

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

1. these products:

   a) originate from *herds* or *flocks* 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 the FMD virus in conformity with one of the procedures referred to in Article 8.5.36. and in Article 8.5.37.;

2. the necessary precautions were taken after processing to avoid contact of the products with any potential source of FMD virus.

Article 8.5.27.

Recommendations for importation from FMD infected countries

for blood and meat-meals (from domestic or wild ruminants and pigs)

Veterinary Authorities should require the presentation of an *international veterinary certificate* attesting that the manufacturing method for these products included heating to a minimum core temperature of 70°C for at least 30 minutes.

Article 8.5.28.

Recommendations for importation from FMD infected countries

for wool, hair, bristles, raw hides and skins (from domestic or wild ruminants and pigs)

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

1. these products have been processed to ensure the destruction of the FMD virus in conformity with one of the procedures referred to in Articles 8.5.33., 8.5.34. and 8.5.35.;

2. the necessary precautions were taken after collection or processing to avoid contact of the products with any potential source of FMD virus.

Veterinary Authorities can authorise, without restriction, the import or transit through their territory of semi-processed hides and skins (limed hides, pickled pelts, and semi-processed leather - e.g. 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 8.5.29.

Recommendations for importation from FMD infected countries or zones

for straw and forage

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

1. are free of grossly identifiable 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 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 8 hours and at a minimum temperature of 19°C;

OR

3. have been kept in bond for at least 3 months (under study) before being released for export.

Article 8.5.30.

Recommendations for importation from FMD free countries or zones (where vaccination either is or is not practised)

for skins and trophies derived from FMD susceptible wild animals

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*, or which have been imported from a country or zone free of FMD (where vaccination either is or is not practised).

Article 8.5.31.

Recommendations for importation from FMD infected countries or zones

for skins and trophies derived from FMD susceptible wild animals

Veterinary Authorities should require the presentation of an *international veterinary certificate* attesting that these products have been processed to ensure the destruction of the FMD virus in conformity with the procedures referred to in Article 8.5.38.

Article 8.5.32.

Procedures for the inactivation of the FMD virus in meat

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

1. Canning

   Meat is 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 the FMD virus.

2. Thorough cooking

   Meat, previously deboned and defatted, shall be subjected to heating so that an internal temperature of 70°C or greater is maintained for a minimum of 30 minutes.

   After cooking, it shall be packed and handled in such a way that it cannot be exposed to a source of virus.

3. Drying after salting

When *rigor mortis* is complete, the meat must be deboned, salted with cooking salt (NaCl) and completely dried. It must not deteriorate at ambient temperature.

'Drying' is defined in terms of the ratio between water and protein which must not be greater than 2.25:1.

Article 8.5.33.

Procedures for the inactivation of the FMD virus in wool and hair

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

1. industrial washing, which consists of the immersion of the wool in a series of baths of water, soap and sodium hydroxide (soda) or potassium hydroxide (potash);

2. chemical depilation by means of slaked lime or sodium sulphide;

3. fumigation in formaldehyde in a hermetically sealed chamber for at least 24 hours. The most practical method is to place potassium permanganate in containers (which must NOT be made of plastic or polyethylene) and add commercial formalin; the amounts of formalin and potassium permanganate are respectively 53 ml and 35 g per cubic metre of the chamber;

4. industrial scouring which consists of the immersion of wool in a water-soluble detergent held at 60-70°C;

5. storage of wool at 18°C for 4 weeks, or 4°C for 4 months, or 37°C for 8 days.

Article 8.5.34.

Procedures for the inactivation of the FMD virus in bristles

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

1. boiling for at least one hour;

2. immersion for at least 24 hours in a 1% solution of formaldehyde prepared from 30 ml commercial formalin per litre of water.

Article 8.5.35.

Procedures for the inactivation of the FMD virus in raw hides and skins

For the inactivation of viruses present in raw hides and skins for industrial use, the following procedure should be used: salting for at least 28 days in sea salt containing 2% sodium carbonate.

Article 8.5.36.

Procedures for the inactivation of the FMD virus in milk and cream for human consumption

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

1. a sterilisation 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 sterilisation 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 over, the HTST process applied twice.

Article 8.5.37.

Procedures for the inactivation of the FMD virus in milk for animal consumption

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

1. the HTST process applied twice;

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 dessication;

3. UHT combined with another physical treatment referred to in point 2 above.

Article 8.5.38.

Procedures for the inactivation of the FMD virus in skins and trophies from wild animals susceptible to the disease

For the inactivation of viruses present in skins and trophies from 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;

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

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

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

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

Annex XX (contd)

Article 8.5.39.

Procedures for the inactivation of the FMD virus in casings of ~~small~~ ruminants and pigs

For the inactivation of viruses present in casings of small ruminants and pigs, the following procedures should be used: salting for at least 30 days either with dry salt (NaCl) or with saturated brine (Aw < 0.80), or with phosphate salts/sodium chloride mixture, and kept at room temperature at about 20?C during this entire period.

Article 8.5.40.

Surveillance: introduction

Articles 8.5.40. to 8.5.46. define the principles and provide a guide for the *surveillance* of FMD in accordance with Chapter 1.4. applicable to Members seeking establishment of freedom from FMD, either with or without the use of vaccination. Guidance is provided for Members seeking reestablishment of freedom from FMD for the entire country or for a *zone*, either with or without vaccination or a *compartment*, following an *outbreak*, and for the maintenance of FMD status.

The impact and epidemiology of FMD differ widely in different regions of the world and therefore it is impossible to provide specific recommendations for all situations. *Surveillance* strategies employed for demonstrating freedom from FMD at an acceptable level of confidence will need to be adapted to the local situation. For example, the approach to proving freedom from FMD following an *outbreak* caused by a pig-adapted strain of FMD virus (FMDV) should differ significantly from an application designed to prove freedom from FMD for a country or *zone* where African buffaloes (*Syncerus caffer*) provide a potential reservoir of *infection*. It is incumbent upon the Member to 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 are managed. This should include provision of scientifically-based supporting data. There is therefore considerable latitude available to Members to provide a well-reasoned argument to prove that the absence of FMDV *infection* (in non-vaccinated populations) or circulation (in vaccinated populations) is assured at an acceptable level of confidence.

Surveillance for FMD should be in the form of a continuing programme designed to establish that the whole territory or part of it is free from FMDV *infection*/circulation.

For the purposes of this Chapter, virus circulation means transmission of FMDV as demonstrated by clinical signs, serological evidence or virus isolation.

Article 8.5.41.

Surveillance: general conditions and methods

1. A *surveillance* system in accordance with Chapter 1.4. should be under the responsibility of the *Veterinary Authority*. A procedure should be in place for the rapid collection and transport of samples from suspect cases of FMD to a *laboratory* for FMD diagnoses as described in the *Terrestrial Manual*.

2. The FMD *surveillance* programme should:

a) include an early warning system throughout the production, marketing and processing chain for reporting suspicious cases. Farmers and workers who have day-to-day contact with livestock, as well as diagnosticians, should report promptly any suspicion of FMD. They should be supported directly or indirectly (e.g. through private *veterinarians* or *veterinary para-professionals*) by government information programmes and the *Veterinary Authority*. All suspect cases of FMD should be investigated immediately. Where suspicion cannot be resolved by epidemiological and clinical investigation, samples should be taken and submitted to a *laboratory*. This requires that sampling kits and other equipment are available for those responsible for *surveillance*. Personnel responsible for *surveillance* should be able to call for assistance from a team with expertise in FMD diagnosis and control;

b) implement, when relevant, regular and frequent clinical inspection and serological testing of high-risk groups of animals, such as those adjacent to a FMD infected country or *infected zone* (for example, bordering a game park in which infected wildlife are present).

An effective *surveillance* system will periodically identify suspicious cases that require follow-up and investigation to confirm or exclude that the cause of the condition is FMDV. The rate at which such suspicious cases are likely to occur will differ between epidemiological situations and cannot therefore be predicted reliably. Applications for freedom from FMDV *infection*/circulation should, in consequence, provide details of the occurrence of suspicious cases and how they were investigated and dealt with. This should include the results of *laboratory* testing and the control measures to which the animals concerned were subjected during the investigation (quarantine, movement stand-still orders, etc.).

Article 8.5.42.

Surveillance strategies

1. Introduction

The target population for *surveillance* aimed at identifying *disease* and *infection* should cover all the susceptible species within the country ~~or,~~ *zone* or *compartment*.

The design of *surveillance* programmes to prove the absence of FMDV *infection*/circulation needs to be carefully followed to avoid producing results that are either insufficiently reliable to be accepted by the OIE or international trading partners, or excessively costly and logistically complicated. The design of any *surveillance* programme, therefore, requires inputs from professionals competent and experienced in this field.

The strategy employed may be based on randomised sampling requiring *surveillance* consistent with demonstrating the absence of FMDV *infection*/circulation at an acceptable level of statistical confidence. The frequency of sampling should be dependent on the epidemiological situation.

Targeted *surveillance* (e.g. based on the increased likelihood of *infection* in particular localities or species) may be an appropriate strategy. The Member should justify the *surveillance* strategy chosen as adequate to detect the presence of FMDV *infection*/circulation in accordance with Chapter 1.4. and the epidemiological situation. It may, for example, be appropriate to target clinical *surveillance* at particular species likely to exhibit clear clinical signs (e.g. cattle and pigs). If a Member wishes to apply for recognition of a specific *zone* within the country as being free from FMDV *infection*/circulation, the design of the survey and the basis for the sampling process would need to be aimed at the population within the *zone*.

For random surveys, the design of the sampling strategy will need to incorporate an epidemiologically appropriate design prevalence. The sample size selected for testing will need to be large enough to detect *infection*/circulation if it were to occur at a predetermined minimum rate. The sample size and expected *disease* prevalence determine the level of confidence in the results of the survey. The Member must justify the choice of design prevalence and confidence level based on the objectives of *surveillance* and the epidemiological situation, in accordance with Chapter 1.4. Selection of the design prevalence in particular clearly needs to be based on the prevailing or historical epidemiological situation.

Irrespective of the survey design selected, the sensitivity and specificity of the diagnostic tests employed are key factors in the design, sample size determination and interpretation of the results obtained. Ideally, the sensitivity and specificity of the tests used should be validated for the vaccination/*infection* history and production class of animals in the target population.

Irrespective of the testing system employed, *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 needs to be an effective procedure for following-up positives to ultimately determine with a high level of confidence, whether they are indicative of *infection*/circulation or not. This should involve both supplementary tests and follow-up investigation to collect diagnostic material from the original sampling unit as well as *herds* which may be epidemiologically linked to it.

2. Clinical surveillance

Clinical *surveillance* aims at detecting clinical signs of FMD by close physical examination of susceptible animals. Whereas significant emphasis is placed on the diagnostic value of mass serological screening, *surveillance* based on clinical inspection should not be underrated. It may be able to provide a high level of confidence of detection of *disease* if a sufficiently large number of clinically susceptible animals is examined.

Clinical *surveillance* and *laboratory* testing should always be applied in series to clarify the status of FMD suspects detected by either of these complementary diagnostic approaches. *Laboratory* testing may confirm clinical suspicion, while clinical *surveillance* may contribute to confirmation of positive serology. Any sampling unit within which suspicious animals are detected should be classified as infected until contrary evidence is produced.

A number of issues must be considered in clinical *surveillance* for FMD. The often underestimated labour intensity and the logistical difficulties involved in conducting clinical examinations should not be underestimated and should be taken into account.

Identification of clinical cases is fundamental to FMD *surveillance*. Establishment of the molecular, antigenic and other biological characteristics of the causative virus, as well as its source, is dependent upon disclosure of such animals. It is essential that FMDV isolates are sent regularly to the regional reference *laboratory* for genetic and antigenic characterization.

3. Virological surveillance

Virological *surveillance* using tests described in the *Terrestrial Manual* should be conducted:

a) to monitor at risk populations;

b) to confirm clinically suspect cases;

c) to follow up positive serological results;

d) to test "normal" daily mortality, to ensure early detection of *infection* in the face of vaccination or in *establishments* epidemiologically linked to an *outbreak*.

4. Serological surveillance

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

a) natural *infection* with FMDV;

b) vaccination against FMD;

c) maternal antibodies derived from an immune dam (maternal antibodies in cattle are usually found only up to 6 months of age but in some individuals and in some species, maternal antibodies can be detected for considerably longer periods);

d) heterophile (cross) reactions.

It is important that serological tests, where applicable, contain antigens appropriate for detecting antibodies against viral variants (types, subtypes, lineages, topotypes, etc.) that have recently occurred in the region concerned. Where the probable identity of FMDVs is unknown or where exotic viruses are suspected to be present, tests able to detect representatives of all serotypes should be employed (e.g. tests based on nonstructural viral proteins – see below).

It may be possible to use serum collected for other survey purposes for FMD *surveillance*. However, the principles of survey design described in this Chapter and the requirement for a statistically valid survey for the presence of FMDV should not be compromised.

The discovery of clustering of seropositive reactions should be foreseen. It may reflect any of a series of events, including but not limited to the demographics of the population sampled, vaccinal exposure or the presence of field strain *infection*. As clustering may signal field strain *infection*, the investigation of all instances must be incorporated in the survey design. If vaccination cannot be excluded as the cause of positive serological reactions, diagnostic methods should be employed that detect the presence of antibodies to nonstructural proteins (NSPs) of FMDVs as described in the *Terrestrial Manual*.

The results of random or targeted serological surveys are important in providing reliable evidence that FMDV *infection* is not present in a country ~~or,~~ *zone* or *compartment*. It is therefore essential that the survey be thoroughly documented.

Article 8.5.43.

Members applying for recognition of freedom from FMD for the whole country or a zone where vaccination is not practised: additional surveillance procedures

In addition to the general conditions described in the above-mentioned articles, a Member applying for recognition of FMD freedom for the country or a *zone* where vaccination is not practised should provide evidence for the existence of an effective *surveillance* programme. The strategy and design of the *surveillance* programme will depend on the prevailing epidemiological circumstances and will be planned and implemented according to general conditions and methods in this Chapter, to demonstrate absence of FMDV *infection*, during the preceding 12 months in susceptible populations. This requires the support of a national or other *laboratory* able to undertake identification of FMDV *infection* through virus/antigen/genome detection and antibody tests described in the *Terrestrial Manual*.

Annex XX (contd)

Article 8.5.44.

Members applying for recognition of freedom from FMD for the whole country or a zone where vaccination is practised: additional surveillance procedures

In addition to the general conditions described in the above-mentioned articles, a Member applying for recognition of country or *zone* freedom from FMD with vaccination should show evidence of an effective *surveillance* programme planned and implemented according to general conditions and methods in this Chapter. Absence of clinical *disease* in the country or *zone* for the past 2 years should be demonstrated. Furthermore, *surveillance* should demonstrate that FMDV has not been circulating in any susceptible population during the past 12 months. This will require serological *surveillance* incorporating tests able to detect antibodies to NSPs as described in the *Terrestrial Manual*. Vaccination to prevent the transmission of FMDV may be part of a disease control programme. The level of *herd* immunity required to prevent transmission will depend on the size, composition (e.g. species) and density of the susceptible population. It is therefore impossible to be prescriptive. However, the aim should, in general, be to vaccinate at least 80% of the susceptible population. The vaccine must comply with the *Terrestrial Manual*. Based on the epidemiology of FMD in the country or *zone*, it may be that a decision is reached to vaccinate only certain species or other subsets of the total susceptible population. In that case, the rationale should be contained within the dossier accompanying the application to the OIE for recognition of status.

Evidence to show the effectiveness of the vaccination programme should be provided.

Article 8.5.45.

Members re-applying for recognition of freedom from FMD for the whole country or a zone where vaccination is either practised or not practised, following an outbreak: additional surveillance procedures

In addition to the general conditions described in the above-mentioned articles, a country re-applying for country or *zone* freedom from FMD where vaccination is practised or not practised should show evidence of an active *surveillance* programme for FMD as well as absence of FMDV *infection*/circulation.

This will require serological *surveillance* incorporating, in the case of a country or a *zone* practising vaccination, tests able to detect antibodies to NSPs as described in the *Terrestrial Manual*.

Four strategies are recognised by the OIE in a programme to eradicate FMDV *infection* following an *outbreak*:

1. *slaughter* of all clinically affected and in-contact susceptible animals;

2. *slaughter* of all clinically affected and in-contact susceptible animals and vaccination of at-risk animals, with subsequent *slaughter* of vaccinated animals;

3. *slaughter* of all clinically affected and in-contact susceptible animals and vaccination of at-risk animals, without subsequent *slaughter* of vaccinated animals;

4. vaccination used without *slaughter* of affected animals or subsequent *slaughter* of vaccinated animals.

The time periods before which an application can be made for re-instatement of freedom from FMD depends on which of these alternatives is followed. The time periods are prescribed in Article 8.5.8.

In all circumstances, a Member re-applying for country or *zone* freedom from FMD with vaccination or without vaccination should report the results of an active *surveillance* programme implemented according to general conditions and methods in this Chapter.

Article 8.5.46.

The use and interpretation of serological tests (see Figure 1)

The recommended serological tests for FMD *surveillance* are described in the *Terrestrial Manual*.

Animals infected with FMDV produce antibodies to both the structural proteins (SP) and the nonstructural proteins (NSP) of the virus. Tests for SP antibodies to include SP-ELISAs and the virus neutralisation test (VNT). The SP tests are serotype specific and for optimal sensitivity should utilise an antigen or virus closely related to the field strain against which antibodies are being sought. Tests for NSP antibodies include NSP I-ELISA 3ABC and the electro-immunotransfer blotting technique (EITB) as recommended in the *Terrestrial Manual* or equivalent validated tests. In contrast to SP tests, NSP tests can detect antibodies to all serotypes of FMD virus. Animals vaccinated and subsequently infected with FMD virus develop antibodies to NSPs, but in some, the titre may be lower than that found in infected animals that have not been vaccinated. Both the NSP I-ELISA 3ABC and EITB tests have been extensively used in cattle. Validation in other species is ongoing. Vaccines used should comply with the standards of the *Terrestrial Manual* insofar as purity is concerned to avoid interference with NSP antibody testing.

Serological testing is a suitable tool for FMD *surveillance*. The choice of a serosurveillance system will depend on, amongst other things, the vaccination status of the country. A country, which is free from FMD without vaccination, may choose serosurveillance of high-risk subpopulations (e.g. based on geographical risk for exposure to FMDV). SP tests may be used in such situations for screening sera for evidence of FMDV *infection*/circulation if a particular virus of serious threat has been identified and is well characterised. In other cases, NSP testing is recommended in order to cover a broader range of strains and even serotypes. In both cases, serological testing can provide additional support to clinical *surveillance*. Regardless of whether SP or NSP tests are used in countries that do not vaccinate, a diagnostic follow-up protocol should be in place to resolve any presumptive positive serological test results.

In areas where animals have been vaccinated, SP antibody tests may be used to monitor the serological response to the vaccination. However, NSP antibody tests should be used to monitor for FMDV *infection*/circulation. NSP-ELISAs may be used for screening sera for evidence of *infection*/circulation irrespective of the vaccination status of the animal. All *herds* with seropositive reactors should be investigated. Epidemiological and supplementary *laboratory* investigation results should document the status of FMDV *infection*/circulation for each positive *herd*. Tests used for confirmation should be of high diagnostic specificity to eliminate as many false positive screening test reactors as possible. The diagnostic sensitivity of the confirmatory test should approach that of the screening test. The EITB or another OIE-accepted test should be used for confirmation.

Information should be provided on the protocols, reagents, performance characteristics and validation of all tests used.

1. <u>The follow-up procedure in case of positive test results if no vaccination is used in order to establish or re-establish FMD free status without vaccination</u>

   Any positive test result (regardless of whether SP or NSP tests were used) should be followed up immediately using appropriate clinical, epidemiological, serological and, where possible, virological investigations of the reactor animal at hand, of susceptible animals of the same *epidemiological unit* and of susceptible animals that have been in contact or otherwise epidemiologically associated with the reactor animal. If the follow-up investigations provide no evidence for FMDV *infection*, the reactor animal shall be classified as FMD negative. In all other cases, including the absence of such follow-up investigations, the reactor animal should be classified as FMD positive.

Annex XX (contd)

2. The follow-up procedure in case of positive test results if vaccination is used in order to establish or re-establish FMD free status with vaccination

In case of vaccinated populations, one has to exclude that positive test results are indicative of virus circulation. To this end, the following procedure should be followed in the investigation of positive serological test results derived from *surveillance* conducted on FMD vaccinated populations.

The investigation should examine all evidence that might confirm or refute the hypothesis that the positive results to the serological tests employed in the initial survey were not due to virus circulation.

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

It is suggested that in the primary sampling units where at least one animal reacts positive to the NSP test, the following strategy(ies) should be applied:

a) Following clinical examination, a second serum sample should be taken from the animals tested in the initial survey after an adequate interval of time has lapsed, on the condition that they are individually identified, accessible and have not been vaccinated during this period. Antibod~~y~~ies ~~titres~~ against NSP in the population at the time of retest should be statistically either equal to or lower than those observed in the initial test if virus is not circulating.

The animals sampled should remain in the holding pending test results and should be clearly identifiable. If the three conditions for retesting mentioned above cannot be met, a new serological survey should be carried out in the holding after an adequate period of time, repeating the application of the primary survey design and ensuring that all animals tested are individually identified. These animals should remain in the holding and should not be vaccinated, so that they can be retested after an adequate period of time.

b) Following clinical examination, serum samples should be collected from representative numbers of ~~cattle~~ susceptible animals that were in physical contact with the primary sampling unit. The magnitude and prevalence of antibody reactivity observed should not differ in a statistically significant manner from that of the primary sample if virus is not circulating.

c) Following clinical examination, epidemiologically linked *herds* should be serologically tested and satisfactory results should be achieved if virus is not circulating.

d) Sentinel animals can also be used. These can be young, unvaccinated animals or animals in which maternally conferred immunity has lapsed and belonging to the same species resident within the positive initial sampling units. They should be serologically negative if virus is not circulating. If other susceptible, unvaccinated ~~ruminants (sheep, goats)~~ animals are present, they could act as sentinels to provide additional serological evidence.

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 circulation includes but is not limited to:

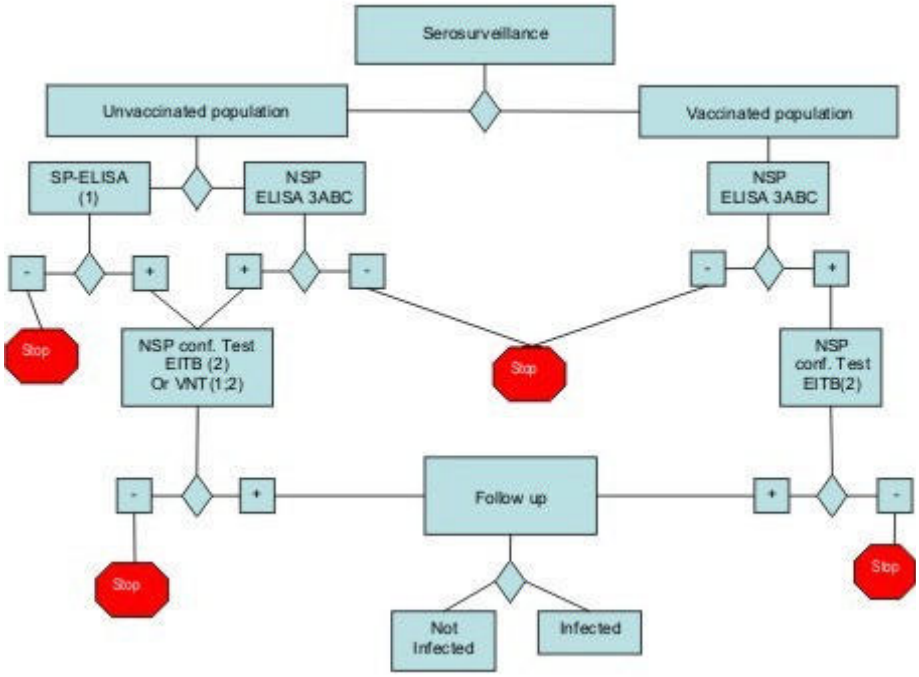
- characterization of the existing production systems;
- results of clinical *surveillance* of the suspects and their cohorts;
- quantification of vaccinations performed on the affected sites;
- sanitary protocol and history of the *establishments* with positive reactors;

- control of *animal identification* and movements;

- other parameters of regional significance in historic FMDV transmission.

The entire investigative process should be documented as standard operating procedure within the *surveillance* programme.

Fig. 1. ***Schematic representation of laboratory tests for determining evidence of FMDV infection through or following serological surveys***



Key:	
ELISA	Enzyme-linked immunosorbent assay
VNT	Virus neutralisation test
NSP	Nonstructural protein(s) of foot and mouth disease virus (FMDV)
3ABC	NSP antibody test
EITB	Electro-immuno transfer blotting technique (Western blot for NSP antibodies of FMDV)
SP	Structural protein test
S	No evidence of FMDV

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Annex XXI

CHAPTER 8.16.

WEST NILE FEVER

Article 8.16.1.

General provisions

West Nile fever (WNF) is a zoonotic disease caused by certain strains of the mosquito transmitted West Nile virus (WNV).

For the purpose of this chapter, the susceptible species are equidae, geese, ducks (under study) and ~~chicken and turkey chicks less than 12 days old (under study)~~ and birds other than *poultry*.

WNV is maintained in a mosquito–bird–mosquito transmission cycle, whereas humans and equidae are considered dead-end hosts. Most human *infections* occur by natural transmission from mosquitoes.

In relation to domestic animal trade, geese and ducks pose a *risk* for the spread of the WNV as some species have been documented to develop a viraemia sufficient to infect mosquitoes.

Surveillance for WNF should be carried out according to Chapter X.X.

The following criteria define the occurrence of WNF:

1. WNV has been isolated from an animal that shows signs consistent with WNF; or

2. viral antigen or viral ribonucleic acid (RNA) specific to WNV has been identified in samples from one or more animals that show clinical signs consistent with WNF, or that is epidemiologically linked to a confirmed or suspected *outbreak* of WNF; or

3. antibodies to WNV that are not a consequence of vaccination, have been identified in an animal, that shows clinical signs consistent with WNF, or that is epidemiologically linked to a confirmed or suspected *outbreak* of WNF.

For the purposes of the *Terrestrial Code*, the *incubation period* for WNF shall be 15 days.

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

When authorising import or transit of the *commodities* covered in the chapter, with the exception of those listed in Article 8.16.2., *Veterinary Authorities* should require the conditions prescribed in this chapter relevant to the WNF status of the *exporting country* or *zone*.

Article 8.16.2.

~~Trade in~~ Safe commodities

Members should not impose trade restrictions on dead-end hosts such as horses.

When authorising import or transit of the following *commodities* and any products made from these, *Veterinary Authorities* should not require any WNV related conditions, regardless of the WNF status of the *exporting country* or *zone*:

Annex XXI (contd)

1. *hatching eggs* ;
2. eggs for human consumption;
3. egg products;
4. *poultry* semen;
5. *fresh meat* and *meat products* of *poultry*;
6. products of *poultry* origin intended for use in animal feeding, or for agricultural or industrial use;
7. feathers and down from *poultry*;
8. semen of horses;
9. *meat* and *meat products* of horses.

~~When authorising import or transit of other *commodities* listed in this chapter, *Veterinary Authorities* should require the conditions prescribed in this chapter relevant to the WNF status of the *exporting country* or *zone*.~~

Article 8.16.3.

WNF free country or zone

1. A country or *zone* may be considered free from WNF when WNF is notifiable in the whole country and either:

   a) no occurrence of WNF *cases*, where *infection* occurred within the territory of the Member, have been recorded for the past 2 years; or

   b) a *surveillance* programme in accordance with Chapter X.X. has demonstrated no evidence of WNV in the country or *zone* during the past 2 years.

2. A WNF free country or *zone* will not lose its free status through the importation from WNF infected countries or *infected zones* of:

   a) seropositive animals;

   b) semen, embryo or ova;

   c) animals vaccinated in accordance with the *Terrestrial Manual* at least 30 days prior to dispatch, and are identified in the accompanying certification as having been vaccinated; or

   d) animals not vaccinated if a *surveillance* programme in accordance with Chapter X.X. has been in place in the source population for a period of 30 days immediately prior to dispatch, and no evidence of WNV transmission has been detected.

Article 8.16.4.

WNF seasonally free country or zone

1. A WNF seasonally free country or *zone* is one in which for part of a year, *surveillance* demonstrates no evidence either of WNV transmission or presence of mosquitoes likely to be competent WNV vectors.

2. For the application of Article 8.16.6., the seasonally free period is taken to commence 21 days following the last evidence of WNV transmission (as demonstrated by the *surveillance* programme), or the cessation of activity of mosquitoes likely to be competent WNV vectors.

3. For the application of Article 8.16.6., the seasonally free period is taken to conclude either:

   a) at least 21 days before the earliest date that historical data show WNV transmission cycle has recommenced; or

   b) immediately if current climatic data or data from a *surveillance* programme indicate an earlier resurgence of activity of mosquitoes likely to be competent WNV vectors.

4. A WNF seasonally free country or *zone* will not lose its free status through the importation from WNF infected countries or *infected zones* of:

   a) seropositive animals;

   b) semen, embryo or ova;

   c) animals vaccinated in accordance with the *Terrestrial Manual* at least 30 days prior to dispatch, and are identified in the accompanying certification as having been vaccinated; or

   d) animals not vaccinated if a *surveillance* programme in accordance with Chapter X.X. has been in place in the source population for a period of 30 days immediately prior to dispatch, and no evidence of WNV transmission has been detected.

Article 8.16.5.

Recommendations for importation from WNF free countries or zones

for ~~susceptible species (other than horses)~~ ducks (under study), geese and birds other than poultry

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

1. the animals were kept in a WNF free country or *zone* since birth or for at least 30 days prior to shipment; or

2. the animals were kept in a WNF free country or *zone* for at least 15 days, were subjected, with negative results, to an agent identification test according to the *Terrestrial Manual* carried out on a sample collected at least 3 days after the commencement of the residence period and remained in the WNF free country or *zone* until shipment; or

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3. the animals:

   a) were vaccinated in accordance with the *Terrestrial Manual* 30 days before introduction into the free country or *zone*; and

   b) were identified as having been vaccinated; and

   c) were kept in a WNF free country or *zone* for at least 15 days; and

   d) remained in the WNF free country or *zone* until shipment;

AND

4. if the animals were exported from a WNF free *zone*, either:

   a) did not transit through an infected country or *infected zone* during transportation to the *place of shipment*; or

   b) were protected from mosquito attacks at all times when transiting through an infected country or *infected zone*; or

   c) had been vaccinated in accordance with point 3 above.

Article 8.16.6.

Recommendations for importation from WNF seasonally free countries or zones

for ~~susceptible species (other than horses)~~ ducks (under study), geese and birds other than poultry

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

1. were kept during the seasonally free period in a WNF seasonally free country or *zone* since birth or for at least 30 days prior to shipment; or

2. were kept during the WNF seasonally free period in a WNF seasonally free country or *zone* for at least 15 days prior to shipment, and were subjected during the residence period in the country or *zone* to an agent identification test according to the *Terrestrial Manual*, with negative results, carried out on a sample collected at least 3 days after the commencement of the residence period and remained in the WNF seasonally free country or *zone* until shipment; or

3. were kept during the seasonally free period in a WNF seasonally free country or *zone* for at least 15 days, and were vaccinated in accordance with the *Terrestrial Manual* 30 days before introduction into the free country or *zone* against WNF, were identified as having been vaccinated and remained in the WNF seasonally free country or *zone* until shipment;

AND

4. if the animals were exported from a WNF seasonally free country or *zone*, either:

   a) did not transit through an infected country or *infected zone* during transportation to the *place of shipment*; or

b) were protected from mosquito attacks at all times when transiting through an infected country or *infected zone*; or

c) were vaccinated in accordance with point 3 above.

Article 8.16.7.

Recommendations for importation from WNF infected countries or infected zones

for ~~susceptible species (other than horses)~~ ducks (under study) and geese

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

1. were protected from mosquito attacks for at least 30 days prior to shipment; or

2. were subjected to a serological test according to the *Terrestrial Manual* to detect WNV neutralizing antibodies with positive results; or

3. were protected from mosquito attacks for at least 15 days prior to shipment, and were subjected during that period to an agent identification test according to the *Terrestrial Manual*, with negative results, carried out on a sample collected at least 3 days after being introduced in the mosquito-free *zone*; or

4. were vaccinated at least 30 days before shipment in accordance with the *Terrestrial Manual* against WNV and were identified in the accompanying certification as having been vaccinated; or

5. are not vaccinated and a *surveillance* programme in accordance with Chapter X.X. has been in place in the source population for a period of 30 days immediately prior to shipment, and no evidence of WNV transmission has been detected;

AND

6. were protected from mosquito attacks during transportation to the *place of shipment*.

Article 8.16.8.

Recommendations for the importation from WNF infected countries ~~of birds~~

for birds other than poultry

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

1. the birds showed no clinical sign of WNF on the day of shipment; and

2. the birds were kept in a *quarantine station* in a mosquito-free environment for 30 days prior to shipment and a statistically valid sample was subjected, with negative results, to an agent identification test at least 3 days after the commencement of the residence period.

Annex XXI (contd)

Article 8.16.9.

Protecting animals from mosquito attacks

When transporting animals through WNF infected countries or *infected zones*, *Veterinary Authorities* should require strategies to protect susceptible animals from mosquito attacks during transport, taking into account the local ecology of the mosquitoes.

Potential *risk management* strategies include:

1. treating animals with insect repellents prior to and during transportation;

2. ensuring *vehicles* do not stop en route unless the animals are held behind insect proof netting;

3. *surveillance* for vectors at common stopping and offloading points to gain information on seasonal variations;

4. integrated pest management practices at holding, common stopping and offloading points;

5. using historical, ongoing and/or WNF modelling information to identify low risk ports and transport routes.

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Annex XXII

CHAPTER 9.1.

ACARAPISOSIS OF HONEY BEES

Article 9.1.1.

General provisions

For the purposes of this Chapter, acarapisosis, acarine disease or tracheal mite infestation is a *disease* of the adult honey bee *Apis mellifera L.*, and possibly of other *Apis* species (such as *Apis cerana*). It is caused by the Tarsonemid mite *Acarapis woodi* (Rennie). The mite is an internal obligate parasite of the respiratory system, living and reproducing mainly in the large prothoracic trachea of the bee. Early signs of *infection* normally go unnoticed, and only when *infection* is heavy does it become apparent; this is generally in the early spring. The *infection* spreads by direct contact from adult bee to adult bee, with newly emerged bees under 10 days old being the most susceptible. The mortality rate may range from moderate to high.

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

When authorising import or transit of the *commodities* covered in the chapter, with the exception of those listed in Article 9.1.2., *Veterinary Authorities* should require the conditions prescribed in this chapter relevant to the acarapisosis status of the honey bee population of the *exporting country* or *zone*.

Article 9.1.2.

~~Trade in~~ Safe commodities

When authorising import or transit of the following *commodities*, *Veterinary Authorities* should not require any acarapisosis related conditions, regardless of the acarapisosis status of the honey bee population of the *exporting country* or *zone*:

1. honey bee semen and honey bee venom;

2. used equipment associated with beekeeping;

3. honey for human consumption, beeswax, honey bee-collected pollen, propolis and royal jelly.

~~When authorising import or transit of other *commodities* listed in this Chapter, *Veterinary Authorities* should require the conditions prescribed in this Chapter relevant to the acarapisosis status of the honey bee population of the *exporting country* or *zone*.~~

Article 9.1.3.

Determination of the acarapisosis status of a country or zone/compartment

The acarapisosis status of a country or *zone/compartment* (under study) can only be determined after considering the following criteria:

1. a *risk assessment* has been conducted, identifying all potential factors for acarapisosis occurrence and their historic perspective;

2. acarapisosis should be notifiable in the whole country or *zone/compartment* (under study) and all clinical signs suggestive of acarapisosis should be subjected to field and laboratory investigations;

Annex XXII (contd)

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

4. the *Veterinary Authority* or other *Competent Authority* with responsibility for reporting and control of *diseases* of honey bees should have current knowledge of, and authority over, all domesticated *apiaries* in the whole country.

Article 9.1.4.

Country or zone/compartment (under study) free from acarapisosis

1. Historically free status

A country or *zone / compartment* (under study) may be considered free from acarapisosis after conducting a *risk assessment* as referred to in Article 9.1.3. but without formally applying a specific *surveillance* programme if the country or *zone/compartment* (under study) complies with the provisions of Chapter 1.4.

2. Free status as a result of an eradication programme

A country or *zone/compartment* (under study) which does not meet the conditions of point 1 above may be considered free from acarapisosis after conducting a *risk assessment* as referred to in Article 9.1.3. and when:

a) the *Veterinary Authority* or other *Competent Authority* with responsibility for reporting and control of *diseases* of honey bees has current knowledge of, and authority over, all domesticated *apiaries* existing in the country or *zone/compartment* (under study);

b) acarapisosis is notifiable in the whole country or *zone/compartment* (under study), and any clinical cases suggestive of acarapisosis are subjected to field and laboratory investigations;

c) for the 3 years following the last reported *case* of acarapisosis, annual surveys supervised by the *Veterinary Authority*, with negative results, have been carried out on a representative sample of *apiaries* in the country or *zone/compartment* (under study) to provide a confidence level of at least 95% of detecting acarapisosis if at least 1% of the *apiaries* were infected at a within-*apiary* prevalence rate of at least 5% of the hives; such surveys may be targeted towards *apiaries*, areas and seasons with a higher likelihood of *disease*;

d) to maintain free status, an annual survey supervised by the *Veterinary Authority*, with negative results, is carried out on a representative sample of *apiaries* in the country or *zone/compartment* (under study) to indicate that there has been no new *cases*; such surveys may be targeted towards areas with a higher likelihood of *disease*;

e) (under study) there is no self-sustaining feral population of *A. mellifera* or other possible host species in the country or *zone/compartment* (under study);

f) the importation of the *commodities* listed in this Chapter into the country or *zone/compartment* (under study) is carried out in conformity with the recommendations of this Chapter.

Article 9.1.5.

Recommendations for the importation of live queen honey bees, worker bees and drones with or without associated brood combs

Veterinary Authorities of *importing countries* should require the presentation of an *international veterinary certificate* attesting that the bees come from a country or *zone/compartment* (under study) free from acarapisosis.

Article 9.1.6.

Recommendations for the importation of eggs, larvae and pupae of honey bees

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

1. were sourced from an officially free country or *zone/compartment* (under study); or

2. were examined by an official laboratory and declared free of all life stages of *A. woodi*; or

3. have originated from queens in a *quarantine station* and were examined microscopically and found free of all life stages of *A. woodi*.

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CHAPTER 9.2.

AMERICAN FOULBROOD OF HONEY BEES

Article 9.2.1.

General provisions

For the purposes of this Chapter, American foulbrood is a *disease* of the larval and pupal stages of the honey bee *Apis mellifera* and other *Apis* spp., and occurs in most countries where such bees are kept. *Paenibacillus larvae*, the causative organism, is a bacterium that can produce over one billion spores in each infected larva. The spores are very long-living and extremely resistant to heat and chemical agents, and only the spores are capable of inducing the *disease*.

Combs of infected *apiaries* may show distinctive clinical signs which can allow the *disease* to be diagnosed in the field. However, subclinical *infections* are common and require laboratory diagnosis.

For the purposes of the *Terrestrial Code*, the *incubation period* for American foulbrood shall be 15 days (not including the wintering period which may vary according to country).

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

When authorising import or transit of the *commodities* covered in the chapter, with the exception of those listed in Article 9.2.2., *Veterinary Authorities* should require the conditions prescribed in this chapter relevant to the American foulbrood status of the honey bee population of the *exporting country* or *zone*.

Article 9.2.2.

~~Trade in~~ Safe commodities

When authorising import or transit of the following *commodities*, *Veterinary Authorities* should not require any American foulbrood related conditions, regardless of the American foulbrood status of the honey bee population of the *exporting country* or *zone*:

1. honey bee semen;

2. honey bee venom.

~~When authorising import or transit of other *commodities* listed in this Chapter, *Veterinary Authorities* should require the conditions prescribed in this Chapter relevant to the American foulbrood status of the honey bee population of the *exporting country* or *zone*.~~

Article 9.2.3.

Determination of the American foulbrood status of a country or zone/compartment

The American foulbrood status of a country or *zone*/*compartment* (under study) can only be determined after considering the following criteria:

1. a *risk assessment* has been conducted, identifying all potential factors for American foulbrood occurrence and their historic perspective;

Annex XXII (contd)

2. American foulbrood should be notifiable in the whole country or *zone/compartment* (under study) and all clinical signs suggestive of American foulbrood should be subjected to field and/or laboratory investigations;

3. an on-going awareness programme should be in place to encourage reporting of all cases suggestive of American foulbrood;

4. the *Veterinary Authority* or other *Competent Authority* with responsibility for reporting and control of *diseases* of honey bees should have current knowledge of, and authority over, all domesticated *apiaries* in the country.

Article 9.2.4.

Country or zone/compartment (under study) free from American foulbrood

1. Historically free status

A country or *zone/compartment* (under study) may be considered free from the *disease* after conducting a *risk assessment* as referred to in Article 9.2.3. but without formally applying a specific *surveillance* programme if the country or *zone/compartment* (under study) complies with the provisions of Chapter 1.4.

2. Free status as a result of an eradication programme

A country or *zone/compartment* (under study) which does not meet the conditions of point 1 above may be considered free from American foulbrood after conducting a *risk assessment* as referred to in Article 9.2.3. and when:

a) the *Veterinary Authority* or other *Competent Authority* with responsibility for reporting and control of *diseases* of honey bees has current knowledge of, and authority over, all domesticated *apiaries* existing in the country or *zone/compartment* (under study);

b) American foulbrood is notifiable in the whole country or *zone /compartment* (under study), and any clinical cases suggestive of American foulbrood are subjected to field and/or laboratory investigations;

c) for the 5 years following the last reported isolation of the American foulbrood agent, annual surveys supervised by the *Veterinary Authority*, with negative results, have been carried out on a representative sample of *apiaries* in the country or *zone/compartment* (under study) to provide a confidence level of at least 95% of detecting American foulbrood if at least 1% of the *apiaries* were infected at a within-*apiary* prevalence rate of at least 5% of the hives; such surveys may be targeted towards areas with the last reported isolation of the American foulbrood agent;

d) to maintain free status, an annual survey supervised by the *Veterinary Authority*, with negative results, is carried out on a representative sample of hives in the country or *zone/compartment* (under study) to indicate that there has been no new isolations; such surveys may be targeted towards areas with a higher likelihood of isolation;

e) (under study) there is no self-sustaining feral population of *A. mellifera* or other possible host species in the country or *zone/compartment* (under study);

f) all equipment associated with previously infected *apiaries* has been sterilised or destroyed;

g) the importation of the *commodities* listed in this Chapter into the country or *zone/compartment* (under study) is carried out in conformity with the recommendations of this Chapter.

Article 9.2.5.

Recommendations for the importation of live queen honey bees, worker bees and drones with or without associated brood combs

Veterinary Authorities of *importing countries* should require the presentation of an *international veterinary certificate* attesting that the bees come from a country or *zone/compartment* (under study) officially free from American foulbrood.

Article 9.2.6.

Recommendations for the importation of eggs, larvae and pupae of honey bees

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

1. were sourced from a free country or *zone/compartment* (under study); or

2. have been isolated from queens in a *quarantine station*, and all workers which accompanied the queen or a representative sample of eggs or larvae were examined for the presence of *P. larvae* by bacterial culture or PCR in accordance with the *Terrestrial Manual*.

Article 9.2.7.

Recommendations for the importation of used equipment associated with beekeeping

Veterinary Authorities of *importing countries* should require the presentation of an *international veterinary certificate* attesting that the equipment was sterilised under the supervision of the *Veterinary Authority* by either immersion in 1% sodium hypochlorite for at least 30 minutes (suitable only for non-porous materials such as plastic and metal), gamma irradiation using a cobalt-60 source at a dose rate of 10 kGy, or processing to ensure the destruction of both bacillary and spore forms of *P. larvae*, in conformity with one of the procedures referred to in Chapter X.X. (under study).

Article 9.2.8.

Recommendations for the importation of honey, honey bee-collected pollen, beeswax, propolis and royal jelly

Veterinary Authorities of *importing countries* officially free from American foulbrood should require the presentation of an *international veterinary certificate* attesting that the products:

Annex XXII (contd)

1. were collected in a country or *zone/compartment* (under study) free from American foulbrood; or

2. have been processed to ensure the destruction of both bacillary and spore forms of *P. larvae*, in conformity with one of the procedures referred to in Chapter X.X. (under study).

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CHAPTER 9.3.

EUROPEAN FOULBROOD OF HONEY BEES

Article 9.3.1.

General provisions

For the purposes of this Chapter, European foulbrood is a *disease* of the larval and pupal stages of the honey bee *Apis mellifera* and other *Apis* spp., and occurs in most countries where such bees are kept. The causative agent is the non-sporulating bacterium *Melissococcus plutonius*. Subclinical *infections* are common and require laboratory diagnosis. *Infection* remains enzootic because of mechanical contamination of the honeycombs. Recurrences of *disease* can therefore be expected in subsequent years.

For the purposes of the *Terrestrial Code*, the *incubation period* for European foulbrood shall be 15 days (not including the wintering period which may vary according to country).

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

When authorising import or transit of the *commodities* covered in the chapter, with the exception of those listed in Article 9.3.2., *Veterinary Authorities* should require the conditions prescribed in this chapter relevant to the European foulbrood status of the honey bee population of the *exporting country* or *zone.*

Article 9.3.2.

~~Trade in~~ Safe commodities

When authorising import or transit of the following *commodities*, *Veterinary Authorities* should not require any European foulbrood related conditions, regardless of the European foulbrood status of the honey bee population of the *exporting country* or *zone*:

1. honey bee semen;

2. honey bee venom.

~~When authorising import or transit of other *commodities* listed in this Chapter, *Veterinary Authorities* should require the conditions prescribed in this Chapter relevant to the European foulbrood status of the honey bee population of the *exporting country* or *zone*.~~

Article 9.3.3.

Determination of the European foulbrood status of a country or zone/compartment

The European foulbrood status of a country or *zone/compartment* (under study) can only be determined after considering the following criteria:

1. a *risk assessment* has been conducted, identifying all potential factors for European foulbrood occurrence and their historic perspective;

2. European foulbrood should be notifiable in the whole country or *zone/compartment* (under study) and all clinical signs suggestive of European foulbrood should be subjected to field and laboratory investigations;

3. an on-going awareness programme should be in place to encourage reporting of all cases suggestive of European foulbrood;

4. the *Veterinary Authority* or other *Competent Authority* with responsibility for reporting and control of *diseases* of honey bees should have current knowledge of, and authority over, all *apiaries* in the whole country.

Article 9.3.4.

Country or zone/compartment (under study) free from European foulbrood

1. Historically free status

A country or *zone /compartment* (under study) may be considered free from the *disease* after conducting a *risk assessment* as referred to in Article 9.3.3. but without formally applying a specific *surveillance* programme if the country or *zone/compartment* (under study) complies with the provisions of Chapter 1.4.

2. Free status as a result of an eradication programme

A country or *zone/compartment* (under study) which does not meet the conditions of point 1 above may be considered free from European foulbrood after conducting a *risk assessment* as referred to in Article 9.3.3. and when:

a) the *Veterinary Authority* or other *Competent Authority* with responsibility for reporting and control of *diseases* of honey bees has current knowledge of, and authority over, all domesticated *apiaries* existing in the country or *zone/compartment* (under study);

b) European foulbrood is notifiable in the whole country or *zone/compartment* (under study), and any clinical cases suggestive of European foulbrood are subjected to field and laboratory investigations;

c) for the 3 years following the last reported isolation of the European foulbrood agent, an annual survey supervised by the *Veterinary Authority*, with negative results, have been carried out on a representative sample of *apiaries* in the country or *zone/compartment* (under study) to provide a confidence level of at least 95% of detecting European foulbrood if at least 1% of the *apiaries* were infected at a within-*apiary* prevalence rate of at least 5% of the hives; such surveys may be targeted towards areas with the last reported isolation of the European foulbrood agent;

d) to maintain free status, an annual survey supervised by the *Veterinary Authority*, with negative results, is carried out on a representative sample of hives in the country or *zone/compartment* (under study) to indicate that there has been no new isolations; such surveys may be targeted towards areas with a higher likelihood of isolation;

e) (under study) there is no self-sustaining feral population of *A. mellifera* or other possible host species in the country or *zone/compartment* (under study);

f) the importation of the *commodities* listed in this Chapter into the country or *zone/compartment* (under study) is carried out in conformity with the recommendations of this Chapter.

Article 9.3.5.

Recommendations for the importation of live queen honey bees, worker bees and drones with or without associated brood combs

Veterinary Authorities of *importing countries* should require the presentation of an *international veterinary certificate* attesting that the bees come from a country or *zone/compartment* (under study) free from European foulbrood.

Article 9.3.6.

Recommendations for the importation of eggs, larvae and pupae of honey bees

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

1. were sourced from a free country or *zone/compartment* (under study); or

2. have been isolated from queens in a *quarantine station*, and all workers which accompanied the queen or a representative sample of eggs or larvae were examined for the presence of *M. plutonius* by bacterial culture or PCR in accordance with the *Terrestrial Manual*.

Article 9.3.7.

Recommendations for the importation of used equipment associated with beekeeping

Veterinary Authorities of *importing countries* should require the presentation of an *international veterinary certificate* attesting that the equipment was sterilised under the supervision of the *Veterinary Authority* by either immersion in 0.5% sodium hypochlorite for at least 20 minutes (suitable only for non-porous materials such as plastic and metal), gamma irradiation using a cobalt-60 source at a dose rate of 10 kGy, or processing to ensure the destruction of *M. plutonius*, in conformity with one of the procedures referred to in Chapter X.X. (under study).

Article 9.3.8.

Recommendations for the importation of honey, honey bee-collected pollen, beeswax, propolis and royal jelly

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

1. were collected in a country or *zone/compartment* (under study) free from European foulbrood; or

2. have been processed to ensure the destruction of *M. plutonius*, in conformity with one of the procedures referred to in Chapter X.X. (under study).

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CHAPTER 9.4.

SMALL HIVE BEETLE INFESTATION
(*Aethina tumida*)

Article 9.4.1.

General provisions

For the purposes of this Chapter, small hive beetle (SHB) is an infestation of bee colonies by the beetle *Aethina tumida*, which is a free-living predator and scavenger affecting populations of the honey bee *Apis mellifera* L. It can also parasitise bumble bee *Bombus terrestris* colonies under experimental conditions, and although infestation has not been demonstrated in wild populations, *Bombus* spp. must also be considered to be susceptible to infestation.

The adult beetle is attracted to bee colonies to reproduce, although it can survive and reproduce independently in other natural environments, using other food sources, including certain types of fruit. Hence once it is established within a localised environment, it is extremely difficult to eradicate.

The life cycle of *A. tumida* begins with the adult beetle laying eggs within infested hives. These are usually laid in irregular masses in crevices or brood combs. After 2-6 days, the eggs hatch and the emerging larvae begin to feed voraciously on brood comb, bee eggs, pollen and honey within the hive. The SHB has a high reproductive potential. Each female can produce about 1,000 eggs in its 4 to 6 months of life. At maturation (approximately 10-29 days after hatching), the larvae exit the hive and burrow into soil around the hive entrance. Adult beetles emerge after an average of 3-4 weeks, although pupation can take between 8 and 60 days depending on temperature and moisture levels.

The life span of an adult beetle depends on environmental conditions such as temperature and humidity but, in practice, adult beetles can live for at least 6 months and, in favourable reproductive conditions, the female is capable of laying new egg batches every 5-12 weeks. The beetle is able to survive at least 2 weeks without food and 50 days on brood combs.

Early signs of infestation may go unnoticed, but the growth of the beetle population is rapid, leading to high bee mortality in the hive. Because *A. tumida* can be found and can thrive within the natural environment, and can fly up to 6-13 km from its nest site, it is capable of dispersing rapidly and directly colonising hives. Dispersal includes following or accompanying swarms. Spread of infestation does not require contact between adult bees. However, the movement of adult bees, honeycomb and other apiculture products and used equipment associated with bee-keeping may all cause infestations to spread to previously unaffected colonies.

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

When authorising import or transit of the *commodities* covered in the chapter, with the exception of those listed in Article 9.4.2., *Veterinary Authorities* should require the conditions prescribed in this chapter relevant to the *A. tumida* status of the honey bee population of the *exporting country* or *zone*.

Annex XXII (contd)

Article 9.4.2.

~~Trade in~~ Safe commodities

When authorising import or transit of the following *commodities*, *Veterinary Authorities* should not require any small hive beetle infestation related conditions, regardless of the *A. tumida* status of the honey bee and bumble bee population of the *exporting country* or *zone*:

1. honey bee semen and honey bee venom;

2. packaged extracted honey for human consumption, refined or rendered beeswax, propolis and frozen or dried royal jelly.

~~When authorising import or transit of other *commodities* listed in this Chapter, *Veterinary Authorities* should require the conditions prescribed in this Chapter relevant to the *A. tumida* status of the honey bee and bumble bee population of the *exporting country* or *zone*.~~

Article 9.4.3.

Determination of the *A. tumida* status of a country or zone

The *A. tumida* status of a country or *zone* can only be determined after considering the following criteria:

1. *A. tumida* infestation should be notifiable in the whole country, and all signs suggestive of *A. tumida* infestation should be subjected to field and *laboratory* investigations;

2. on-going awareness and training programmes should be in place to encourage reporting of all cases suggestive of *A. tumida* infestation;

3. the *Veterinary Authority* or other *Competent Authority* with responsibility for reporting and control of *diseases* of honey bees should have current knowledge of, and authority over, all domesticated *apiaries* in the country.

Article 9.4.4.

Country or zone free from *A. tumida*

1. Historically free status

   A country or *zone* may be considered free from the pest after conducting a *risk assessment* as referred to in Article 9.4.3. but without formally applying a specific *surveillance* programme if the country or *zone* complies with the provisions of Chapter 1.4.

2. Free status as a result of an eradication programme

   A country or *zone* which does not meet the conditions of point 1 above may be considered free from *A. tumida* infestation after conducting a *risk assessment* as referred to in Article 9.4.3. and when:

   a) the *Veterinary Authority* or other *Competent Authority* with responsibility for reporting and control of *diseases* of honey bees has current knowledge of, and authority over, all domesticated *apiaries* existing in the country or *zone*;

b) *A. tumida* infestation is notifiable in the whole country or *zone*, and any clinical cases suggestive of *A. tumida* infestation are subjected to field and *laboratory* investigations; a contingency plan is in place describing controls and inspection activities;

c) for the 5 years following the last reported *case* of *A. tumida* infestation, an annual survey supervised by the *Veterinary Authority*, with negative results, has been carried out on a representative sample of *apiaries* in the country or *zone* to provide a confidence level of at least 95% of detecting *A. tumida* infestation if at least 1% of the *apiaries* were infested at a within-*apiary* prevalence rate of at least 5% of the hives; such surveys may be targeted towards areas with a higher likelihood of infestation;

d) to maintain free status, an annual survey supervised by the *Veterinary Authority*, with negative results, is carried out on a representative sample of *apiaries* to indicate that there have been no new *cases*; such surveys may be targeted towards areas with a higher likelihood of infestation;

e) all equipment associated with previously infested *apiaries* has been destroyed, or cleaned and sterilised to ensure the destruction of *A. tumida* spp., in conformity with one of the procedures referred to in Chapter X.X. (under study);

f) the soil and undergrowth in the immediate vicinity of all infested *apiaries* has been treated with a soil drench or similar suitable treatment that is efficacious in destroying incubating *A. tumida* larvae and pupae;

g) the importation of the *commodities* listed in this Chapter into the country or *zone* is carried out, in conformity with the recommendations of this Chapter.

Article 9.4.5.

Recommendations for the importation of individual consignments containing a single live queen honey bee or queen bumble bee, accompanied by a small number of associated attendants (a maximum of 20 attendants per queen)

Veterinary Authorities of *importing countries* should require the presentation of an *international veterinary certificate* attesting that the bees come from a country or *zone* officially free from *A. tumida* infestation.

OR

Veterinary Authorities of *importing countries* should require the presentation of an *international veterinary certificate* including an attestation from the *Veterinary Authority* of the exporting third country stating that:

1. the bees come from hives or colonies which were inspected immediately prior to dispatch and show no signs or suspicion of the presence of *A. tumida* or its eggs, larvae or pupae; and

2. the bees come from an area of at least 100 km radius where no *apiary* has been subject to any restrictions associated with the occurrence of *A. tumida* for the previous 6 months; and

3. the bees and accompanying packaging presented for export have been thoroughly and individually inspected and do not contain *A. tumida* or its eggs, larvae or pupae; and

4. the consignment of bees is covered with fine mesh through which a live beetle cannot enter.

Article 9.4.6.

Recommendations for the importation of live worker bees, drone bees or bee colonies with or without associated brood combs or for live bumble bees

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

1. the bees come from a country or *zone* officially free from *A. tumida* infestation; and

2. the bees and accompanying packaging presented for export have been inspected and do not contain *A. tumida* or its eggs, larvae or pupae; and

3. the consignment of bees is covered with fine mesh through which a live beetle cannot enter.

Article 9.4.7.

Recommendations for the importation of eggs, larvae and pupae of honey bees or bumble bees

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

1. the products were sourced from a country or *zone* free from *A. tumida* infestation;

OR

2. the products have been bred and kept under a controlled environment within a recognised establishment which is supervised and controlled by the *Veterinary Authority*;

3. the establishment was inspected immediately prior to dispatch and all eggs, larvae and pupae show no clinical signs or suspicion of the presence of *A. tumida* or its eggs or larvae or pupae, and

4. the packaging material, containers, accompanying products and food are new and all precautions have been taken to prevent contamination with *A. tumida* or its eggs, larvae or pupae.

Article 9.4.8.

Recommendations for the importation of used equipment associated with beekeeping

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

1. the equipment:

   EITHER

   a) comes from a country or *zone* free from *A. tumida* infestation; and

   b) contains no live honey bees or bee brood;

OR

c) contains no live honey bees or bee brood; and

d) has been thoroughly cleaned, and treated to ensure the destruction of *A. tumida* spp., in conformity with one of the procedures referred to in Chapter X.X. (under study); and

AND

2. all precautions have been taken to prevent infestation/contamination.

Article 9.4.9.

Recommendations for the importation of honey-bee collected pollen and beeswax (in the form of honeycomb)

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

1. the products:

   EITHER

   a) comes from a country or *zone* free from *A. tumida* infestation; and

   b) contains no live honey bees or bee brood;

   OR

   c) contains no live honey bees or bee brood; and

   d) has been thoroughly cleaned, and treated to ensure the destruction of *A. tumida* spp., in conformity with one of the procedures referred to in Chapter X.X. (under study);

AND

2. all precautions have been taken to prevent infestation/contamination.

Article 9.4.10.

Recommendations for the importation of comb honey

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

1. comes from a country or *zone* free from *A. tumida* infestation; and

2. contains no live honey bees or bee brood;

OR

3. were subjected to a treatment at a temperature of -12°C or lower in the core of the product during at least 24 hours.

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CHAPTER 9.5.

TROPILAELAPS INFESTATION OF HONEY BEES

Article 9.5.1.

General provisions

For the purposes of this Chapter, *Tropilaelaps* infestation of the honey bee *Apis mellifera* L. is caused by the mites *Tropilaelaps clareae*, *T. koenigerum*, *T. thaii* and *T. mercedesae*. The mite is an ectoparasite of brood of *Apis mellifera* L., *Apis laboriosa* and *Apis dorsata*, and cannot survive for periods of more than 7 days away from bee brood.

Early signs of *infection* normally go unnoticed, but the growth in the mite population is rapid leading to high hive mortality. The *infection* spreads by direct contact from adult bee to adult bee, and by the movement of infested bees and bee brood. The mite can also act as a vector for viruses of the honey bee.

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

When authorising import or transit of the *commodities* covered in the chapter, with the exception of those listed in Article 9.5.2., *Veterinary Authorities* should require the conditions prescribed in this chapter relevant to the *Tropilaelaps* status of the honey bee population of the *exporting country* or *zone*.

Article 9.5.2.

~~Trade in~~ Safe commodities

When authorising import or transit of the following *commodities*, *Veterinary Authorities* should not require any *Tropilaelaps* infestation related conditions, regardless of the *Tropilaelaps* status of the honey bee population of the *exporting country* or *zone*:

1. honey bee semen, honey bee eggs and honey bee venom;

2. extracted honey for human consumption and beeswax (not in the form of honeycomb).

~~When authorising import or transit of other *commodities* listed in this Chapter, *Veterinary Authorities* should require the conditions prescribed in this Chapter relevant to the *Tropilaelaps* status of the honey bee population of the *exporting country* or *zone*.~~

Article 9.5.3.

Determination of the *Tropilaelaps* status of a country or zone/compartment

The *Tropilaelaps* status of a country or *zone/compartment* (under study) can only be determined after considering the following criteria:

1. a *risk assessment* has been conducted, identifying all potential factors for *Tropilaelaps* occurrence and their historic perspective;

2. *Tropilaelaps* infestation should be notifiable in the whole country or *zone/compartment* (under study) and all clinical signs suggestive of *Tropilaelaps* infestation should be subjected to field and laboratory investigations;

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

4. the *Veterinary Authority* or other *Competent Authority* with responsibility for reporting and control of *diseases* of honey bees should have current knowledge of, and authority over, all domesticated *apiaries* in the country.

Article 9.5.4.

Country or zone/compartment (under study) free from *Tropilaelaps* spp

1. Historically free status

   A country or *zone/compartment* (under study) may be considered free from the *disease* after conducting a *risk assessment* as referred to in Article 9.5.3. but without formally applying a specific *surveillance* programme if the country or *zone/compartment* (under study) complies with the provisions of Chapter 1.4.

2. Free status as a result of an eradication programme

   A country or *zone/compartment* (under study) which does not meet the conditions of point 1 above may be considered free from *Tropilaelaps* infestation after conducting a *risk assessment* as referred to in Article 9.5.3. and when:

   a) the *Veterinary Authority* or other *Competent Authority* with responsibility for reporting and control of *diseases* of honey bees has current knowledge of, and authority over, all domesticated *apiaries* existing in the country or *zone/compartment* (under study);

   b) *Tropilaelaps* infestation is notifiable in the whole country or *zone/compartment* (under study), and any clinical cases suggestive of *Tropilaelaps* infestation are subjected to field and laboratory investigations;

   c) for the 3 years following the last reported *case* of *Tropilaelaps* infestation, an annual survey supervised by the *Veterinary Authority*, with negative results, have been carried out on a representative sample of *apiaries* in the country or *zone/compartment* (under study) to provide a confidence level of at least 95% of detecting *Tropilaelaps* infestation if at least 1% of the *apiaries* were infected at a within-*apiary* prevalence rate of at least 5% of the hives; such surveys may be targeted towards areas with a higher likelihood of infestation;

   d) to maintain free status, an annual survey supervised by the *Veterinary Authority*, with negative results, is carried out on a representative sample of *apiaries* in the country or *zone/compartment* (under study) to indicate that there has been no new *cases*; such surveys may be targeted towards areas with a higher likelihood of *disease*;

   e) (under study) there is no self-sustaining feral population of *A. mellifera*, *A. dorsata* or *A. laboriosa*, or other possible host species in the country or *zone/compartment* (under study);

   f) the importation of the *commodities* listed in this Chapter into the country or *zone/compartment* (under study) is carried out, in conformity with the recommendations of this Chapter.

Article 9.5.5.

Recommendations for the importation of live queen honey bees, worker bees and drones with associated brood combs

Veterinary Authorities of *importing countries* should require the presentation of an *international veterinary certificate* attesting that the bees come from a country or *zone/compartment* (under study) officially free from *Tropilaelaps* infestation.

Article 9.5.6.

Recommendations for the importation of live queen honey bees, worker bees and drones without associated brood combs

Veterinary Authorities of *importing countries* should require the presentation of an *international veterinary certificate* attesting that the bees have been held in isolation from brood and bees with access to brood, for a period of at least 7 days.

Article 9.5.7.

Recommendations for the importation of used equipment associated with beekeeping

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

1. comes from a country or *zone/compartment* (under study) free from *Tropilaelaps* infestation; or

2. contains no live honey bees or bee brood and has been held away from contact with live honey bees for at least 7 days prior to shipment; or

3. has been treated to ensure the destruction of *Tropilaelaps* spp., in conformity with one of the procedures referred to in Chapter X.X. (under study).

Article 9.5.8.

Recommendations for the importation of honey-bee collected pollen, beeswax (in the form of honeycomb), comb honey and propolis

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

1. come from a country or *zone/compartment* (under study) free from *Tropilaelaps* infestation; or

2. contain no live honey bees or bee brood and has been held away from contact with live honey bees for at least 7 days prior to shipment; or

3. have been treated to ensure the destruction of *Tropilaelaps* spp., in conformity with one of the procedures referred to in Chapter X.X. (under study).

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CHAPTER 9.6.

VARROOSIS OF HONEY BEES

Article 9.6.1.

General provisions

For the purposes of this Chapter, varroosis is a *disease* of the honey bee *Apis mellifera* L. It is caused by the Korea and Japan haplotypes of the mite *Varroa destructor*, the original hosts of which are the Korea and Japan haplotypes of *Apis cerana* (under study). The mite is an ectoparasite of adults and brood of *Apis mellifera* L. During its life cycle, sexual reproduction occurs inside the honey bee brood cells. Early signs of *infection* normally go unnoticed, and only when *infection* is heavy does it become apparent. The *infection* spreads by direct contact from adult bee to adult bee, and by the movement of infested bees and bee brood. The mite can also act as a vector for viruses of the honey bee.

The number of parasites steadily increases with increasing brood activity and the growth of the bee population, especially late in the season when clinical signs of infestation can first be recognised. The life span of an individual mite depends on temperature and humidity but, in practice, it can be said to last from some days to a few months.

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

When authorising import or transit of the *commodities* covered in the chapter, with the exception of those listed in Article 9.6.2., *Veterinary Authorities* should require the conditions prescribed in this chapter relevant to the varroosis status of the honey bee population of the *exporting country* or *zone*.

Article 9.6.2.

~~Trade in~~ Safe commodities

When authorising import or transit of the following *commodities*, *Veterinary Authorities* should not require any varroosis related conditions, regardless of the varroosis status of the honey bee population of the *exporting country* or *zone*:

1. honey bee semen, honey bee eggs and honey bee venom;

2. extracted honey for human consumption and beeswax (not in the form of honeycomb).

~~When authorising import or transit of other *commodities* listed in this Chapter, *Veterinary Authorities* should require the conditions prescribed in this Chapter relevant to the varroosis status of the honey bee population of the *exporting country* or *zone*.~~

Article 9.6.3.

Determination of the varroosis status of a country or zone/compartment

The varroosis status of a country or *zone/compartment* (under study) can only be determined after considering the following criteria:

1. a *risk assessment* has been conducted, identifying all potential factors for varroosis occurrence and their historic perspective;

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2. varroosis should be notifiable in the whole country or *zone/compartment* (under study) and all clinical signs suggestive of varroosis should be subjected to field and laboratory investigations;

3. an on-going awareness programme should be in place to encourage reporting of all cases suggestive of varroosis;

4. the *Veterinary Authority* or other *Competent Authority* with responsibility for reporting and control of *diseases* of honey bees should have current knowledge of, and authority over, all domesticated *apiaries* in the country.

Article 9.6.4.

Country or zone/compartment (under study) free from varroosis

1. Historically free status

A country or *zone/compartment* (under study) may be considered free from the *disease* after conducting a *risk assessment* as referred to in Article 9.6.3. but without formally applying a specific *surveillance* programme (historical freedom) if the country or *zone/compartment* (under study) complies with the provisions of Chapter 1.4.

2. Free status as a result of an eradication programme

A country or *zone/compartment* (under study) which does not meet the conditions of point 1 above may be considered free from varroosis after conducting a *risk assessment* as referred to in Article 9.6.3. and when:

a) the *Veterinary Authority* or other *Competent Authority* with responsibility for reporting and control of *diseases* of honey bees has current knowledge of, and authority over, all domesticated *apiaries* existing in the country or *zone/compartment* (under study);

b) varroosis is notifiable in the whole country or *zone/compartment* (under study), and any clinical cases suggestive of varroosis are subjected to field and laboratory investigations;

c) for the 3 years following the last reported *case* of varroosis, an annual survey supervised by the *Veterinary Authority*, with negative results, have been carried out on a representative sample of *apiaries* in the country or *zone/compartment* (under study) to provide a confidence level of at least 95% of detecting varroosis if at least 1% of the *apiaries* were infected at a within-*apiary* prevalence rate of at least 5% of the hives; such surveys may be targeted towards areas with a higher likelihood of *disease*;

d) to maintain free status, an annual survey supervised by the *Veterinary Authority*, with negative results, is carried out on a representative sample of *apiaries* in the country or *zone/compartment* (under study) to indicate that there has been no new *cases*; such surveys may be targeted towards areas with a higher likelihood of *disease*;

e) (under study) there is no self-sustaining feral population of *A. mellifera*, the Korea and Japan haplotypes of *Apis cerana* or other possible host species in the country or *zone/compartment* (under study);

f) the importation of the *commodities* listed in this Chapter into the country or *zone/compartment* (under study) is carried out in conformity with the recommendations of this Chapter.

Article 9.6.5.

Recommendations for the importation of live queen honey bees, worker bees and drones with or without associated brood combs

Veterinary Authorities of *importing countries* should require the presentation of an *international veterinary certificate* attesting that the bees come from a country or *zone/compartment* (under study) officially free from varroosis.

Article 9.6.6.

Recommendations for the importation of larvae and pupae of honey bees

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

1. were sourced from a free country or *zone/compartment* (under study); or

2. have originated from queens in a *quarantine station* and were inspected and found free of *Varroa destructor*.

Article 9.6.7.

Recommendations for the importation of used equipment associated with beekeeping

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

1. comes from a country or *zone/compartment* (under study) free from varroosis; or
2. contains no live honey bees or bee brood and has been held away from contact with live honey bees for at least 7 days prior to shipment; or
3. has been treated to ensure the destruction of *Varroa destructor*, in conformity with one of the procedures referred to in Chapter X.X. (under study).

Article 9.6.8.

Recommendations for the importation of honey-bee collected pollen, beeswax (in the form of honeycomb), comb honey and propolis

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

1. come from a country or *zone/compartment* (under study) free from varroosis; or

2. contain no live honey bees or bee brood and has been held away from contact with live honey bees for at least 7 days prior to shipment; or

3. have been treated to ensure the destruction of *Varroa destructor*, in conformity with one of the procedures referred to in Chapter X.X. (under study).

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Annex XXIII

CHAPTER 10.4.

AVIAN INFLUENZA

Article 10.4.1.

General provisions

1. For the purposes of *international trade*, avian influenza in its notifiable form (NAI) is defined as an *infection* of *poultry* caused by any influenza A virus of the H5 or H7 subtypes or by any AI virus with an intravenous pathogenicity index (IVPI) greater than 1.2 (or as an alternative at least 75% mortality) as described below. NAI viruses can be divided into highly pathogenic notifiable avian influenza (HPNAI) and low pathogenicity notifiable avian influenza (LPNAI):

   a) HPNAI viruses have an IVPI in 6-week-old chickens greater than 1.2 or, as an alternative, cause at least 75% mortality in 4-to 8-week-old chickens infected intravenously. H5 and H7 viruses which do not have an IVPI of greater than 1.2 or cause less than 75% mortality in an intravenous lethality test should be sequenced to determine whether multiple basic amino acids are present at the cleavage site of the haemagglutinin molecule (HA0); if the amino acid motif is similar to that observed for other HPNAI isolates, the isolate being tested should be considered as HPNAI;

   b) LPNAI are all influenza A viruses of H5 and H7 subtype that are not HPNAI viruses.

2. *Poultry* is defined as 'all domesticated birds, including backyard *poultry*, used for the production of meat or eggs for consumption, for the production of other commercial products, for restocking supplies of game, or for breeding these categories of birds, as well as fighting cocks used for any purpose'.

   Birds that are kept in captivity for any reason other than those reasons referred to in the preceding paragraph, including those that are kept for shows, races, exhibitions, competitions or for breeding or selling these categories of birds as well as pet birds, are not considered to be *poultry*.

3. For the purposes of *international trade*, this chapter deals not only with the occurrence of clinical signs caused by NAI virus, but also with the presence of *infection* with NAI virus in the absence of clinical signs.

4. For the purposes of *international trade*, a Member should not impose immediate bans on the trade in *poultry commodities* in response to a notification, according to Article 1.2.3. of the *Terrestrial Code*, of *infection* with HPAI and LPAI virus in birds other than *poultry*, including wild birds.

5. Antibodies to H5 or H7 subtype of NAI virus, which have been detected in *poultry* and are not a consequence of vaccination, have to be immediately investigated. In the case of isolated serological positive results, NAI infection may be ruled out on the basis of a thorough epidemiological and laboratory investigation that does not demonstrate further evidence of NAI infection.

6. The following defines the occurrence of *infection* with NAI virus:

   a) HPNAI virus has been isolated and identified as such or viral RNA specific for HPNAI has been detected in *poultry* or a product derived from *poultry*; or

   b) LPNAI virus has been isolated and identified as such or viral RNA specific for LPNAI has been detected in *poultry* or a product derived from *poultry*.

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For the purposes of the *Terrestrial Code*, 'NAI free establishment' means an *establishment* in which the *poultry* have shown no evidence of NAI infection, based on *surveillance* in accordance with Articles 10.4.28. to 10.4.34.

For the purposes of the *Terrestrial Code*, the *incubation period* for NAI shall be 21 days.

Standards for diagnostic tests, including pathogenicity testing, are described in the *Terrestrial Manual*. Any vaccine used should comply with the standards described in the *Terrestrial Manual*.

Article 10.4.2.

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

The NAI status of a country, a *zone* or a *compartment* can be determined on the basis of the following criteria:

1. NAI is notifiable in the whole country, an on-going NAI awareness programme is in place, and all notified suspect occurrences of NAI are subjected to field and, where applicable, *laboratory* investigations;

2. appropriate *surveillance* is in place to demonstrate the presence of *infection* in the absence of clinical signs in *poultry*, and the risk posed by birds other than *poultry*; this may be achieved through a NAI *surveillance* programme in accordance with Articles 10.4.28. to 10.4.34.;

3. consideration of all epidemiological factors for NAI occurrence and their historical perspective.

Article 10.4.3.

NAI free country, zone or compartment

A country, *zone* or *compartment* may be considered free from NAI when it has been shown that neither HPNAI nor LPNAI infection in *poultry* has been present in the country, *zone* or *compartment* for the past 12 months, based on *surveillance* in accordance with Articles 10.4.28. to 10.4.34.

If *infection* has occurred in *poultry* in a previously free country, *zone* or *compartment*, NAI free status can be regained:

1. In the case of HPNAI *infections*, 3 months after a *stamping-out policy* (including *disinfection* of all affected *establishments*) is applied, providing that *surveillance* in accordance with Articles 10.4.28. to 10.4.34. has been carried out during that three-month period.

2. In the case of LPNAI *infections*, *poultry* may be kept for *slaughter* for human consumption subject to conditions specified in Articles 10.4.20. or 10.4.21. or a *stamping-out policy* may be applied; in either case, 3 months after the *disinfection* of all affected *establishments*, providing that *surveillance* in accordance with Articles 10.4.28. to 10.4.34. has been carried out during that three-month period.

Article 10.4.4.

HPNAI free country, zone or compartment

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

1. it has been shown that HPNAI infection in *poultry* has not been present in the country, *zone* or *compartment* for the past 12 months, although its LPNAI status may be unknown; or

2. when, based on *surveillance* in accordance with Articles 10.4.28. to 10.4.34., it does not meet the criteria for freedom from NAI but any NAI virus detected has not been identified as HPNAI virus.

The *surveillance* may need to be adapted to parts of the country or existing *zones* or *compartments* depending on historical or geographical factors, industry structure, population data, or proximity to recent *outbreaks*.

If *infection* has occurred in *poultry* in a previously free country, *zone* or *compartment*, HPNAI free status can be regained 3 months after a *stamping-out policy* (including *disinfection* of all affected *establishments*) is applied, providing that *surveillance* in accordance with Articles 10.4.28. to 10.4.34. has been carried out during that three-month period.

Article 10.4.5.

Recommendations for importation from a NAI free country, zone or compartment

for live poultry (other than day-old poultry)

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

1. the *poultry* showed no clinical sign of NAI on the day of shipment;

2. the *poultry* were kept in a NAI free country, *zone* or *compartment* since they were hatched or for at least the past 21 days;

3. the *poultry* are transported in new or appropriately sanitized *containers*;

4. if the *poultry* have been vaccinated against NAI, it has been done in accordance with the provisions of the *Terrestrial Manual* and the nature of the vaccine used and the date of vaccination have been attached to the *certificate*.

Article 10.4.6.

Recommendations for the importation of live birds other than poultry

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

1. on the day of shipment, the birds showed no clinical sign of *infection* with a virus which would be considered NAI in *poultry* ~~on the day of shipment~~;

2. the birds were kept in isolation approved by the *Veterinary Services* since they were hatched or for at least the 21 days prior to shipment and showed no clinical sign of *infection* with a virus which would be considered NAI in *poultry* during the isolation period;

3. a statistically valid sample of the birds, selected in accordance with the provisions of Article 10.4.30, ~~at a design prevalence acceptable to the *importing country*~~ was subjected to a diagnostic test within 14 days prior to shipment to demonstrate freedom from *infection* with a virus which would be considered NAI in *poultry*;

4. the birds are transported in new or appropriately sanitized *containers*;

5. if the birds have been vaccinated against NAI, it has been done in accordance with the provisions of the *Terrestrial Manual* and the nature of the vaccine used and the date of vaccination have been attached to the *certificate*.

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Article 10.4.7.

Recommendations for importation from a NAI free country, zone or compartment

for day-old live poultry

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

1. the *poultry* were kept in a NAI free country, *zone* or *compartment* since they were hatched;

2. the *poultry* were derived from parent *flocks* which had been kept in a NAI free country, *zone* or *compartment* for at least 21 days prior to and at the time of the collection of the eggs;

3. the *poultry* are transported in new or appropriately sanitized *containers*;

4. if the *poultry* or the parent *flocks* have been vaccinated against NAI, it has been done in accordance with the provisions of the *Terrestrial Manual* and the nature of the vaccine used and the date of vaccination have been attached to the *certificate*.

Article 10.4.8.

Recommendations for importation from a HPNAI free country, zone or compartment

for day-old live poultry

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

1. the *poultry* were kept in a HPNAI free country, *zone* or *compartment* since they were hatched;

2. the *poultry* were derived from parent *flocks* which had been kept in a NAI free *establishment* for at least 21 days prior to and at the time of the collection of the eggs;

3. the *poultry* are transported in new or appropriately sanitized *containers*;

4. if the *poultry* or the parent *flocks* have been vaccinated against NAI, it has been done in accordance with the provisions of the *Terrestrial Manual* and the nature of the vaccine used and the date of vaccination have been attached to the *certificate*.

Article 10.4.9.

Recommendations for the importation of day-old live birds other than poultry

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

1. on the day of shipment, the birds showed no clinical signs of *infection* with a virus which would be considered ~~suggestive of~~ NAI in *poultry* ~~on the day of shipment~~;

2. the birds were hatched and kept in isolation approved by the *Veterinary Services*;

3. the parent *flock* birds were subjected to a diagnostic test at the time of the collection of the eggs to demonstrate freedom from *infection* with NAIV;

4. the birds are transported in new or appropriately sanitized *containers*;

5. if the birds or parent *flocks* have been vaccinated against NAI, it has been done in accordance with the provisions of the *Terrestrial Manual* and the nature of the vaccine used and the date of vaccination have been attached to the *certificate*.

Article 10.4.10.

Recommendations for importation from a NAI free country, zone or compartment

for hatching eggs of poultry

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

1. the eggs came from a NAI free country, *zone* or *compartment*;

2. the eggs were derived from parent *flocks* which had been kept in a NAI free country, *zone* or *compartment* for at least 21 days prior to and at the time of the collection of the eggs;

3. the eggs are transported in new or appropriately sanitized ~~*containers*~~ packaging materials;

4. if the parent *flocks* have been vaccinated against NAI, it has been done in accordance with the provisions of the *Terrestrial Manual* and the nature of the vaccine used and the date of vaccination have been attached to the *certificate*.

Article 10.4.11.

Recommendations for importation from a HPNAI free country, zone or compartment

for hatching eggs of poultry

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

1. the eggs came from a HPNAI free country, *zone* or *compartment*;

2. the eggs were derived from parent *flocks* which had been kept in a NAI free *establishment* for at least 21 days prior to and at the time of the collection of the eggs;

3. the eggs have had their surfaces sanitised (in accordance with Chapter 6.4.);

4. the eggs are transported in new or appropriately sanitized ~~*containers*~~ packaging materials;

5. if the parent *flocks* have been vaccinated against NAI, it has been done in accordance with the provisions of the *Terrestrial Manual* and the nature of the vaccine used and the date of vaccination have been attached to the *certificate*.

Article 10.4.12.

Recommendations for the importation of hatching eggs from birds other than poultry

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

1. the parent *flock* birds were subjected to a diagnostic test 7 days prior to and at the time of the collection of the eggs to demonstrate freedom from *infection* with NAIV;

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2. the eggs have had their surfaces sanitized (in accordance with Chapter 6.4.);

3. the eggs are transported in new or appropriately sanitized ~~*containers*~~ packaging materials;

4. if the parent *flocks* have been vaccinated against NAI, it has been done in accordance with the provisions of the *Terrestrial Manual* and the nature of the vaccine used and the date of vaccination have been attached to the *certificate*.

Article 10.4.13.

Recommendations for importation from a NAI free country, zone or compartment

for eggs for human consumption

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

1. the eggs were produced and packed in a NAI free country, *zone* or *compartment*;

2. the eggs are transported in new or appropriately sanitized ~~*containers*~~ packaging materials.

Article 10.4.14.

Recommendations for importation from a HPNAI free country, zone or compartment

for eggs for human consumption

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

1. the eggs were produced and packed in a HPNAI free country, *zone* or *compartment*;

2. the eggs have had their surfaces sanitized (in accordance with Chapter 6.4.);

3. the eggs are transported in new or appropriately sanitized ~~*containers*~~ packaging materials.

Article 10.4.15.

Recommendations for importation of egg products of poultry

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

1. the *commodity* is derived from eggs which meet the requirements of Articles 10.4.11. or 10.4.14.; or

2. the *commodity* has been processed to ensure the destruction of NAI virus in accordance with Article 10.4.26.;

AND

3. the necessary precautions were taken to avoid contact of the *commodity* with any source of NAI virus.

Article 10.4.16.

Recommendations for importation from a NAI free country, zone or compartment

for poultry semen

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

1. showed no clinical sign of NAI on the day of semen collection;

2. were kept in a NAI free country, *zone* or *compartment* for at least the 21 days prior to and at the time of semen collection.

Article 10.4.17.

Recommendations for the importation from a HPNAI free country, zone or compartment

for poultry semen

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

1. showed no clinical sign of HPNAI on the day of semen collection;

2. were kept in a HPNAI free country, *zone* or *compartment* for at least the 21 days prior to and at the time of semen collection.

Article 10.4.18.

Recommendations for the importation of semen of birds other than poultry

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

1. were kept in isolation approved by the *Veterinary Services* for at least the 21 days prior to semen collection;

2. showed no clinical sign of *infection* with a virus which would be considered NAI in *poultry* during the isolation period;

3. were tested within 14 days prior to semen collection and shown to be free of NAI infection.

~~Article 10.4.19.~~

~~**Recommendations for importation from a NAI free country, zone or compartment**~~

~~for *fresh meat* of poultry~~

~~*Veterinary Authorities* should require the presentation of an *international veterinary certificate* attesting that the entire consignment of *fresh meat* comes from *poultry*.~~

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~~1. which have been kept in a NAI free country, *zone* or *compartment* since they were hatched or for at least the past 21 days;~~

~~2. which have been slaughtered in an approved *abattoir* in a NAI free country, *zone* or *compartment* and have been subjected to ante-mortem and post-mortem inspections in accordance with Chapter 6.2. and have been found free of any signs suggestive of NAI.~~

Article 10.4.20.

Recommendations for importation from either a NAI or HPNAI free country, zone or compartment

for *fresh meat* of poultry

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

1. which have been kept in a ~~HPNAI free~~ country, *zone* or *compartment* free from HPNAI since they were hatched or for at least the past 21 days;

2. which have been slaughtered in an approved *abattoir* in a ~~HPNAI free~~ country, *zone* or *compartment* free from HPNAI and have been subjected to ante-mortem and post-mortem inspections in accordance with Chapter 6.2. and have been found free of any signs suggestive of NAI.

Article 10.4.21.

Recommendations for the importation of meat products of poultry

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

1. the *commodity* is derived from *fresh meat* which meet the requirements of Article~~s 10.4.19. or~~ 10.4.20.; or

2. the *commodity* has been processed to ensure the destruction of NAI virus in accordance with Article 10.4.27.;

   AND

3. the necessary precautions were taken to avoid contact of the *commodity* with any source of NAI virus.

Article 10.4.22.

Recommendations for the importation of products of poultry origin, other than feather meal and poultry meat meal, intended for use in animal feeding, or for agricultural or industrial use ~~other than feather meal~~

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

1. these *commodities* were processed in a NAI free country, *zone* or *compartment* from poultry which were kept in a NAI free country, *zone* or *compartment* from the time they were hatched until the time of *slaughter* or for at least the 21 days preceding *slaughter*; or

2. these *commodities* have been processed to ensure the destruction of NAI virus (under study);

AND

3. the necessary precautions were taken to avoid contact of the *commodity* with any source of NAI virus.

Article 10.4.23.

Recommendations for the importation of feathers and down of poultry

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

1. these *commodities* originated from *poultry* as described in Articles 10.4.19. or 10.4.20. and were processed in a NAI free country, *zone* or *compartment*; or

2. these *commodities* have been processed to ensure the destruction of NAI virus (under study);

AND

3. the necessary precautions were taken to avoid contact of the *commodity* with any source of NAI virus.

Article 10.4.24.

Recommendations for the importation of feathers and down of birds other than poultry

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

1. these *commodities* have been processed to ensure the destruction of NAI virus (under study); and

2. the necessary precautions were taken to avoid contact of the *commodity* with any source of NAI virus.

Article 10.4.25.

Recommendations for the importation of feather meal and poultry meat meal

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

1. these *commodities* were processed in a NAI free country, *zone* or *compartment* from *poultry* which were kept in a NAI free country, *zone* or *compartment* from the time they were hatched until the time of *slaughter* or for at least the 21 days preceding *slaughter*; or

2. these *commodities* have been processed either;

    a) with moist heat at a minimum temperature of 118ºC for minimum of 40 minutes; or

    b) with a continuous hydrolysing process under at least 3.79 bar of pressure with steam at a minimum temperature of 122 ºC for a minimum of 15 minutes; or

    c) with an alternative rendering process that ensures that the internal temperature throughout the product reaches at least 74 ºC.

Annex XXIII (contd)

AND

3. the necessary precautions were taken to avoid contact of the *commodity* with any source of NAI virus.

Article 10.4.26.

Procedures for the inactivation of the AI virus in eggs and egg products

The following times for industry standard temperatures are suitable for the inactivation of AI virus present in eggs and egg products:

	Temperature (°C)	**Time**
Whole egg	60	188 seconds
Whole egg blends	60	188 seconds
Whole egg blends	61.1	94 seconds
Liquid egg white	55.6	870 seconds
Liquid egg white	56.7	232 seconds
10% salted yolk	62.2	138 seconds
Dried egg white	67	20 hours
Dried egg white	54.4	513 hours

The listed temperatures are indicative of a range that achieves a 7-log kill. Where scientifically documented, variances from these times and temperatures may also be suitable when they achieve the inactivation of the virus.

Article 10.4.27.

Procedures for the inactivation of the AI virus in meat

A procedure which produces a core temperature of 70ºC for 3.5 seconds is suitable for the inactivation of AI virus present in meat.

	Temperature (°C)	**Time**
Poultry meat	60.0	507 seconds
	65.0	42 seconds
	70.0	3.5 seconds
	73.9	0.51 seconds

Article 10.4.28.

Surveillance: introduction

Articles 10.4.28. to 10.4.34. define the principles and provide a guide on the *surveillance* ~~of~~ for NAI complementary to Chapter 1.4., applicable to Members seeking to determine their NAI status. This may be for the entire country, *zone* or *compartment*. Guidance for Members seeking free status following an *outbreak* and for the maintenance of NAI status is also provided.

The presence of avian influenza viruses in wild birds creates a particular problem. In essence, no Member can declare itself free from avian influenza (AI) in wild birds. However, the definition of NAI in this Chapter refers to the *infection* in *poultry* only, and Articles 10.4.28. to 10.4.34. were developed under this definition.

The impact and epidemiology of NAI differ widely in different regions of the world and therefore it is impossible to provide specific recommendations for all situations. *Surveillance* strategies employed for demonstrating freedom from NAI at an acceptable level of confidence will need to be adapted to the local situation. Variables such as the frequency of contacts of *poultry* with wild birds, different biosecurity levels and production systems and the commingling of different susceptible species including domestic waterfowl require specific *surveillance* strategies to address each specific situation. It is incumbent upon the Member to provide scientific data that explains the epidemiology of NAI in the region concerned and also demonstrates how all the risk factors are managed. There is therefore considerable latitude available to Members to provide a well-reasoned argument to prove that absence of NAI virus (NAIV) infection is assured at an acceptable level of confidence.

Surveillance for NAI should be in the form of a continuing programme designed to establish that the country, *zone* or *compartment*, for which application is made, is free from NAIV infection.

Article 10.4.29.

Surveillance: general conditions and methods

1. A *surveillance* system in accordance with Chapter 1.4. should be under the responsibility of the *Veterinary Authority*. In particular:

   a) a formal and ongoing system for detecting and investigating *outbreaks of disease* or NAI infection should be in place;

   b) a procedure should be in place for the rapid collection and transport of samples from suspect cases of NAI to a *laboratory* for NAI diagnosis as described in the *Terrestrial Manual*;

   c) a system for recording, managing and analysing diagnostic and *surveillance* data should be in place.

2. The NAI *surveillance* programme should:

   a) include an early warning system throughout the production, marketing and processing chain for reporting suspicious cases. Farmers and workers, who have day-to-day contact with *poultry*, as well as diagnosticians, should report promptly any suspicion of NAI to the *Veterinary Authority*. They should be supported directly or indirectly (e.g. through private *veterinarians* or *veterinary para-professionals*) by government information programmes and the *Veterinary Authority*. All suspected cases of NAI should be investigated immediately. As suspicion cannot always be resolved by epidemiological and clinical investigation alone, samples should be taken and submitted to a *laboratory* for appropriate tests. This requires that sampling kits and other equipment are available for those responsible for *surveillance*. Personnel responsible for *surveillance* should be able to call for assistance from a team with expertise in NAI diagnosis and control. In cases where potential public health implications are suspected, notification to the appropriate public health authorities is essential;

   b) implement, when relevant, regular and frequent clinical inspection, serological and virological testing of high-risk groups of animals, such as those adjacent to a NAI infected country, *zone* or *compartment*, places where birds and *poultry* of different origins are mixed, such as live bird markets, *poultry* in close proximity to waterfowl or other potential sources of NAIV.

Annex XXIII (contd)

An effective *surveillance* system will periodically identify suspicious cases that require follow-up and investigation to confirm or exclude that the cause of the condition is NAIV. The rate at which such suspicious cases are likely to occur will differ between epidemiological situations and cannot therefore be predicted reliably. Applications for freedom from NAIV infection should, in consequence, provide details of the occurrence of suspicious cases and how they were investigated and dealt with. This should include the results of *laboratory* testing and the control measures to which the animals concerned were subjected during the investigation (quarantine, movement stand-still orders, etc.).

Article 10.4.30.

Surveillance strategies

1. Introduction

The target population for *surveillance* aimed at identification of *disease* and *infection* should cover all the susceptible *poultry* species within the country, *zone* or *compartment*. Active and passive *surveillance* for NAI should be ongoing. The frequency of active *surveillance* should be at least every 6 months. *Surveillance* should be composed of random and targeted approaches using virological, serological and clinical methods.

The strategy employed may be based on randomised sampling requiring *surveillance* consistent with demonstrating the absence of NAIV infection at an acceptable level of confidence. Random *surveillance* is conducted using serological tests described in the *Terrestrial Manual*. Positive serological results should be followed up with virological methods.

Targeted *surveillance* (e.g. based on the increased likelihood of *infection* in particular localities or species) may be an appropriate strategy. Virological and serological methods should be used concurrently to define the NAI status of high risk populations.

A Member should justify the *surveillance* strategy chosen as adequate to detect the presence of NAIV infection in accordance with Chapter 1.4. and the prevailing epidemiological situation, including *cases* of HPAI detected in any birds. It may, for example, be appropriate to target clinical *surveillance* at particular species likely to exhibit clear clinical signs (e.g. chickens). Similarly, virological and serological testing could be targeted to species that may not show clinical signs (e.g. ducks).

If a Member wishes to declare freedom from NAIV infection in a specific *zone* or *compartment*, the design of the survey and the basis for the sampling process would need to be aimed at the population within the *zone* or *compartment*.

For random surveys, the design of the sampling strategy will need to incorporate epidemiologically appropriate design prevalence. The sample size selected for testing will need to be large enough to detect *infection* if it were to occur at a predetermined minimum rate. The sample size and expected *disease* prevalence determine the level of confidence in the results of the survey. The Member must justify the choice of design prevalence and confidence level based on the objectives of *surveillance* and the epidemiological situation, in accordance with Chapter 1.4. Selection of the design prevalence in particular clearly needs to be based on the prevailing or historical epidemiological situation.

Irrespective of the survey approach selected, the sensitivity and specificity of the diagnostic tests employed are key factors in the design, sample size determination and interpretation of the results obtained. Ideally, the sensitivity and specificity of the tests used should be validated for the vaccination/*infection* history and the different species in the target population.

Irrespective of the testing system employed, *surveillance* system 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 needs to be an effective procedure for following up positives to ultimately determine with a high level of confidence, whether they are indicative of *infection* or not. This should involve both supplementary tests and follow-up investigation to collect diagnostic material from the original sampling unit as well as *flocks* which may be epidemiologically linked to it.

The principles involved in *surveillance* for *disease/infection* are technically well defined. The design of *surveillance* programmes to prove the absence of NAIV infection/circulation needs to be carefully followed to avoid producing results that are either insufficiently reliable, or excessively costly and logistically complicated. The design of any *surveillance* programme, therefore, requires inputs from professionals competent and experienced in this field.

2. Clinical surveillance

Clinical *surveillance* aims at the detection of clinical signs of NAI at the *flock* level. Whereas significant emphasis is placed on the diagnostic value of mass serological screening, *surveillance* based on clinical inspection should not be underrated. Monitoring of production parameters, such as increased mortality, reduced feed and water consumption, presence of clinical signs of a respiratory *disease* or a drop in egg production, is important for the early detection of NAIV infection. In some cases, the only indication of LPNAIV infection may be a drop in feed consumption or egg production.

Clinical *surveillance* and *laboratory* testing should always be applied in series to clarify the status of NAI suspects detected by either of these complementary diagnostic approaches. *Laboratory* testing may confirm clinical suspicion, while clinical *surveillance* may contribute to confirmation of positive serology. Any sampling unit within which suspicious animals are detected should have restrictions imposed upon it until NAI infection is ruled out.

Identification of suspect *flocks* is vital to the identification of sources of NAIV and to enable the molecular, antigenic and other biological characteristics of the virus to be determined. It is essential that NAIV isolates are sent regularly to the regional Reference Laboratory for genetic and antigenic characterization.

3. Virological surveillance

Virological *surveillance* using tests described in the *Terrestrial Manual* should be conducted:

a) to monitor at risk populations;

b) to confirm clinically suspect cases;

c) to follow up positive serological results;

d) to test 'normal' daily mortality, to ensure early detection of *infection* in the face of vaccination or in *establishments* epidemiologically linked to an *outbreak*.

4. Serological surveillance

Serological *surveillance* aims at the detection of antibodies against NAIV. Positive NAIV antibody test results can have four possible causes:

a) natural *infection* with NAIV;

b) vaccination against NAI;

c) maternal antibodies derived from a vaccinated or infected parent *flock* are usually found in the yolk and can persist in progeny for up to 4 weeks;

d) false positive results due to the lack of specificity of the test.

It may be possible to use serum collected for other survey purposes for NAI *surveillance*. However, the principles of survey design described in these recommendations and the requirement for a statistically valid survey for the presence of NAIV should not be compromised.

The discovery of clusters of seropositive *flocks* may reflect any of a series of events, including but not limited to the demographics of the population sampled, vaccinal exposure or *infection*. As clustering may signal *infection*, the investigation of all instances must be incorporated in the survey design. Clustering of positive *flocks* is always epidemiologically significant and therefore should be investigated.

If vaccination cannot be excluded as the cause of positive serological reactions, diagnostic methods to differentiate antibodies due to *infection* or vaccination should be employed.

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

5. Virological and serological surveillance in vaccinated populations

The *surveillance* strategy is dependent on the type of vaccine used. The protection against AI is haemagglutinin subtype specific. Therefore, two broad vaccination strategies exist: 1) inactivated whole AI viruses, and 2) haemagglutinin expression-based vaccines.

In the case of vaccinated populations, the *surveillance* strategy should be based on virological and/or serological methods and clinical *surveillance*. It may be appropriate to use sentinel birds for this purpose. These birds should be unvaccinated, AI virus antibody free birds and clearly and permanently identified. Sentinel birds should be used only if no appropriate *laboratory* procedures are available. The interpretation of serological results in the presence of vaccination is described in Article 10.4.34.

Article 10.4.31.

Documentation of NAI or HPNAI free status

1. Members declaring freedom from NAI or HPNAI for the country, zone or compartment: additional surveillance procedures

In addition to the general conditions described in above mentioned articles, a Member declaring freedom from NAI or HPNAI for the entire country, or a *zone* or a *compartment* should provide evidence for the existence of an effective *surveillance* programme. The strategy and design of the *surveillance* programme will depend on the prevailing epidemiological circumstances and should be planned and implemented according to general conditions and methods described in this Chapter, to demonstrate absence of NAIV or HPNAIV infection, during the preceding 12 months in susceptible *poultry* populations (vaccinated and non-vaccinated). This requires the support of a *laboratory* able to undertake identification of NAIV or HPNAIV infection through virus detection and antibody tests described in the *Terrestrial Manual*. This *surveillance* may be targeted to *poultry* population at specific risks linked to the types of production, possible direct or indirect contact with wild birds, multi-age *flocks*, local trade patterns including live bird markets, use of possibly contaminated surface water, and the presence of more than one species on the holding and poor biosecurity measures in place.

2. Additional requirements for countries, zones or compartments that practise vaccination

Vaccination to prevent the transmission of HPNAI virus may be part of a *disease* control programme. The level of *flock* immunity required to prevent transmission will depend on the *flock* size, composition (e.g. species) and density of the susceptible *poultry* population. It is therefore impossible to be prescriptive. The vaccine must also comply with the provisions stipulated for NAI vaccines in the *Terrestrial Manual*. Based on the epidemiology of NAI in the country, *zone* or *compartment*, it may be that a decision is reached to vaccinate only certain species or other *poultry* subpopulations.

In all vaccinated *flocks* there is a need to perform virological and serological tests to ensure the absence of virus circulation. The use of sentinel *poultry* may provide further confidence of the absence of virus circulation. The tests have to be repeated at least every 6 months or at shorter intervals according to the risk in the country, *zone* or *compartment*.

Evidence to show the effectiveness of the vaccination programme should also be provided.

Article 10.4.32.

Countries, zones or compartments declaring that they have regained freedom from NAI or HPNAI following an outbreak: additional surveillance procedures

In addition to the general conditions described in the above-mentioned articles, a Member declaring that it has regained country, *zone* or *compartment* freedom from NAI or HPNAI virus infection should show evidence of an active *surveillance* programme depending on the epidemiological circumstances of the *outbreak* to demonstrate the absence of the *infection*. This will require *surveillance* incorporating virus detection and antibody tests described in the *Terrestrial Manual*. The use of sentinel birds may facilitate the interpretation of *surveillance* results.

A Member declaring freedom of country, *zone* or *compartment* after an *outbreak* of NAI or HPNAI (with or without vaccination) should report the results of an active *surveillance* programme in which the NAI or HPNAI susceptible *poultry* population undergoes regular clinical examination and active *surveillance* planned and implemented according to the general conditions and methods described in these recommendations. The *surveillance* should at least give the confidence that can be given by a randomized representative sample of the populations at risk.

Article 10.4.33.

NAI free establishments within HPNAI free compartments: additional surveillance procedures

The declaration of NAI free *establishments* requires the demonstration of absence of NAIV infection. Birds in these *establishments* should be randomly tested using virus detection or isolation tests, and serological methods, following the general conditions of these recommendations. The frequency of testing should be based on the risk of *infection* and at a maximum interval of 21 days.

Article 10.4.34.

The use and interpretation of serological and virus detection tests

Poultry infected with NAI virus produce antibodies to haemagglutinin (HA), neuraminidase (NA), nonstructural proteins (NSPs), nucleoprotein/matrix (NP/M) and the polymerase complex proteins. Detection of antibodies against the polymerase complex proteins will not be covered in this Chapter. Tests for NP/M antibodies include direct and blocking ELISA, and agar gel immunodiffusion (AGID)

tests. Tests for antibodies against NA include the neuraminidase inhibition (NI), indirect fluorescent antibody and direct and blocking ELISA tests. For the HA, antibodies are detected in haemagglutination inhibition (HI), ELISA and neutralization (SN) tests. The HI test is reliable in avian species but not in mammals. The SN test can be used to detect subtype specific antibodies to the haemagglutinin and is the preferred test for mammals and some avian species. The AGID test is reliable for detection of NP/M antibodies in chickens and turkeys, but not in other avian species. As an alternative, blocking ELISA tests have been developed to detect NP/M antibodies in all avian species.

The HI and NI tests can be used to subtype AI viruses into 16 haemagglutinin and 9 neuraminidase subtypes. Such information is helpful for epidemiological investigations and in categorization of AI viruses.

Poultry can be vaccinated with a variety of AI vaccines including inactivated whole AI virus vaccines, and haemagglutinin expression-based vaccines. Antibodies to the haemagglutinin confer subtype specific protection. Various strategies can be used to differentiate vaccinated from infected birds including serosurveillance in unvaccinated sentinel birds or specific serological tests in the vaccinated birds.

AI virus *infection* of unvaccinated birds including sentinels is detected by antibodies to the NP/M, subtype specific HA or NA proteins, or NSP. *Poultry* vaccinated with inactivated whole AI vaccines containing an influenza virus of the same H sub-type but with a different neuraminidase may be tested for field exposure by applying serological tests directed to the detection of antibodies to the NA of the field virus. For example, birds vaccinated with H7N3 in the face of a H7N1 epidemic may be differentiated from infected birds (DIVA) by detection of subtype specific NA antibodies of the N1 protein of the field virus. Alternatively, in the absence of DIVA, inactivated vaccines may induce low titres of antibodies to NSP and the titre in infected birds would be markedly higher. Encouraging results have been obtained experimentally with this system, but it has not yet been validated in the field. In *poultry* vaccinated with haemagglutinin expression-based vaccines, antibodies are detected to the specific HA, but not any of the other AI viral proteins. *Infection* is evident by antibodies to the NP/M or NSP, or the specific NA protein of the field virus. Vaccines used should comply with the standards of the *Terrestrial Manual*.

All *flocks* with seropositive results should be investigated. Epidemiological and supplementary *laboratory* investigation results should document the status of NAI infection/circulation for each positive *flock*.

A confirmatory test should have a higher specificity than the screening test and sensitivity at least equivalent than that of the screening test.

Information should be provided on the performance characteristics and validation of tests used.

1. The follow-up procedure in case of positive test results if vaccination is used

   In case of vaccinated populations, one has to exclude the likelihood that positive test results are indicative of virus circulation. To this end, the following procedure should be followed in the investigation of positive serological test results derived from *surveillance* conducted on NAI-vaccinated *poultry*. The investigation should examine all evidence that might confirm or refute the hypothesis that the positive results to the serological tests employed in the initial survey were not due to virus circulation. All the epidemiological information should be substantiated, and the results should be collated in the final report.

Knowledge of the type of vaccine used is crucial in developing a serological based strategy to differentiate infected from vaccinated animals.

a) Inactivated whole AI virus vaccines can use either homologous or heterologous neuraminidase subtypes between the vaccine and field strains. If *poultry* in the population have antibodies to NP/M and were vaccinated with inactivated whole AI virus vaccine, the following strategies should be applied:

   i) sentinel birds should remain NP/M antibody negative. If positive for NP/M antibodies, indicating AI virus infection, specific HI tests should be performed to identify H5 or H7 AI virus infection;

   ii) if vaccinated with inactivated whole AI virus vaccine containing homologous NA to field virus, the presence of antibodies to NSP could be indicative of *infection*. Sampling should be initiated to exclude the presence of NAIV by either virus isolation or detection of virus specific genomic material or proteins;

   iii) if vaccinated with inactivated whole AI virus vaccine containing heterologous NA to field virus, presence of antibodies to the field virus NA or NSP would be indicative of *infection*. Sampling should be initiated to exclude the presence of NAIV by either virus isolation or detection of virus specific genomic material or proteins.

b) Haemagglutinin expression-based vaccines contain the HA protein or gene homologous to the HA of the field virus. Sentinel birds as described above can be used to detect AI infection. In vaccinated or sentinel birds, the presence of antibodies against NP/M, NSP or field virus NA is indicative of *infection*. Sampling should be initiated to exclude the presence of NAIV by either virus isolation or detection of virus specific genomic material or proteins.

2. The follow-up procedure in case of positive test results indicative of infection for determination of infection due to HPNAI or LPNAI virus

The detection of antibodies indicative of a NAI virus infection as indicated in point a)i) above will result in the initiation of epidemiological and virological investigations to determine if the infections are due to HPNAI or LPNAI viruses.

Virological testing should be initiated in all antibody-positive and at risk populations. The samples should be evaluated for the presence of AI virus, by virus isolation and identification, and/or detection of influenza A specific proteins or nucleic acids (Figure 2). Virus isolation is the gold standard for detecting *infection* by AI virus and the method is described in the *Terrestrial Manual*. All AI virus isolates should be tested to determine HA and NA subtypes, and *in vivo* tested in chickens and/or sequencing of HA proteolytic cleavage site of H5 and H7 subtypes for determination of classification as HPNAI, LPNAI or LPAI (not notifiable) viruses. As an alternative, nucleic acid detection tests have been developed and validated; these tests have the sensitivity of virus isolation, but with the advantage of providing results within a few hours. Samples with detection of H5 and H7 HA subtypes by nucleic acid detection methods should either be submitted for virus isolation, identification, and *in vivo* testing in chickens, or sequencing of nucleic acids for determination of proteolytic cleavage site as HPNAI or LPNAI viruses. The antigen detection systems, because of low sensitivity, are best suited for screening clinical field cases for *infection* by Type A influenza virus looking for NP/M proteins. NP/M positive samples should be submitted for virus isolation, identification and pathogenicity determination.

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 circulation includes but is not limited to:

a) characterization of the existing production systems;

b) results of clinical *surveillance* of the suspects and their cohorts;

c) quantification of vaccinations performed on the affected sites;

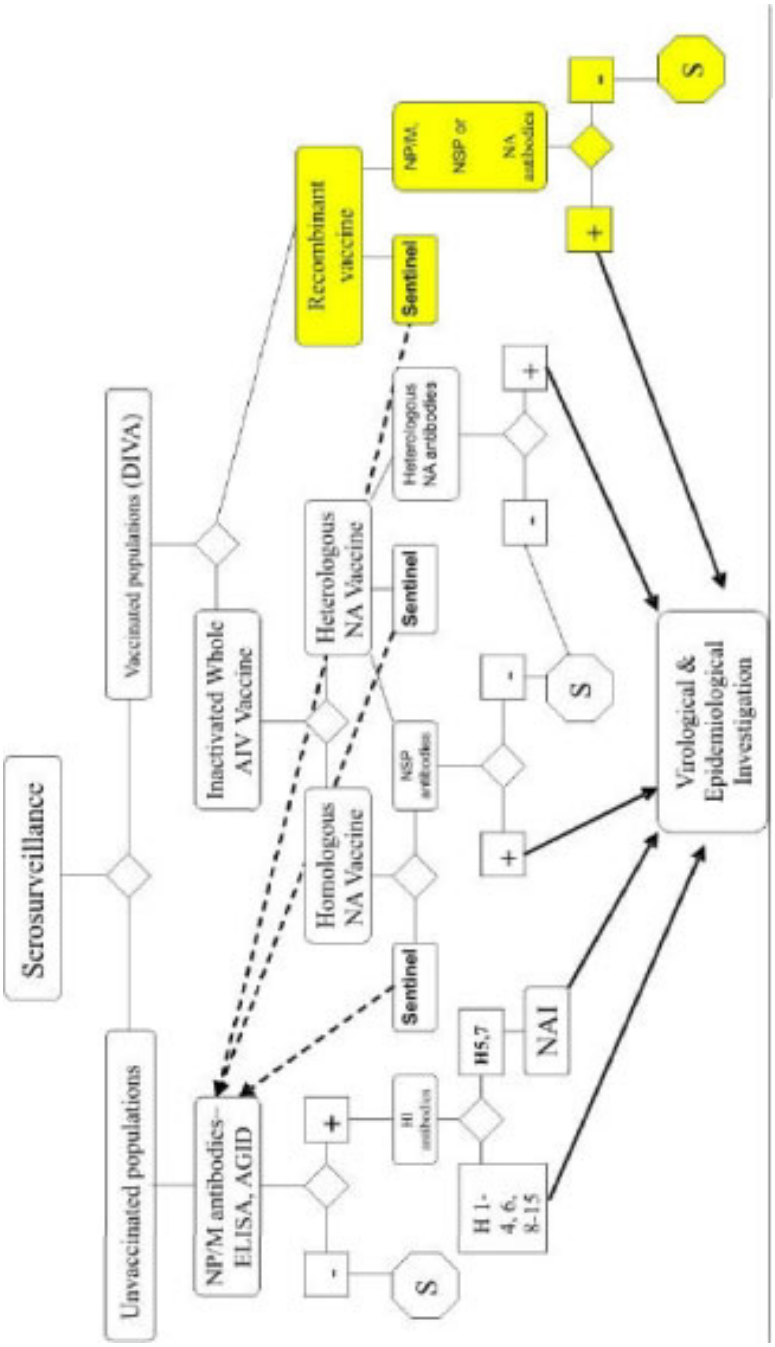
d) sanitary protocol and history of the affected *establishments*;

e) control of *animal identification* and movements;

f) ther parameters of regional significance in historic NAIV transmission.

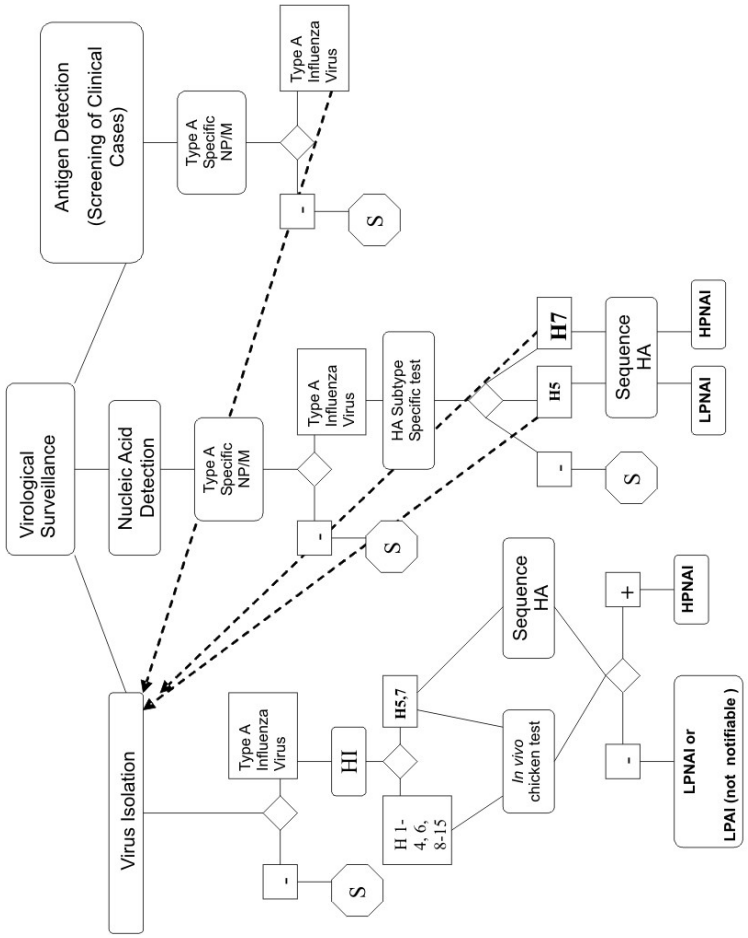
The entire investigative process should be documented as standard operating procedure within the epidemiological *surveillance* programme.

Fig. 1. ***Schematic representation of laboratory tests for determining evidence of NAI infection through or following serological surveys***



Annex XXIII (contd)

Fig. 2. ***Schematic representation of laboratory tests for determining evidence of NAI infection using virological methods***



The above diagram indicates the tests which are recommended for use in the investigation of poultry flocks.

Key:	
AGID	Agar gel immunodiffusion
DIVA	Differentiating infected from vaccinated animals
ELISA	Enzyme-linked immunosorbant assay
HA	Haemagglutinin
HI	Haemagglutination inhibition
NA	Neuraminidase
NP/M	Nucleoprotein and matrix protein
NSP	Nonstructural protein
S	No evidence of NAIV

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Annex XXIV

CHAPTER 10.13.

NEWCASTLE DISEASE

Article 10.13.1.

General provisions

1. For the purposes of *international trade*, Newcastle disease (ND) is defined as an *infection* of *poultry* caused by a virus (NDV) of avian paramyxovirus serotype 1 (APMV-1) that meets one of the following criteria for virulence:

   a) the virus has an intracerebral pathogenicity index (ICPI) in day-old chicks (*Gallus gallus*) of 0.7 or greater; or

   b) multiple basic amino acids have been demonstrated in the virus (either directly or by deduction) at the C-terminus of the F2 protein and phenylalanine at residue 117, which is the N-terminus of the F1 protein. The term 'multiple basic amino acids' refers to at least three arginine or lysine residues between residues 113 and 116. Failure to demonstrate the characteristic pattern of amino acid residues as described above would require characterisation of the isolated virus by an ICPI test.

   In this definition, amino acid residues are numbered from the N-terminus of the amino acid sequence deduced from the nucleotide sequence of the F0 gene, 113–116 corresponds to residues –4 to –1 from the cleavage site.'

2. *Poultry* is defined as 'all domesticated birds, including backyard *poultry*, used for the production of meat or eggs for consumption, for the production of other commercial products, for restocking supplies of game, or for breeding these categories of birds, as well as fighting cocks used for any purpose'.

   Birds that are kept in captivity for any reason other than those reasons referred to in the preceding paragraph, including those that are kept for shows, races, exhibitions, competitions, or for breeding or selling these categories of birds as well as pet birds, are not considered to be *poultry*.

3. This Chapter deals with NDV *infection* of *poultry* as defined in point 2 above, in the presence or absence of clinical signs. For the purposes of *international trade*, a Member should not impose immediate bans on the trade in *poultry commodities* in response to a notification, according to Article 1.2.3. of the *Terrestrial Code*, of *infection* with NDV in birds other than *poultry*, including wild birds.

4. The occurrence of *infection* with NDV is defined as the isolation and identification of NDV as such or the detection of viral RNA specific for NDV.

5. For the purposes of the *Terrestrial Code*, the *incubation period* for ND shall be 21 days.

6. Standards for diagnostic tests, including pathogenicity testing, are described in the *Terrestrial Manual*. When the use of ND vaccines is appropriate, those vaccines should comply with the standards described in the *Terrestrial Manual*.

Annex XXIV (contd)

Article 10.13.2.

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

The ND status of a country, a *zone* or a *compartment* can be determined on the basis of the following criteria:

1. ND is notifiable in the whole country, an on-going ND awareness programme is in place, and all notified suspect occurrences of ND are subjected to field and, where applicable, *laboratory* investigations;

2. appropriate *surveillance* is in place to demonstrate the presence of NDV *infection* in the absence of clinical signs in *poultry*, this may be achieved through an ND *surveillance* programme in accordance with Articles 10.13.22. to 10.13.26.;

3. consideration of all epidemiological factors for ND occurrence and their historical perspective.

Article 10.13.3.

ND free country, zone or compartment

A country, *zone* or *compartment* may be considered free from ND when it has been shown that NDV *infection* in *poultry* has not been present in the country, *zone* or *compartment* for the past 12 months, based on *surveillance* in accordance with Articles 10.13.22. to 10.13.26.

If *infection* has occurred in *poultry* in a previously free country, *zone* or *compartment*, ND free status can be regained three months after a *stamping-out policy* (including *disinfection* of all affected *establishments*) is applied, providing that *surveillance* in accordance with Articles 10.13.22. to 10.13.26. has been carried out during that three-month period.

Article 10.13.4.

Recommendations for importation from an ND free country, zone or compartment as defined in Article 10.13.3.

for live poultry (other than day-old poultry)

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

1. the *poultry* showed no clinical sign suggestive of ND on the day of shipment;

2. the *poultry* were kept in an ND free country, *zone* or *compartment* since they were hatched or for at least the past 21 days;

3. the *poultry* are transported in new or appropriately sanitized *containers*;

4. if the *poultry* have been vaccinated against ND, it has been done in accordance with the provisions of the *Terrestrial Manual* and the nature of the vaccine used and the date of vaccination have been attached to the *certificate*.

Article 10.13.5.

Recommendations for the importation of live birds other than poultry

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

1. the birds showed no clinical sign suggestive of infection by NDV on the day of shipment;

2. the birds were kept in isolation approved by the *Veterinary Services* since they were hatched or for at least the 21 days prior to shipment and showed no clinical sign of *infection* during the isolation period;

3. a statistically valid sample of the birds at a design prevalence acceptable to the *importing country* was subjected to a diagnostic test within 14 days prior to shipment to demonstrate freedom from *infection* with NDV;

4. the birds are transported in new or appropriately sanitized *containers*;

5. if the birds have been vaccinated against ND, it has been done in accordance with the provisions of the *Terrestrial Manual* and the nature of the vaccine used and the date of vaccination have been attached to the *certificate*.

Article 10.13.6.

Recommendations for importation from an ND free country, zone or compartment

for day-old live poultry

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

1. the *poultry* were hatched and kept in an ND free country, *zone* or *compartment* since they were hatched;

2. the *poultry* were derived from parent *flocks* which had been kept in an ND free country, *zone* or *compartment* for at least 21 days prior to and at the time of the collection of the eggs;

3. the *poultry* are transported in new or appropriately sanitized *containers*.

4. if the *poultry* or parent *flocks* have been vaccinated against ND, it has been done in accordance with the provisions of the *Terrestrial Manual* and the nature of the vaccine used and the date of vaccination have been attached to the *certificate*.

Article 10.13.7.

Recommendations for the importation of day-old live birds other than poultry

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

1. the birds showed no clinical sign suggestive of infection by NDV on the day of shipment;

2. the birds were hatched and kept in isolation approved by the *Veterinary Services*;

3. the parent *flock* birds were subjected to a diagnostic test at the time of the collection of the eggs to demonstrate freedom from *infection* with NDV;

4. the birds are transported in new or appropriately sanitized *containers*;

5. if the birds or parent *flocks* have been vaccinated against ND, it has been done in accordance with the provisions of the *Terrestrial Manual* and the nature of the vaccine used and the date of vaccination have been attached to the *certificate*.

Article 10.13.8.

Recommendations for importation from an ND free country, zone or compartment

for hatching eggs of poultry

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

1. the eggs came from an ND free country, *zone* or *compartment*;

2. the eggs were derived from parent *flocks* which had been kept in an ND free country, *zone* or *compartment* for at least 21 days prior to and at the time of the collection of the eggs;

3. the eggs are transported in new or appropriately sanitized ~~*containers*~~ packaging materials;

4. if the parent *flocks* have been vaccinated against ND, it has been done in accordance with the provisions of the *Terrestrial Manual* and the nature of the vaccine used and the date of vaccination have been attached to the *certificate*.

Article 10.13.9.

Recommendations for the importation of hatching eggs from birds other than poultry

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

1. the parent *flock* birds were subjected to a diagnostic test 7 days prior to and at the time of the collection of the eggs to demonstrate freedom from *infection* with NDV;

2. the eggs have had their surfaces sanitized (in accordance with Chapter 6.4.);

3. the eggs are transported in new or appropriately sanitized ~~*containers*~~ packaging materials;

4. if the parent *flocks* have been vaccinated against ND, it has been done in accordance with the provisions of the *Terrestrial Manual* and the nature of the vaccine used and the date of vaccination have been attached to the *certificate*.

Article 10.13.10.

Recommendations for importation from an ND free country, zone or compartment

for eggs for human consumption

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

1. the eggs were produced and packed in an ND free country, *zone* or *compartment*;

2. the eggs are transported in new or appropriately sanitized ~~*containers*~~ packaging materials.

Article 10.13.11.

Recommendations for importation of egg products of poultry

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

1. the *commodity* is derived from eggs which meet the requirements of Article 10.13.10.; or

2. the *commodity* has been processed to ensure the destruction of NDV in accordance with Article 10.13.20. (under study);

AND

3. the necessary precautions were taken to avoid contact of the egg products with any source of NDV.

Article 10.13.12.

Recommendations for importation from an ND free country, zone or compartment

for poultry semen

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

1. showed no clinical sign suggestive of ND on the day of semen collection;

2. were kept in an ND free country, *zone* or *compartment* for at least the 21 days prior to and at the time of semen collection.

Article 10.13.13.

Recommendations for the importation of semen of birds other than poultry

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

1. were kept in isolation approved by the *Veterinary Services* for at least the 21 days prior to and on the day of semen collection;

2. showed no clinical sign suggestive of *infection* with NDV during the isolation period and on the day of semen collection;

3. were subjected to a diagnostic test within 14 days prior to semen collection to demonstrate freedom from *infection* with NDV.

Annex XXIV (contd)

Article 10.13.14.

Recommendations for importation from an ND free country, zone or compartment

for *fresh meat* of poultry

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

1. which have been kept in an ND free country, *zone* or *compartment* since they were hatched or for at least the past 21 days;

2. which have been slaughtered in an approved *abattoir* in an ND free country, *zone* or *compartment* and have been subjected to ante-mortem and post-mortem inspections in accordance with Chapter 6.2. and have been found free of any sign suggestive of ND.

Article 10.13.15.

Recommendations for importation of meat products of poultry

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

1. the *commodity* is derived from *fresh meat* which meet the requirements of Article 10.13.14.; or

2. the *commodity* has been processed to ensure the destruction of NDV in accordance with Article 10.13.21. (under study);

AND

3. the necessary precautions were taken to avoid contact of the *commodity* with any source of NDV.

Article 10.13.16.

Recommendations for the importation of products of poultry origin, other than feather meal and poultry meat meal, intended for use in animal feeding, or for agricultural or industrial use ~~other than feather meal~~

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

1. these *commodities* were processed in a ND free country, *zone* or *compartment* from poultry which were kept in a ND free country, *zone* or *compartment* from the time they were hatched until the time of *slaughter* or for at least the 21 days preceding *slaughter*; or

2. these *commodities* have been processed to ensure the destruction of NDV (under study);

AND

3. the necessary precautions were taken to avoid contact of the *commodity* with any source of NDV.

Article 10.13.17.

Recommendations for the importation of feathers and down of poultry

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

1. these *commodities* originated from *poultry* as described in Article 10.13.14. and were processed in a ND free country, *zone* or *compartment*; or

2. these *commodities* have been processed to ensure the destruction of NDV (under study);

AND

3. the necessary precautions were taken to avoid contact of the *commodity* with any source of NDV.

Article 10.13.18.

Recommendations for the importation of feathers and down of birds other than poultry

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

1. these *commodities* have been processed to ensure the destruction of NDV (under study); and

2. the necessary precautions were taken to avoid contact of the *commodity* with any source of NDV

Article 10.13.19.

Recommendations for the importation of feather meal and poultry meat meal

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

1. these *commodities* were processed in a ND free country, *zone* or *compartment* from *poultry* which were kept in a ND free country, *zone* or *compartment* from the time they were hatched until the time of *slaughter* or for at least the 21 days preceding *slaughter*; or

2. these *commodities* have been processed either:

   a) with moist heat at a minimum temperature of 118ºC for minimum of 40 minutes; or

   b) with a continuous hydrolysing process under at least 3.79 bar of pressure with steam at a minimum temperature of 122 ºC for a minimum of 15 minutes; or

   c) with an alternative rendering process that ensures that the internal temperature throughout the product reaches at least 74 ºC for a minimum of 280 seconds;

AND

3. the necessary precautions were taken to avoid contact of the *commodity* with any source of ND virus.

Annex XXIV (contd)

Article 10.13.20.~~(under study)~~

Procedures for the inactivation of the ND virus in eggs and egg products

The following times and temperatures are suitable for the inactivation of ND virus present in eggs and egg products:

	Temperature (°C)	**Time**
Whole egg	55	2,521 seconds
Whole egg	57	1,596 seconds
Whole egg	59	674 seconds
Liquid egg white	55	2,278 seconds
Liquid egg white	57	986 seconds
Liquid egg white	59	301 seconds
10% salted yolk	55	176 seconds
Dried egg white	57	50.4 hours

The listed temperatures are indicative of a range that achieves a 7-log kill. Where scientifically documented, variances from these times and temperatures may also be suitable when they achieve the inactivation of the virus.

Article 10.13.21.~~(under study)~~

Procedures for the inactivation of the ND virus in meat

A procedure which produces a core temperature of 70ºC for 574 seconds is suitable for the inactivation of ND virus present in meat.

	Temperature (°C)	**Time**
Poultry meat	65.0	840 seconds
	70.0	574 seconds
	74.0	280 seconds
	80.0	203 seconds

Article 10.13.22.

Surveillance: introduction

Articles 10.13.22. to 10.13.26. define the principles and provide a guide on the *surveillance* for ND as defined in Article 10.13.1. and is complementary to Chapter 1.4. It is applicable to Members seeking to determine their ND status. This may be for the entire country, *zone* or *compartment*. Guidance for Members seeking free status following an *outbreak* and for the maintenance of ND status is also provided.

Surveillance for ND is complicated by the known occurrence of avian paramyxovirus serotype 1 (APMV-1) infections in many bird species, both domestic and wild, and the widespread utilization of ND vaccines in domestic *poultry*.

The impact and epidemiology of ND differ widely in different regions of the world and therefore it is not possible to provide specific recommendations for all situations. Therefore, *surveillance* strategies employed for demonstrating freedom from ND at an acceptable level of confidence will need to be adapted to the local situation. Variables such as the frequency of contacts of *poultry* with wild birds, different biosecurity levels, production systems and the commingling of different susceptible species require specific *surveillance* strategies to address each specific situation. It is incumbent upon the Member to provide scientific data that explains the epidemiology of ND in the region concerned and also demonstrates how all the risk factors are managed. There is, therefore, considerable latitude available to Members to provide a well-reasoned argument to prove freedom from NDV *infection*.

Surveillance for ND should be in the form of a continuing programme designed to establish that the country, *zone* or *compartment*, for which application is made, is free from NDV *infection*.

Article 10.13.23.

Surveillance: general conditions and methods

1. A *surveillance* system in accordance with Chapter 1.4. should be under the responsibility of the *Veterinary Authority*. In particular there should be in place:

   a) a formal and ongoing system for detecting and investigating outbreaks of *disease* or NDV *infection*;

   b) a procedure for the rapid collection and transport of samples from suspect cases of ND to a *laboratory* for ND diagnosis as described in the *Terrestrial Manual*;

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

2. The ND *surveillance* programme should:

   a) include an early warning system throughout the production, marketing and processing chain for reporting suspicious cases. Farmers and workers, who have day-to-day contact with *poultry*, as well as diagnosticians, should report promptly any suspicion of ND to the *Veterinary Authority*. They should be supported directly or indirectly (e.g. through private *veterinarians* or *veterinary para-professionals*) by government information programmes and the *Veterinary Authority*. All suspected cases of ND should be investigated immediately. As suspicion cannot be resolved by epidemiological and clinical investigation alone, samples should be taken and submitted to a *laboratory* for appropriate tests. This requires that sampling kits and other equipment are available to those responsible for *surveillance*. Personnel responsible for *surveillance* should be able to call for assistance from a team with expertise in ND diagnosis and control;

   b) implement, when relevant, regular and frequent clinical, virological and serological *surveillance* of high risk groups of *poultry* within the target population (e.g. those adjacent to an ND infected country, *zone*, *compartment*, places where birds and *poultry* of different origins are mixed, or other sources of NDV).

   An effective *surveillance* system may identify suspicious cases that require follow-up and investigation to confirm or exclude that the cause of the condition is due to NDV *infection*. The rate at which such suspicious cases are likely to occur will differ between epidemiological situations and cannot therefore be predicted reliably. Applications for freedom from NDV *infection* should provide details of the occurrence of suspicious cases and how they were investigated and dealt with. This should include the results of *laboratory* testing and the control measures to which the animals concerned were subjected during the investigation (quarantine, movement stand-still orders, etc.).

Annex XXIV (contd)

Article 10.13.24.

Surveillance strategies

1. Introduction

Any *surveillance* programme requires inputs from professionals competent and experienced in this field and should be thoroughly documented. The design of *surveillance* programmes to prove the absence of NDV *infection* / circulation needs to be carefully followed to avoid producing results that are either unreliable, or excessively costly and logistically complicated.

If a Member wishes to declare freedom from NDV *infection* in a country, *zone* or *compartment*, the subpopulation used for *surveillance* ~~of~~ for the *disease* / *infection* should be representative of all *poultry* within the country, *zone* or *compartment*. Multiple *surveillance* methods should be used concurrently to accurately define the true ND status of *poultry* populations. Active and passive *surveillance* for ND should be ongoing with the frequency of active *surveillance* being appropriate to the disease situation in the country. *Surveillance* should be composed of random and/or targeted approaches, dependent on the local epidemiological situation and using clinical, virological and serological methods as described in the *Terrestrial Manual*. If alternative tests are used they must have been validated as fit-for-purpose in accordance with OIE standards. A Member should justify the *surveillance* strategy chosen as adequate to detect the presence of NDV *infection* in accordance with Chapter 1.4. and the prevailing epidemiological situation.

In surveys, the sample size selected for testing should be statistically justified to detect *infection* at a predetermined target prevalence. The sample size and expected prevalence determine the level of confidence in the results of the survey. The survey design and frequency of sampling should be dependent on the historical and current local epidemiological situation. The Member should justify the choice of survey design and confidence level based on the objectives of *surveillance* and the epidemiological situation, in accordance with Chapter 1.4.

Targeted *surveillance* (e.g. based on the increased likelihood of *infection* in a population) may be an appropriate strategy.

It may, for example, be appropriate to target clinical *surveillance* at particular species likely to exhibit clear clinical signs (e.g. unvaccinated chickens). Similarly, virological and serological testing could target species that may not show clinical signs (Article 10.13.2.) of ND and are not routinely vaccinated (e.g. ducks). *Surveillance* may also target *poultry* populations at specific risk, for example direct or indirect contact with wild birds, multi-age *flocks*, local trade patterns including live *poultry* markets, the presence of more than one species on the holding and poor biosecurity measures in place. In situations where wild birds have been shown to play a role in the local epidemiology of ND, *surveillance* of wild birds may be of value in alerting *Veterinary Services* to the possible exposure of *poultry*, and in particular, of free ranging *poultry*.

The sensitivity and specificity of the diagnostic tests are key factors in the choice of survey design, which should anticipate the occurrence of false positive and false negative reactions. Ideally, the sensitivity and specificity of the tests used should be validated for the vaccination / *infection* history and for the different species in the target population. If the characteristics of the testing system are known, the rate at which these false reactions are likely to occur can be calculated in advance. There needs to be an effective procedure for following up positives to ultimately determine with a high level of confidence, whether they are indicative of *infection* or not. This should involve both supplementary tests and follow-up investigation to collect diagnostic material from the original sampling unit as well as *flocks* which may be epidemiologically linked to it.

The results of active and passive *surveillance* are important in providing reliable evidence that no NDV *infection* is present in a country, *zone* or *compartment*.

2. Clinical surveillance

Clinical *surveillance* aims to detect clinical signs suggestive of ND at the *flock* level and should not be underestimated as an early indication of *infection*. Monitoring of production parameters (e.g. a drop in feed or water consumption or egg production) is important for the early detection of NDV *infection* in some populations, as there may be no, or mild clinical signs, particularly if they are vaccinated. Any sampling unit within which suspicious animals are detected should be considered as infected until evidence to the contrary is produced. Identification of infected *flocks* is vital to the identification of sources of NDV.

A presumptive diagnosis of clinical ND in suspect infected populations should always be confirmed by virological testing in a *laboratory*. This will enable the molecular, antigenic and other biological characteristics of the virus to be determined.

It is desirable that NDV isolates are sent promptly to an OIE Reference Laboratory for archiving and further characterization if required.

3. Virological surveillance

Virological *surveillance* should be conducted using tests described in the *Terrestrial Manual* to:

a) monitor at risk populations;

b) confirm suspect clinical cases;

c) follow up positive serological results in unvaccinated populations or sentinel birds;

d) test 'normal' daily mortalities (if warranted by an increased risk e.g. *infection* in the face of vaccination or in establishments epidemiologically linked to an *outbreak*).

4. Serological surveillance

Where vaccination is carried out, serological *surveillance* is of limited value. Serological *surveillance* cannot be used to discriminate between NDV and other APMV-1. Test procedures and interpretations of results are as described in the *Terrestrial Manual*. Positive NDV antibody test results can have five possible causes:

a) natural *infection* with APMV-1;

b) vaccination against ND;

c) exposure to vaccine virus;

d) maternal antibodies derived from a vaccinated or infected parent *flock* are usually found in the yolk and can persist in progeny for up to 4 weeks;

e) non-specific test reactions.

It may be possible to use serum collected for other survey purposes for ND *surveillance*. However, the principles of survey design described in these recommendations and the requirement for a statistically valid survey for the presence of NDV should not be compromised.

Discovery of seropositive, unvaccinated *flocks* must be investigated further by conducting a thorough epidemiological investigation. Since seropositive results are not necessarily indicative of *infection*, virological methods should be used to confirm the presence of NDV in such populations. Until validated strategies and tools to differentiate vaccinated animals from those infected with field APMV-1 are available, serological tools should not be used to identify NDV *infection* in vaccinated populations.

5. Use of sentinel poultry

There are various applications of the use of sentinel *poultry* as a *surveillance* tool to detect virus circulation. They may be used to monitor vaccinated populations or species which are less susceptible to the development of clinical *disease* for the circulation of virus. Sentinel *poultry* should be immunologically naïve and may be used in vaccinated *flocks*. In case of the use of sentinel *poultry*, the structure and organisation of the *poultry* sector, the type of vaccine used and local epidemiological factors will determine the type of production systems where sentinels should be placed, the frequency of placement and monitoring of the sentinels.

Sentinel *poultry* must be in close contact with, but should be identified to be clearly differentiated from, the target population. Sentinel *poultry* must be observed regularly for evidence of clinical *disease* and any disease incidents investigated by prompt *laboratory* testing. The species to be used as sentinels should be proven to be highly susceptible to *infection* and ideally develop clear signs of clinical *disease*. Where the sentinel *poultry* do not necessarily develop overt clinical *disease* a programme of regular active testing by virological and serological tests should be used (the development of clinical *disease* may be dependent on the sentinel species used or use of live vaccine in the target population that may infect the sentinel *poultry*). The testing regime and the interpretation of the results will depend on the type of vaccine used in the target population. Sentinel birds should be used only if no appropriate *laboratory* procedures are available.

Article 10.13.25.

Documentation of ND free status: additional surveillance procedures

The requirements for a country, *zone* or *compartment* to declare freedom from ND are given in Article 10.13.3.

A Member declaring freedom of a country, *zone* or *compartment* (with or without vaccination) should report the results of a *surveillance* programme in which the ND susceptible *poultry* population undergoes regular *surveillance* planned and implemented according to the general conditions and methods described in these recommendations.

1. Members declaring freedom from ND for the country, zone or compartment

In addition to the general conditions described in the *Terrestrial Code*, a Member declaring freedom from ND for the entire country, or a *zone* or a *compartment* should provide evidence for the existence of an effective *surveillance* programme. The *surveillance* programme should be planned and implemented according to general conditions and methods described in this Chapter to demonstrate absence of NDV *infection* in *poultry* during the preceding 12 months.

2. Additional requirements for countries, zones or compartments that practice vaccination

Vaccination against ND may be used as a component of a disease prevention and control programme. The vaccine used must comply with the provisions of the *Terrestrial Manual*.

In vaccinated populations there is a need to perform *surveillance* to ensure the absence of NDV circulation. The use of sentinel *poultry* may provide further confidence of the absence of virus circulation. The *surveillance* should be repeated at least every 6 months or at shorter intervals according to the risk in the country, *zone* or *compartment*, or evidence to show the effectiveness of the vaccination programme is regularly provided.

Article 10.13.26.

Countries, zones or compartments regaining freedom from ND following an outbreak: additional surveillance procedures

A Member regaining country, *zone* or *compartment* freedom from ND should show evidence of an active *surveillance* programme depending on the epidemiological circumstances of the *outbreak* to demonstrate the absence of the *infection*.

A Member declaring freedom of a country, *zone* or *compartment* after an *outbreak* of ND (with or without vaccination) should report the results of a *surveillance* programme in which the ND susceptible *poultry* population undergoes regular *surveillance* planned and implemented according to the general conditions and methods described in these recommendations.

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Annex XXV

CHAPTER 11.6.

BOVINE SPONGIFORM ENCEPHALOPATHY

Article 11.6.1.

General provisions and safe commodities

The recommendations in this chapter are intended to manage the human and animal health risks associated with the presence of the bovine spongiform encephalopathy (BSE) agent in cattle (*Bos taurus* and *B. indicus*) only.

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

   a) *milk* and *milk products*;

   b) semen and *in vivo* derived cattle embryos collected and handled in accordance with the recommendations of the International Embryo Transfer Society;

   c) hides and skins;

   d) gelatine and collagen prepared exclusively from hides and skins;

   e) tallow with maximum level of insoluble impurities of 0.15% in weight and derivatives made from this tallow;

   f) dicalcium phosphate (with no trace of protein or fat);

   g) deboned skeletal muscle meat (excluding mechanically separated meat) from cattle which were not subjected to a stunning process prior to *slaughter*, with a device injecting compressed air or gas into the cranial cavity or to a pithing process, and which passed ante-mortem and post-mortem inspections and which has been prepared in a manner to avoid contamination with tissues listed in Article 11.6.14.;

   h) blood and blood by-products, from cattle which were not subjected to a stunning process, prior to *slaughter*, with a device injecting compressed air or gas into the cranial cavity, or to a pithing process.

2. When authorising import or transit of other *commodities* listed in this chapter, *Veterinary Authorities* should require the conditions prescribed in this chapter relevant to the BSE risk status of the cattle population of the *exporting country*, *zone* or *compartment*.

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

Annex XXV (contd)

Article 11.6.2.

The BSE risk status of the cattle population of a country, zone or compartment

The BSE risk status of the cattle population of a country, *zone* or *compartment* should be determined on the basis of the following criteria:

1. the outcome of a *risk assessment*, based on the provisions of the *Terrestrial Code*, identifying all potential factors for BSE occurrence and their historic perspective. Members should review the *risk assessment* annually to determine whether the situation has changed.

   a) Release assessment

      Release assessment consists of assessing, through consideration of the following, the likelihood that the BSE agent has either been introduced into the country, *zone* or *compartment* via *commodities* potentially contaminated with it, or is already present in the country, *zone* or *compartment*:

      i) the presence or absence of the BSE agent in the indigenous ruminant population of the country, *zone* or *compartment* and, if present, evidence regarding its prevalence;

      ii) production of *meat-and-bone meal* or *greaves* from the indigenous ruminant population;

      iii) imported *meat-and-bone meal* or *greaves*;

      iv) imported cattle, sheep and goats;

      v) imported animal feed and feed ingredients;

      vi) imported products of ruminant origin for human consumption, which may have contained tissues listed in Article 11.6.14. and may have been fed to cattle;

      vii) imported products of ruminant origin intended for *in vivo* use in cattle.

      The results of *surveillance* and other epidemiological investigations into the disposition of the *commodities* identified above should be taken into account in carrying out the assessment.

   b. Exposure assessment

      If the release assessment identifies a *risk* factor, an exposure assessment should be conducted, consisting of assessing the likelihood of cattle being exposed to the BSE agent, through a consideration of the following:

      i) recycling and amplification of the BSE agent through consumption by cattle of *meat-and-bone meal* or *greaves* of ruminant origin, or other feed or feed ingredients contaminated with these;

      ii) the use of ruminant carcasses (including from fallen stock), by-products and slaughterhouse waste, the parameters of the rendering processes and the methods of animal feed manufacture;

      iii) the feeding or not of ruminants with *meat-and-bone meal* and *greaves* derived from ruminants, including measures to prevent cross-contamination of animal feed;

      iv) the level of *surveillance* for BSE conducted on the cattle population up to that time and the results of that *surveillance*;

2. on-going awareness programme for veterinarians, farmers, and workers involved in transportation, marketing and *slaughter* of cattle to encourage reporting of all *cases* showing clinical signs consistent with BSE in target sub-populations as defined in Articles 11.6.20. to 11.6.22.;

3. the compulsory notification and investigation of all cattle showing clinical signs consistent with BSE;

4. the examination carried out in accordance with the *Terrestrial Manual* in a *laboratory* of brain or other tissues collected within the framework of the aforementioned *surveillance* and monitoring system.

When the *risk assessment* demonstrates negligible risk, the Member should conduct Type B *surveillance* in accordance with Articles 11.6.20. to 11.6.22.

When the *risk assessment* fails to demonstrate negligible risk, the Member should conduct Type A *surveillance* in accordance with Articles 11.6.20. to 11.6.22.

Article 11.6.3.

Negligible BSE risk

Commodities from the cattle population of a country, *zone* or *compartment* pose a negligible risk of transmitting the BSE agent if the following conditions are met:

1. a *risk assessment*, as described in point 1 of Article 11.6.2., has been conducted in order to identify the historical and existing risk factors, and the Member has demonstrated that appropriate specific measures have been taken for the relevant period of time defined below to manage each identified risk;

2. the Member has demonstrated that Type B *surveillance* in accordance with Articles 11.6.20. to 11.6.22. is in place and the relevant points target, in accordance with Table 1, has been met;

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 and has been completely destroyed, and

      i) the criteria in points 2 to 4 of Article 11.6.2. have been complied with for at least 7 years; and

      ii) it has been demonstrated through an appropriate level of control and audit that for at least 8 years neither *meat-and-bone meal* nor *greaves* derived from ruminants has been fed to ruminants;

   OR

   b. if there has been an indigenous *case*, every indigenous *case* was born more than 11 years ago; and

      i) the criteria in points 2 to 4 of Article 11.6.2. have been complied with for at least 7 years; and

      ii) it has been demonstrated through an appropriate level of control and audit that for at least 8 years neither *meat-and-bone meal* nor *greaves* derived from ruminants has been fed to ruminants; and

iii) all BSE *cases*, as well as:

- all cattle which, during their first year of life, were reared with the BSE *cases* during their first year of life, and which investigation showed consumed the same potentially contaminated feed during that period, or

- if the results of the investigation are inconclusive, all cattle born in the same *herd* as, and within 12 months of the birth of, the BSE *cases*,

if alive in the country, *zone* or *compartment*, are permanently identified, and their movements controlled, and, when slaughtered or at *death*, are completely destroyed.

The Member or *zone* will be included in the list of negligible risk only after the submitted evidence has been accepted by the OIE. Retention on the list requires that the information for the previous 12 months on *surveillance* results and feed controls be re-submitted annually and changes in the epidemiological situation or other significant events should be reported to the OIE according to the requirements in Chapter 1.1. To maintain negligible risk status, all imports of cattle should comply with requirements in Articles 11.6.7., 11.6.8. or 11.6.9., as relevant.

Article 11.6.4.

Controlled BSE risk

Commodities from the cattle population of a country, *zone* or *compartment* pose a controlled risk of transmitting the BSE agent if the following conditions are met:

1. a *risk assessment*, as described in point 1 of Article 11.6.2., has been conducted in order to identify the historical and existing risk factors, and the Member has demonstrated that appropriate measures are being taken to manage all identified risks, but these measures have not been taken for the relevant period of time;

2. the Member has demonstrated that Type A *surveillance* in accordance with Articles 11.6.20. to 11.6.22. has been carried out and the relevant points target, in accordance with Table 1, has been met; Type B *surveillance* may replace Type A *surveillance* once the relevant points target is met;

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 and has been completely destroyed, the criteria in points 2 to 4 of Article 11.6.2. are complied with, and it can be demonstrated through an appropriate level of control and audit that neither *meat-and-bone meal* nor *greaves* derived from ruminants has been fed to ruminants, but at least one of the following two conditions applies:

      i) the criteria in points 2 to 4 of Article 11.6.2. have not been complied with for 7 years;

      ii) it cannot be demonstrated that controls over the feeding of *meat-and-bone meal* or *greaves* derived from ruminants to ruminants have been in place for 8 years;

   OR

   b) there has been an indigenous *case* of BSE, the criteria in points 2 to 4 of Article 11.6.2. are complied with, and it can be demonstrated through an appropriate level of control and audit that neither *meat-and-bone meal* nor *greaves* derived from ruminants has been fed to ruminants;

and all BSE *cases*, as well as:

- all cattle which, during their first year of life, were reared with the BSE *cases* during their first year of life, and which investigation showed consumed the same potentially contaminated feed during that period, or

- if the results of the investigation are inconclusive, all cattle born in the same *herd* as, and within 12 months of the birth of, the BSE *cases*,

if alive in the country, *zone* or *compartment*, are permanently identified, and their movements controlled, and, when slaughtered or at *death*, are completely destroyed.

The Member or *zone* will be included in the list of controlled risk only after the submitted evidence has been accepted by the OIE. Retention on the list requires that the information for the previous 12 months on *surveillance* results and feed controls be re-submitted annually and changes in the epidemiological situation or other significant events should be reported to the OIE according to the requirements in Chapter 1.1. To maintain controlled risk status, all imports of cattle should comply with requirements in Articles 11.6.7., 11.6.8. or 11.6.9., as relevant.

Article 11.6.5.

Undetermined BSE risk

The cattle population of a country, *zone* or *compartment* poses an undetermined BSE risk if it cannot be demonstrated that it meets the requirements of another category.

Article 11.6.6.

Recommendations for the importation of bovine commodities from a country, zone or compartment posing a negligible BSE risk

for all *commodities* from cattle not listed in point 1 of Article 11.6.1.

Veterinary Authorities should require the presentation of an *international veterinary certificate* attesting that the country, *zone* or *compartment* complies with the conditions in Article 11.6.3.

Article 11.6.7.

Recommendations for the importation of cattle from a country, zone or compartment posing a negligible BSE risk but where there has been an indigenous case

for cattle selected for export

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

1. are identified by a permanent identification system in such a way as to demonstrate that they are not exposed cattle as described in point 3b)iii) of Article 11.6.3.;

2. were born after the date from which the ban on the feeding of ruminants with *meat-and-bone meal* and *greaves* derived from ruminants had been effectively enforced.

Annex XXV (contd)

Article 11.6.8.

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

for cattle

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

1. the country, *zone* or *compartment* complies with the conditions referred to in Article 11.6.4.;

2. cattle selected for export are identified by a permanent identification system in such a way as to demonstrate that they are not exposed cattle as described in point 3b) of Article 11.6.4.;

3. cattle selected for export were born after the date from which the ban on the feeding of ruminants with *meat-and-bone meal* and *greaves* derived from ruminants was effectively enforced.

Article 11.6.9.

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

for cattle

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

1. the feeding of ruminants with *meat-and-bone meal* and *greaves* derived from ruminants has been banned and the ban has been effectively enforced;

2. all BSE *cases*, as well as:

   a) all cattle which, during their first year of life, were reared with the BSE *cases* during their first year of life, and, which investigation showed consumed the same potentially contaminated feed during that period, or

   b) if the results of the investigation are inconclusive, all cattle born in the same *herd* as, and within 12 months of the birth of, the BSE *cases*,

   if alive in the country, *zone* or *compartment*, are permanently identified, and their movements controlled, and, when slaughtered or at *death*, are completely destroyed;

3. cattle selected for export:

   a) are identified by a permanent identification system in such a way as to demonstrate that they are not exposed cattle as demonstrated in point 2 above;

   b) were born at least 2 years after the date from which the ban on the feeding of ruminants with *meat-and-bone meal* and *greaves* derived from ruminants was effectively enforced.

Article 11.6.10.

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

for *fresh meat* and *meat products* from cattle (other than those listed in point 1 of Article 11.6.1.)

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

1. the country, *zone* or *compartment* complies with the conditions in Article 11.6.3.;

2. the cattle from which the *fresh meat* and *meat products* were derived, passed ante-mortem and post-mortem inspections;

3. in countries with negligible BSE risk where there have been indigenous *cases*, the cattle from which the *fresh meat* and *meat products* were derived were born after the date from which the ban on the feeding of ruminants with *meat-and-bone meal* and *greaves* derived from ruminants had been effectively enforced.

Article 11.6.11.

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

for *fresh meat* and *meat products* from cattle (other than those listed in point 1 of Article 11.6.1.)

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

1. the country, *zone* or *compartment* complies with the conditions referred to in Article 11.6.4.;

2. the cattle from which the *fresh meat* and *meat products* were derived passed ante-mortem and post-mortem inspections;

3. cattle from which the *fresh meat* and *meat products* destined for export were derived were not subjected to a stunning process, prior to *slaughter*, with a device injecting compressed air or gas into the cranial cavity, or to a pithing process;

4. 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 tissues listed in points 1 and 2 of Article 11.6.14.,

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

Article 11.6.12.

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

for *fresh meat* and *meat products* from cattle (other than those listed in point 1 of Article 11.6.1.)

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

1. the cattle from which the *fresh meat* and *meat products* originate:

   a) have not been fed *meat-and-bone meal* or *greaves* derived from ruminants;

   b) passed ante-mortem and post-mortem inspections;

   c) were not subjected to a stunning process, prior to *slaughter*, with a device injecting compressed air or gas into the cranial cavity, or to a pithing process;

2. 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 tissues listed in points 1 and 3 of Article 11.6.14.,

   b) nervous and lymphatic tissues exposed during the deboning process,

   c) mechanically separated meat from the skull and vertebral column from cattle over 12 months of age.

Article 11.6.13.

Recommendations on ruminant-derived meat-and-bone meal or greaves

1. Ruminant-derived *meat-and-bone meal* or *greaves*, or any commodities containing such products, which originate from a country, *zone* or *compartment* defined in Article 11.6.3., but where there has been an indigenous *case* of BSE, should not be traded if such products were derived from cattle born before the date from which the ban on the feeding of ruminants with *meat-and-bone meal* and *greaves* derived from ruminants had been effectively enforced.

2. Ruminant-derived *meat-and-bone meal* or *greaves*, or any commodities containing such products, which originate from a country, *zone* or *compartment* defined in Articles 11.6.4. and 11.6.5. should not be traded between countries.

Article 11.6.14.

Recommendations on commodities that should not be traded

1. From cattle of any age originating from a country, *zone* or *compartment* defined in Articles 11.6.4. and 11.6.5., the following commodities, and any commodity contaminated by them, should not be traded for the preparation of food, feed, fertilisers, cosmetics, pharmaceuticals including biologicals, or medical devices: tonsils and distal ileum. Protein products, food, feed, fertilisers, cosmetics, pharmaceuticals or medical devices prepared using these commodities (unless covered by other Articles in this chapter) should also not be traded.

2. From cattle that were at the time of *slaughter* over 30 months of age originating from a country, *zone* or *compartment* defined in Article 11.6.4., the following commodities, and any commodity contaminated by them, should not be traded for the preparation of food, feed, fertilisers, cosmetics, pharmaceuticals including biologicals, or medical devices: brains, eyes, spinal cord, skull and vertebral column. Protein products, food, feed, fertilisers, cosmetics, pharmaceuticals or medical devices prepared using these commodities (unless covered by other Articles in this chapter) should also not be traded.

3. From cattle that were at the time of *slaughter* over 12 months of age originating from a country, *zone* or *compartment* defined in Article 11.6.5., the following commodities, and any commodity contaminated by them, should not be traded for the preparation of food, feed, fertilisers, cosmetics, pharmaceuticals including biologicals, or medical devices: brains, eyes, spinal cord, skull and vertebral column. Protein products, food, feed, fertilisers, cosmetics, pharmaceuticals or medical devices prepared using these commodities (unless covered by other Articles in this chapter) should also not be traded.

Article 11.6.15.

Recommendations for the importation of gelatine and collagen prepared from bones and intended for food or feed, cosmetics, pharmaceuticals including biologicals, or medical devices

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

1. the *commodities* came from a country, *zone* or *compartment* posing a negligible BSE risk;

OR

2. they originate from a country, *zone* or *compartment* posing a controlled or undetermined BSE risk and are derived from cattle which have passed ante-mortem and post-mortem inspections; and that

    a) vertebral columns from cattle over 30 months of age at the time of *slaughter* and skulls have been excluded;

    b) the bones have been subjected to a process which includes all of the following steps:

        i) degreasing,

        ii) acid demineralisation,

        iii) acid or alkaline treatment,

        iv) filtration,

        v) sterilisation at >138°C for a minimum of 4 seconds,

        or to an equivalent or better process in terms of infectivity reduction (such as high pressure heating).

Article 11.6.16.

Recommendations for the importation of tallow (other than as defined in Article 11.6.1.) intended for food, feed, fertilisers, cosmetics, pharmaceuticals including biologicals, or medical devices

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

1. the tallow came from a country, *zone* or *compartment* posing a negligible BSE risk; or

2. it originates from a country, *zone* or *compartment* posing a controlled BSE risk, is derived from cattle which have passed ante-mortem and post-mortem inspections, and has not been prepared using the tissues listed in points 1 and 2 of Article 11.6.14.

Annex XXV (contd)

Article 11.6.17.

Recommendations for the importation of dicalcium phosphate (other than as defined in Article 11.6.1.) intended for food, feed, fertilisers, cosmetics, pharmaceuticals including biologicals, or medical devices

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

1. the dicalcium phosphate came from a country, *zone* or *compartment* posing a negligible BSE risk; or

2. it originates from a country, *zone* or *compartment* posing a controlled or undetermined BSE risk and is a by-product of bone gelatine produced according to Article 11.6.15.

Article 11.6.18.

Recommendations for the importation of tallow derivatives (other than those made from tallow as defined in Article 11.6.1.) intended for food, feed, fertilisers, cosmetics, pharmaceuticals including biologicals, or medical devices

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

1. the tallow derivatives originate from a country, zone or *compartment* posing a negligible BSE risk; or

2. they are derived from tallow meeting the conditions referred to in Article 11.6.16.; or

3. they have been produced by hydrolysis, saponification or transesterification using high temperature and pressure.

Article 11.6.19.

Procedures for the reduction of BSE infectivity in meat-and-bone meal

The following procedure should be used to reduce the infectivity of any transmissible spongiform encephalopathy agents which may be present during the production of *meat-and-bone 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 11.6.20.

Surveillance: introduction

1. Depending on the risk category of a country, *zone* or *compartment* with regard to bovine spongiform encephalopathy (BSE), *surveillance* for BSE may have one or more goals:

   a) detecting BSE, to a pre-determined design prevalence, in a country, *zone* or *compartment*;

   b) monitoring the evolution of BSE in a country, *zone* or *compartment*;

c) monitoring the effectiveness of a feed ban and/or other risk mitigation measures, in conjunction with auditing;

d) supporting a claimed BSE status;

e) gaining or regaining a higher BSE status.

2. When the BSE agent is present in a country or *zone*, the cattle population will comprise the following sectors, in order of decreasing size:

a) cattle not exposed to the infective agent;

b) cattle exposed but not infected;

c) infected cattle, which may lie within one of three stages in the progress of BSE:

i) the majority will die or be killed before reaching a stage at which BSE is detectable by current methods;

ii) some will progress to a stage at which BSE is detectable by testing before clinical signs appear;

iii) the smallest number will show clinical signs.

3. The BSE status of a country, *zone* or *compartment* cannot be determined only on the basis of a *surveillance* programme but should be determined in accordance with all the factors listed in Article 11.6.2. The *surveillance* programme should take into account the diagnostic limitations associated with the above sectors and the relative distributions of infected cattle among them.

4. With respect to the distribution and expression of the BSE agent within the sectors described above, the following four subpopulations of cattle have been identified for *surveillance* purposes:

a) cattle over 30 months of age displaying behavioural or clinical signs consistent with BSE (clinical suspects);

b) cattle over 30 months of age that are non-ambulatory, recumbent, unable to rise or to walk without assistance; cattle over 30 months of age sent for emergency *slaughter* or condemned at ante-mortem inspection (casualty or emergency *slaughter* or downer cattle);

c) cattle over 30 months of age which are found dead or killed, on farm, during transport or at an *abattoir* (fallen stock);

d) cattle over 36 months of age at routine *slaughter*.

5. A gradient is used to describe the relative value of *surveillance* applied to each subpopulation. *Surveillance* should focus on the first subpopulation, but investigation of other subpopulations will help to provide an accurate assessment of the BSE situation in the country, *zone* or *compartment*. This approach is consistent with Articles 11.6.20. to 11.6.22.

6. When establishing a *surveillance* strategy, authorities need to take into account the inherent difficulties of obtaining samples on farm, and overcome them. These difficulties include higher cost, the necessity to educate and motivate owners, and counteracting potentially negative socio-economic implications.

Annex XXV (contd)

Article 11.6.21.

Surveillance: description of cattle subpopulations

1. Cattle over 30 months of age displaying behavioural or clinical signs consistent with BSE (clinical suspects)

   Cattle affected by illnesses that are refractory to treatment, and displaying progressive behavioural changes such as excitability, persistent kicking when milked, changes in *herd* hierarchical status, hesitation at doors, gates and barriers, as well as those displaying progressive neurological signs without signs of infectious illness are candidates for examination. These behavioural changes, being very subtle, are best identified by those who handle animals on a daily basis. Since BSE causes no pathognomonic clinical signs, all Members with cattle populations will observe individual animals displaying clinical signs consistent with BSE. It should be recognised that cases may display only some of these signs, which may also vary in severity, and such animals should still be investigated as potential BSE affected animals. The rate at which such suspicious cases are likely to occur will differ among epidemiological situations and cannot therefore be predicted reliably.

   This subpopulation is the one exhibiting the highest prevalence. The accurate recognition, reporting and classification of such animals will depend on the ongoing owner/veterinarian awareness programme. This and the quality of the investigation and *laboratory* examination systems (Article 11.6.2.), implemented by the *Veterinary Services*, are essential for the credibility of the *surveillance* system.

2. Cattle over 30 months of age that are non-ambulatory, recumbent, unable to rise or to walk without assistance; cattle over 30 months of age sent for emergency slaughter or condemned at ante-mortem inspection (casualty or emergency slaughter, or downer cattle)

   These cattle may have exhibited some of the clinical signs listed above which were not recognised as being consistent with BSE. Experience in Members where BSE has been identified indicates that this subpopulation is the one demonstrating the second highest prevalence. For that reason, it is the second most appropriate population to target in order to detect BSE.

3. Cattle over 30 months of age which are found dead or killed on farm, during transport or at an abattoir (fallen stock)

   These cattle may have exhibited some of the clinical signs listed above prior to *death*, but were not recognised as being consistent with BSE. Experience in Members where BSE has been identified indicates that this subpopulation is the one demonstrating the third highest prevalence.

4. Cattle over 36 months of age at routine slaughter

   Experience in Members where BSE has been identified indicates that this subpopulation is the one demonstrating the lowest prevalence. For that reason, it is the least appropriate population to target in order to detect BSE. However, sampling in this subpopulation may be an aide in monitoring the progress of the epizootic and the efficacy of control measures applied, because it offers continuous access to a cattle population of known class, age structure and geographical origin. Testing of routine slaughter cattle 36 months of age or less is of relatively very little value (Table 2).

Article 11.6.22.

Surveillance activities

In order to implement efficiently a *surveillance* strategy for BSE, a Member must use documented records or reliable estimates of the age distribution of the adult cattle population and the number of cattle tested for BSE stratified by age and by subpopulation within the country, *zone* or *compartment*.

The approach assigns 'point values' to each sample, based on the subpopulation from which it was collected and the likelihood of detecting infected cattle in that subpopulation. The number of points a sample is assigned is determined by the subpopulation from which the sample is collected and the age of the animal sampled. The total points accumulation is then periodically compared to the target number of points for a country, *zone* or *compartment*.

A *surveillance* strategy should be designed to ensure that samples are representative of the *herd* of the country, *zone* or *compartment*, and include consideration of demographic factors such as production type and geographic location, and the potential influence of culturally unique husbandry practices. The approach used and the assumptions made should be fully documented, and the documentation retained for 7 years.

The points targets and *surveillance* point values in this chapter were obtained by applying the following factors to a statistical model:

a) the design prevalence for Type A or Type B *surveillance*;

b) a confidence level of 95%;

c) the pathogenesis, and pathological and clinical expression of BSE:

   i) sensitivity of diagnostic methods used;

   ii) relative frequency of expression by age;

   iii) relative frequency of expression within each subpopulation;

   iv) interval between pathological change and clinical expression;

d) demographics of the cattle population, including age distribution;

e) influence of BSE on culling or attrition of animals from the cattle population via the four subpopulations;

f) percentage of infected animals in the cattle population which are not detected.

Although the procedure accepts very basic information about a cattle population, and can be used with estimates and less precise data, careful collection and documentation of the data significantly enhance their value. Since samples from clinical suspect animals provide many times more information than samples from healthy or dead-of-unknown-cause animals, careful attention to the input data can substantially decrease the procedure's cost and the number of samples needed. The essential input data are:

g) cattle population numbers stratified by age;

h) the number of cattle tested for BSE stratified by age and by subpopulation.

Annex XXV (contd)

This chapter utilises Tables 1 and 2 to determine a desired *surveillance* points target and the point values of *surveillance* samples collected.

Within each of the subpopulations above in a country, *zone* or *compartment*, a Member may wish to target cattle identifiable as imported from countries or *zones* not free from BSE and cattle which have consumed potentially contaminated feedstuffs from countries or *zones* not free from BSE.

All clinical suspects should be investigated, regardless of the number of points accumulated. In addition, animals from the other subpopulations should be tested.

1. Type A surveillance

   The application of Type A *surveillance* will allow the detection of BSE around a design prevalence of at least one case per 100,000 in the adult cattle population in the country, *zone* or *compartment* of concern, at a confidence level of 95%.

2. Type B surveillance

   The application of Type B *surveillance* will allow the detection of BSE around a design prevalence of at least one case per 50,000 in the adult cattle population in the country, *zone* or *compartment* of concern, at a confidence level of 95%.

   Type B *surveillance* may be carried out by countries, *zones* or *compartments* of negligible BSE risk status (Article 11.6.3.) to confirm the conclusions of the *risk assessment*, for example by demonstrating the effectiveness of the measures mitigating any risk factors identified, through *surveillance* targeted to maximise the likelihood of identifying failures of such measures.

   Type B *surveillance* may also be carried out by countries, *zones* or *compartments* of controlled BSE risk status (Article 11.6.4.), following the achievement of the relevant points target using Type A *surveillance*, to maintain confidence in the knowledge gained through Type A *surveillance*.

3. Selecting the points target

   The *surveillance* points target should be selected from Table 1, which shows target points for adult cattle populations of different sizes. The size of the adult cattle population of a country, *zone* or *compartment* may be estimated or may be set at one million because, for statistical reasons, one million is the point beyond which sample size does not further increase with population size.

4. Determining the point values of samples collected

   Table 2 can be used to determine the point values of the *surveillance* samples collected. The approach assigns point values to each sample according to the likelihood of detecting *infection* based on the subpopulation from which the sample was collected and the age of the animal sampled. This approach takes into account the general principles of *surveillance* described in Chapter 1.4. and the epidemiology of BSE.

   Because precise aging of the animals that are sampled may not be possible, Table 2 combines point values into five age categories. The point estimates for each category were determined as an average for the age range comprising the group. The age groups were selected on their relative likelihoods of expressing BSE according to scientific knowledge of the incubation of the *disease* and the world BSE experience. Samples may be collected from any combination of subpopulations and ages but should reflect the demographics of the cattle *herd* of the country, *zone* or *compartment*. In addition, Members should sample at least three of the four subpopulations.

Table 1. ***Points targets for different adult cattle population sizes in a country, zone or compartment***

Points targets for country, zone or compartment		
Adult cattle population size (24 months and older)	**Type A surveillance**	**Type B surveillance**
>1,000,000	300,000	150,000
800,000-1,000,000	240,000	120,000
600,000-800,000	180,000	90,000
400,000-600,000	120,000	60,000
200,000-400,000	60,000	30,000
100,000-200,000	30,000	15,000
50,000-100,000	15,000	7,500
25,000 -50,000	7,500	3,750

If a country, *zone* or *compartment* determines, based on the demographics and epidemiological characteristics of its cattle population, that precise classification of the subpopulations 'casualty or emergency slaughter, or downer cattle' and 'fallen stock' is not possible, these subpopulations may be combined. In such a case, the *surveillance* point values accorded to the combined subpopulation would be that of 'fallen stock'.

The total points for samples collected may be accumulated over a period of a maximum of 7 consecutive years to achieve the target number of points determined in Table 1.

Surveillance points remain valid for 7 years (the 95th percentile of the incubation period).

Table 2. ***Surveillance point values for samples collected from animals in the given subpopulation and age category***

Surveillance subpopulation			
Routine slaughter[1]	**Fallen stock[2]**	**Casualty slaughter[3]**	**Clinical suspect[4]**
Age≥1 year and <2years			
0.01	0.2	0.4	N/A
Age ≥2 years and <4 years (young adult)			
0.1	0.2	0.4	260
Age ≥4 years and<7 years (middle adult)			
0.2	0.9	1.6.	750
Age ≥7 years and <9 years (older adult)			
0.1	0.4	0.7	220
Age ≥9 years (aged)			
0.0	0.1	0.2	45

Annex XXV (contd)

Article 11.6.23.

BSE risk assessment: introduction

The first step in determining the BSE risk status of the cattle population of a country or *zone* is to conduct a *risk assessment* (reviewed annually), based on Section 2 of this *Terrestrial Code*, identifying all potential factors for BSE occurrence and their historic perspective.

1. Release assessment

   Release assessment consists of assessing the likelihood that a BSE agent has been introduced via the importation of the following *commodities* potentially contaminated with a BSE agent:

   a) *meat-and-bone meal* or *greaves*;

   b) live animals;

   c) animal feed and feed ingredients;

   d) products of animal origin for human consumption.

2. Exposure assessment

   Exposure assessment consists of assessing the likelihood of exposure of the BSE agent to cattle, through a consideration of the following:

   a) epidemiological situation concerning BSE agents in the country or *zone*;

   b) recycling and amplification of the BSE agent through consumption by cattle of *meat-and-bone meal* or *greaves* of ruminant origin, or other feed or feed ingredients contaminated with these;

   c) the origin and use of ruminant carcasses (including fallen stock), by-products and *slaughterhouse* waste, the parameters of the rendering processes and the methods of animal feed manufacture;

   d) implementation and enforcement of feed bans, including measures to prevent cross-contamination of animal feed; the status of the birth cohort of a *case* should be determined when investigating the implementation of feed bans.

The following recommendations are intended to assist *Veterinary Services* in conducting such a *risk assessment*. They provide guidance on the issues that need to be addressed when conducting a country-based assessment of BSE risk. They apply equally to self-assessment in preparation of dossiers for categorisation of countries. The recommendations are supported by greater detail in the questionnaire used for the submission of data for country assessment.

Article 11.6.24.

The potential for the release of the BSE agent through the importation of meat-and-bone meal or greaves

This point is irrelevant if the exposure assessment outlined below in Article 11.6.27. indicates that *meat-and-bone meal* or *greaves* has not been fed, either deliberately or accidentally, in the past 8 years. Nevertheless, documentation should be provided on the control systems (including relevant legislation) in place to ensure that *meat-and-bone meal* or *greaves* has not been fed to ruminants.

Assumption: That *meat-and-bone meal* or *greaves* of ruminant origin plays the only significant role in BSE transmission.

Question to be answered: Has *meat-and-bone meal*, *greaves*, or feedstuffs containing either been imported within the past 8 years? If so, where from and in what quantities?

Rationale: Knowledge of the origin of *meat-and-bone meal*, *greaves* or feedstuffs containing either *meat-and-bone meal* or *greaves*, is necessary to assess the risk of release of BSE agent. *Meat-and-bone meal* and *greaves* originating in countries of high BSE risk pose a higher release risk than that from low risk countries. *Meat-and-bone meal* and *greaves* originating in countries of unknown BSE risk pose an unknown release risk.

Evidence required:

- Documentation to support claims that *meat-and-bone meal*, *greaves* or feedstuffs containing either *meat-and-bone meal* or *greaves* have not been imported, OR

- Where *meat-and-bone meal*, *greaves* or feedstuffs containing them have been imported, documentation of country of origin and, if different, the country of export.

- Documentation on annual volume, by country of origin, of *meat*, *greaves* or feedstuffs containing them imported during the past 8 years.

- Documentation describing the composition (on a species and class of stock basis) of the imported *meat-and-bone meal*, *greaves* or feedstuffs containing them.

- Documentation, from the country of production, supporting why the rendering processes used to produce *meat-and-bone meal*, *greaves* or feedstuffs containing them would have inactivated, or significantly reduced the titre of BSE agent, should it be present.

- Documentation describing the fate of imported *meat-and-bone meal* and *greaves*.

Article 11.6.25.

The potential for the release of the BSE agent through the importation of live animals potentially infected with BSE

Assumptions:

- Countries which have imported ruminants from countries infected with BSEs are more likely to experience BSE.

- Cattle pose the only known risk although other species are under study.

- Animals imported for breeding may pose a greater risk than animals imported for *slaughter* because of the hypothetical risk of maternal transmission and because they are kept to a greater age than animals imported for *slaughter*.

- Risk is influenced by the date at which imports occurred, relative to the BSE status of the country of origin.

- Risk is proportional to volume of imports (Article 2.1.3.).

Annex XXV (contd)

Question to be answered: Have live animals been imported within the past 7 years?

Rationale: The release risks are dependent on:

- country of origin and its BSE status, which will change as more data become available; this may result from the detection of clinical *disease*, or following active *surveillance*, or assessment of geographical BSE risk;
- feeding and management of the animals in the country of origin;
- use to which the *commodity* has been put as apart from representing risk of developing clinical *disease*, the *slaughter*, rendering and recycling in *meat-and-bone meal* of imported animals represents a potential route of exposure of indigenous livestock even if *meat-and-bone meal* and *greaves*, or feedstuffs containing them, have not been imported;
- species;
- dairy versus meat breeds, where there are differences in exposure in the country of origin because feeding practices result in greater exposure of one category;
- age at *slaughter*.

Evidence required:

- Documentation on the country of origin of imports. This should identify the country of breeding of animals, the length of time they lived in that country and of any other country in which they have resided during their lifetime.
- Documentation describing origins, species and volume of imports.
- Documentation describing the fate of imported animals, including their age at *slaughter*.
- Documentation demonstrating that risks are periodically reviewed in light of evolving knowledge on the BSE status of the country of origin.

Article 11.6.26.

The potential for the release of the BSE agent through the importation of products of animal origin potentially infected with BSE

Assumptions:

- Semen, embryos, hides and skins or milk are not considered to play a role in the transmission of BSE.
- Countries which have imported products of animal origin from countries with BSEs are more likely to experience BSE.
- Risk is influenced by the date at which imports occurred, relative to the BSE status of the country of origin.
- Risk is proportional to volume of imports (Article 2.1.3.).

Question to be answered: What products of animal origin have been imported within the past 7 years?

Rationale: The release risks are dependent on:

- the species of origin of the animal products and whether these products contain tissues known to contain BSE infectivity (Article 11.6.14.);
- country of origin and its BSE status, which will change as more data become available; this may result from the detection of clinical *disease*, or following active *surveillance*, or assessment of geographical BSE risk;
- feeding and management of the animals in the country of origin;
- use to which the *commodity* has been put as apart from representing risk of developing clinical *disease*, the *slaughter*, rendering and recycling in *meat-and-bone meal* of imported animals represents a potential route of exposure of indigenous livestock even if *meat-and-bone meal* and *greaves*, or feedstuffs containing them, have not been imported;
- species;
- dairy versus meat breeds, where there are differences in exposure in the country of origin because feeding practices result in greater exposure of one category;
- age at *slaughter*.

Evidence required:

- Documentation on the country of origin of imports. This should identify the country of breeding of animals, the length of time they lived in that country and of any other country in which they have resided during their lifetime.
- Documentation describing origins, species and volume of imports.
- Documentation describing the end use of imported animal products, and the disposal of waste.
- Documentation demonstrating that risks are periodically reviewed in light of evolving knowledge on the BSE status of the country of origin.

Article 11.6.27.

The potential for the exposure of cattle to the BSE agent through consumption of meat-and-bone meal or greaves of ruminant origin

Assumptions:

- That the consumption by bovines of *meat-and-bone meal* or *greaves* of ruminant origin plays the only significant role in BSE transmission.
- That commercially-available products of animal origin used in animal feeds may contain *meat-and-bone meal* or *greaves* of ruminant origin.
- Milk and blood are not considered to play a role in the transmission of BSE.

Annex XXV (contd)

Question to be answered: Has *meat-and-bone meal* or *greaves* of ruminant origin been fed to cattle within the past 8 years (see Articles 11.6.3. and 11.6.4.)?

Rationale: If cattle have not been fed products of animal origin (other than milk or blood) potentially containing *meat-and-bone meal* or *greaves* of ruminant origin within the past 8 years, *meat-and-bone meal* and *greaves* can be dismissed as a risk.

Article 11.6.28.

The origin of animal waste, the parameters of the rendering processes and the methods of animal feed production

Assumptions:

- BSE has a long *incubation period* and insidious onset of signs, so cases may escape detection.
- Pre-clinical BSE infectivity cannot reliably be detected by any method and may enter rendering, in particular if specified risk materials are not removed.
- Tissues most likely to contain high titres of BSE infectivity (brain, spinal cord, eyes) may not be harvested for human consumption and may be rendered.
- BSE may manifest in sudden *death*, chronic disease, or recumbency, and may be presented as fallen stock or materials condemned as unfit for human consumption.
- BSE agent survival in rendering is affected by the method of processing. Adequate rendering processes are described in Article 11.6.19.
- BSE agent is present at much higher titres in central nervous system and reticulo-endothelial tissues (so-called 'Specified Risk Materials', or SRM).

Question to be answered: How has animal waste been processed over the past 8 years?

Rationale: If potentially infected animals or contaminated materials are rendered, there is a risk that the resulting *meat-and-bone meal* could retain BSE infectivity.

Where *meat-and-bone meal* is utilized in the production of any animal feeds, the risk of cross-contamination exists.

Evidence required:

- Documentation describing the collection and disposal of fallen stock and materials condemned as unfit for human consumption.
- Documentation describing the definition and disposal of specified risk material, if any.
- Documentation describing the rendering process and parameters used to produce *meat-and-bone meal* and *greaves*.

- Documentation describing methods of animal feed production, including details of ingredients used, the extent of use of *meat-and-bone meal* in any livestock feed, and measures that prevent cross-contamination of cattle feed with ingredients used in monogastric feed.

- Documentation describing monitoring and enforcement of the above.

Article 11.6.29.

Conclusions of the risk assessment

The overall risk of BSE in the cattle population of a country or *zone* is proportional to the level of known or potential exposure to BSE infectivity and the potential for recycling and amplification of the infectivity through livestock feeding practices. For the *risk assessment* to conclude that the cattle population of a country or *zone* is free from BSE risk, it must have demonstrated that appropriate measures have been taken to manage any risks identified.

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[1] See point 4) of Article 11.6.21.
[2] See point 3) of Article 11.6.21.
[3] See point 2) of Article 11.6.21.
[4] See point 1) of Article 11.6.21.

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Annex XXVI

CHAPTER 11.7.

BOVINE TUBERCULOSIS

Article 11.7.1.

General provisions

The recommendations in this chapter are intended to manage the human and animal health risks associated with *Mycobacterium bovis* (*M. bovis*) infection in domestic (permanently captive and owned free-range) bovines including cattle (*Bos taurus*, *B. indicus* and *B. grunniens*), water buffaloes (*Bubalus bubalis*) and wood bisons (*Bison bison* and *B. bonasus*).

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

Article 11.7.2.

Country or zone free from bovine tuberculosis

To qualify as free from bovine tuberculosis, a country or *zone* should satisfy the following requirements:

1. *M. bovis* infection in domestic (permanently captive and owned free-range) bovines including cattle, water buffalo and wood bison is a *notifiable disease* in the country;

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

3. regular and periodic testing of all cattle, water buffalo, and wood bison *herds* demonstrated that *M. bovis* infection was not present in at least 99.8% of the *herds* and 99.9% of the cattle, water buffalo and wood bison in the country or *zone* for 3 consecutive years;

4. a *surveillance* programme should be in place to detect bovine tuberculosis in the country or *zone* through ante-mortem and post-mortem inspection as described in Chapter 6.2.;

5. if the *surveillance* programme described in points 3 and 4 above ~~has not detected infection with~~ demonstrated that *M. bovis* infection was not present in at least 99.8% of the *herds* and 99.9% of the cattle, water buffalo and wood bison in the country or *zone* for 5 consecutive years, *surveillance* may be maintained through ante-mortem and post-mortem inspection as described in Chapter 6.2.;

6. cattle, water buffalo and wood bison introduced into a country or *zone* free from bovine tuberculosis should be accompanied by a certificate from an *Official Veterinarian* attesting that they come from a country, *zone*, *compartment* or *herd* free from bovine tuberculosis or comply with the relevant provisions in Article 11.7.5. or in Article 11.7.6.

Article 11.7.3.

Compartment free from bovine tuberculosis

To qualify as a *compartment* free from bovine tuberculosis, all cattle, water buffalo or wood bison in a *compartment* should be certified by the *Veterinary Authority* as satisfying the following requirements:

Annex XXVI (contd)

1. the cattle, water buffalo and wood bison:

    a) showed no sign of bovine tuberculosis or lesions at ante-mortem or post-mortem inspection for at least 3 consecutive years;

    b) were over 6 weeks of age at the time of the first test and have shown a negative result to at least two tuberculin tests carried out at an interval of a minimum of 6 months, the first test being performed at least 6 months following the *slaughter* of the last affected animal;

    c) met one of the following conditions:

        i) showed a negative result to a biannual tuberculin test to ensure the continuing absence of bovine tuberculosis if the annual percentage of *herds* confirmed as infected with tuberculosis is more than 1% of all *herds* in the country or *zone* during the last 2 years; or

        ii) showed a negative result to an annual tuberculin test to ensure the continuing absence of bovine tuberculosis if the annual percentage of *herds* confirmed as infected with tuberculosis is more than 0.2% but not more than 1% of all *herds* in the country or *zone* during the last 2 years; or

        iii) showed a negative result to a tuberculin test every 3 years to ensure the continuing absence of bovine tuberculosis if the annual percentage of *herds* confirmed as infected with tuberculosis is not more than 0.2% of all *herds* in the country or *zone* during the last 4 years; or

        iv) showed a negative result to a tuberculin test every 4 years to ensure the continuing absence of bovine tuberculosis if the annual percentage of *herds* confirmed as infected with tuberculosis is not more than 0.1% of all *herds* in the country or *zone* during the last 6 years;

2. cattle, water buffalo and wood bison introduced into the *compartment* come from a *herd* free from bovine tuberculosis. This condition may be waived for animals which have been isolated for at least 90 days and which, prior to entry into the *compartment*, were subjected to at least two tuberculin tests carried out at a 6-month interval with negative results with the second tuberculin test performed during the 30 days prior to entry into the *compartment*;

3. cattle, water buffalo and wood bison in a *compartment* free from bovine tuberculosis are protected from contact with wildlife reservoirs of bovine tuberculosis and are managed under a common biosecurity plan protecting them from contamination with *M. bovis*, and the *compartment* has been approved by the *Veterinary Authority* in accordance with Chapters 4.3. and 4.4.

Article 11.7.4.

Herd free from bovine tuberculosis

To qualify as free from bovine tuberculosis, a *herd* of cattle, water buffalo, or wood bisons should satisfy the following requirements:

1. the *herd* is in a country, *zone* or *compartment* free from bovine tuberculosis and is certified free by the *Veterinary Authority*; or

2. cattle, water buffalo and wood bison in the *herd*:

    a) showed no signs of bovine tuberculosis or lesions at ante-mortem or post-mortem inspection for at least 3 consecutive years;

b) were over 6 weeks of age at the time of the first test and have shown a negative result to at least two tuberculin tests carried out at an interval of a minimum of 6 months, the first test being performed at least 6 months following the *slaughter* of the last affected animal;

c) met one of the following conditions:

i) showed a negative result to an annual tuberculin test to ensure the continuing absence of bovine tuberculosis; or

ii) showed a negative result to a tuberculin test every 2 years to ensure the continuing absence of bovine tuberculosis if the annual percentage of *herds* confirmed as infected with tuberculosis is not more than 1% of all *herds* in the country or *zone* during the last 2 years; or

iii) showed a negative result to a tuberculin test every 3 years to ensure the continuing absence of bovine tuberculosis if the annual percentage of *herds* confirmed as infected with tuberculosis is not more than 0.2% of all *herds* in the country or *zone* during the last 4 years; or

iv) showed a negative result to a tuberculin test every 4 years to ensure the continuing absence of bovine tuberculosis if the annual percentage of *herds* confirmed as infected with tuberculosis is not more than 0.1% of all *herds* in the country or *zone* during the last 6 years;

3. cattle, water buffalo and wood bison introduced into the *herd* come from a *herd* free from bovine tuberculosis. This condition may be waived for animals which have been isolated for at least 90 days and which, prior to entry into the *herd*, were subjected to at least two tuberculin tests carried out at a 6-month interval with negative results.

Article 11.7.5.

Recommendations for the importation of cattle, water buffalo and wood bison for breeding or rearing

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

1. showed no signs of bovine tuberculosis on the day of shipment;

2. originate from a *herd* free from bovine tuberculosis that is in a country, *zone* or *compartment* free from bovine tuberculosis; or

3. were subjected to the tuberculin test for bovine tuberculosis with negative results during the 30 days prior to shipment and come from a *herd* free from bovine tuberculosis; or

4. have been isolated for at least 90 days prior to entry into the *herd,* including protection from contact with wildlife reservoirs of bovine tuberculosis and were subjected to at least two tuberculin tests carried out at a six-month interval with negative results with the second tuberculin test performed during the 30 days prior to entry into the *herd.*

Article 11.7.6.

Recommendations for the importation of cattle, water buffalo and wood bison for slaughter

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

1. showed no signs of bovine tuberculosis on the day of shipment;

2. originated from a *herd* free from bovine tuberculosis or were subjected to a tuberculin test for bovine tuberculosis with negative results during the 30 days prior to shipment;

3. were not being eliminated as part of an eradication programme against bovine tuberculosis.

Article 11.7.7.

Recommendations for the importation of semen of cattle, water buffalo and wood bison

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

1. the donor animals showed no signs of bovine tuberculosis on the day of collection of the semen and either:

   a) were kept in an *artificial insemination centre* free from bovine tuberculosis in a country, *zone* or *compartment* free from bovine tuberculosis and which only accepts animals from free *herds* in a free country, *zone* or *compartment*; or

   b) showed negative results to tuberculin tests carried out annually and were kept in a *herd* free from bovine tuberculosis;

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

Article 11.7.8.

Recommendations for the importation of embryos/ova of cattle, water buffalo and wood bison

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

1. the donor females and all other susceptible animals in the *herd* of origin showed no signs of bovine tuberculosis during the 24 hours prior to embryo collection; and either

   a) originated from a *herd* free from bovine tuberculosis in a country, *zone* or *compartment* free from bovine tuberculosis; or

   b) were kept in a *herd* free from bovine tuberculosis, and were subjected to a tuberculin test for bovine tuberculosis with negative results during an isolation period of 30 days in the *establishment* of origin prior to collection;

2. the embryos/ova were collected, processed and stored in conformity with the provisions of Chapters 4.7., 4.8. and 4.9., as relevant.

Article 11.7.9.

Recommendations for the importation of fresh meat and meat products of cattle, water buffalo, and wood bison

Veterinary Authorities of *importing countries* should require the presentation of an *international veterinary certificate* attesting that the entire consignment of *meat* comes from animals which have been subjected to ante-mortem and post-mortem inspections as described in Chapter 6.2.

Article 11.7.10.

Recommendations for the importation of milk and milk products of cattle, water buffalo and wood bison

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

1. has been derived from animals in a *herd* free from bovine tuberculosis; or

2. was subjected to pasteurization; or

3. was subjected to a combination of control measures with equivalent performance as described in the Codex Alimentarius Code of Hygienic Practice for Milk and Milk Products.

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CHAPTER 11.8.

BOVINE TUBERCULOSIS OF FARMED CERVIDAE

Article 11.8.1.

General provisions

The recommendations in this chapter are intended to manage the human and animal health risks associated with *Mycobacterium bovis* (*M. bovis*) infection in domestic (permanently captive and owned free-range) farmed cervidae (red deer, wapiti, sika, samba, rusa, fallow deer, white-tailed, black-tailed and mule deer [*Cervus elephus*, *C. canadensis*, *C. nippon*, *C. unicolor unicolor*, *C. timorensis*, *Dama dama dama*, *Odocoileus virginianus borealis*, *Odocoileus hemionus columbianus* and *Odocoileus hemionus hemionus*]). The chapter does not address the management of tuberculosis in wild cervid populations.

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

Article 11.8.2.

Country or zone free from bovine tuberculosis of farmed cervidae

To qualify as free from bovine tuberculosis of farmed cervidae, a country or *zone* should satisfy the following requirements:

1. *M. bovis* infection in domestic bovines and in farmed cervidae as specified in Article 11.8.1. is a *notifiable disease* in the country;

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

3. regular and periodic testing of all *herds* of farmed cervidae has demonstrated that *M. bovis* infection was not present in at least 99.8% of the *herds* and 99.9% of the farmed cervidae in the country or *zone* for 3 consecutive years;

4. a *surveillance* programme should be in place to detect bovine tuberculosis in the country or *zone* through ante-mortem and post-mortem inspection as described in Chapter 6.2.;

5. if the *surveillance* programme described in points 3 and 4 above ~~has not detected infection with~~ demonstrated that *M. bovis* infection was not present in at least 99.8% of the *herds* and 99.9% of the farmed cervidae in the country or *zone* for 5 consecutive years, *surveillance* may be maintained through ante-mortem and post-mortem inspection as described in Chapter 6.2.;

6. farmed cervidae introduced into a country or *zone* free from bovine tuberculosis should be accompanied by a certificate from an *Official Veterinarian* attesting that they come from a country, *zone*, *compartment* or *herd* free from bovine tuberculosis or comply with the relevant provisions in Article 11.8.5. or in Article 11.8.6.

Article 11.8.3.

Compartment free from bovine tuberculosis of farmed cervidae

To qualify as a *compartment* free from bovine tuberculosis of farmed cervidae, the *Veterinary Authority* should be able to certify that the following requirements are satisfied:

1. all farmed cervidae:

    a) showed no sign of bovine tuberculosis or lesions at ante-mortem or post-mortem inspection for at least 3 consecutive years;

    b) were over 6 weeks of age at the time of the first test and have shown a negative result to at least two tuberculin tests carried out at an interval of a minimum of 6 months, the first test being performed at least 6 months following the *slaughter* of the last affected animal;

    c) met one of the following conditions:

        i) showed a negative result to a biannual tuberculin test to ensure the continuing absence of bovine tuberculosis if the annual percentage of *herds* confirmed as infected with tuberculosis is more than 1% of all *herds* in the country or *zone* during the last 2 years; or

        ii) showed a negative result to an annual tuberculin test to ensure the continuing absence of bovine tuberculosis if the annual percentage of *herds* confirmed as infected with tuberculosis is more than 0.2% but not more than 1% of all *herds* in the country or *zone* during the last 2 years; or

        iii) showed a negative result to a tuberculin test every 3 years to ensure the continuing absence of bovine tuberculosis if the annual percentage of *herds* confirmed as infected with tuberculosis is not more than 0.2% of all *herds* in the country or *zone* during the last 4 years; or

        iv) showed a negative result to a tuberculin test every 4 years to ensure the continuing absence of bovine tuberculosis if the annual percentage of *herds* confirmed as infected with tuberculosis is not more than 0.1% of all *herds* in the country or *zone* during the last 6 years;

2. farmed cervidae introduced into the *compartment* come from a *herd* free from bovine tuberculosis. This condition may be waived for animals which have been isolated for at least 90 days and which, prior to entry into the *compartment*, were subjected to at least two tuberculin tests carried out at a 6-month interval with negative results with the second tuberculin test performed during the 30 days prior to entry into the *compartment*;

3. farmed cervidae in a *compartment* free from bovine tuberculosis are protected from contact with wildlife reservoirs of bovine tuberculosis and are managed under a common biosecurity plan protecting them from contamination with *M. bovis*, and the *compartment* has been approved by the *Veterinary Authority* in accordance with Chapters 4.3. and 4.4.

Article 11.8.4.

Herd free from bovine tuberculosis

To qualify as free from bovine tuberculosis, a *herd* of farmed cervidae should satisfy the following requirements:

1. the *herd* is in a country, a *zone* or a *compartment* free from bovine tuberculosis and is certified free by the *Veterinary Authority*; or

2. farmed cervidae in the *herd*:

   a) showed no sign of bovine tuberculosis or lesions at ante-mortem or post-mortem inspection for at least 3 consecutive years;

   b) were over 6 weeks of age at the time of the first test and have shown a negative result to at least two tuberculin tests carried out at an interval of a minimum of 6 months, the first test being performed at least 6 months following the *slaughter* of the last affected animal;

   c) met one of the following conditions:

      i) showed a negative result to an annual tuberculin test to ensure the continuing absence of bovine tuberculosis; or

      ii) showed a negative result to a tuberculin test every 2 years to ensure the continuing absence of bovine tuberculosis if the annual percentage of *herds* confirmed as infected with tuberculosis is not more than 1% of all *herds* in the country or *zone* during the last 2 years; or

      iii) showed a negative result to a tuberculin test every 3 years to ensure the continuing absence of bovine tuberculosis if the annual percentage of *herds* confirmed as infected with tuberculosis is not more than 0.2% of all *herds* in the country or *zone* during the last 4 years; or

      iv) showed a negative result to a tuberculin test every 4 years to ensure the continuing absence of bovine tuberculosis if the annual percentage of *herds* confirmed as infected with tuberculosis is not more than 0.1% of all *herds* in the country or *zone* during the last 6 years;

3. farmed cervidae introduced into the *herd* come from a *herd* free from bovine tuberculosis. This condition may be waived for animals which have been isolated for at least 90 days and which, prior to entry into the *herd*, were subjected to at least two tuberculin tests carried out at a 6-month interval with negative results.

Article 11.8.5.

Recommendations for the importation of farmed cervidae for breeding or rearing

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

1. showed no signs of bovine tuberculosis on the day of shipment;

2. originate from a *herd* free from bovine tuberculosis of farmed cervidae that is in a country, *zone* or *compartment* free from bovine tuberculosis of farmed cervidae; or

3. were subjected to the tuberculin test for bovine tuberculosis with negative results during the 30 days prior to shipment and come from a *herd* free from bovine tuberculosis of farmed cervidae; or

4. have been isolated for at least 90 days prior to entry into the *herd,* including protection from contact with wildlife reservoirs of bovine tuberculosis and were subjected to at least two tuberculin tests carried out at a six-month interval with negative results with the second tuberculin test performed during the 30 days prior to entry into the *herd*.

Article 11.8.6.

Recommendations for the importation of farmed cervidae for slaughter

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

1. showed no signs of bovine tuberculosis on the day of shipment;

2. originated from a *herd* free from bovine tuberculosis of farmed cervidae or were subjected to a tuberculin test for bovine tuberculosis with negative results during the 30 days prior to shipment;

3. were not being eliminated as part of an eradication programme against bovine tuberculosis.

Article 11.8.7.

Recommendations for the importation of semen of farmed cervidae

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

1. the donor animals showed no signs of bovine tuberculosis on the day of collection of the semen; and either:

    a) were kept in a *herd* free from bovine tuberculosis in any species, in a country, *zone* or *compartment* free from bovine tuberculosis of farmed cervidae, and which only accepts animals from free *herds* in a free country, *zone* or *compartment*; or

    b) showed negative results to tuberculin tests carried out annually and were kept in a *herd* free from bovine tuberculosis;

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

Article 11.8.8.

Recommendations for the importation of embryos/ova of farmed cervidae

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

1. the donor females and all other susceptible animals in the *herd* of origin showed no signs of bovine tuberculosis during the 24 hours prior to embryo collection; and either

    a) originated from a *herd* free from bovine tuberculosis of farmed cervidae in a country, *zone* or *compartment* free from bovine tuberculosis; or

    b) were kept in a *herd* free from bovine tuberculosis of farmed cervidae and were subjected to a tuberculin test for bovine tuberculosis with negative results during an isolation period of 30 days in the *establishment* of origin prior to collection;

2. the embryos/ova were collected, processed and stored in conformity with the provisions of Chapters 4.7., 4.8. and 4.9., as relevant.

Article 11.8.9.

Recommendations for the importation of fresh meat and meat products of farmed cervidae

Veterinary Authorities of *importing countries* should require the presentation of an *international veterinary certificate* attesting that the entire consignment of *meat* comes from animals which have been subjected to ante-mortem and post-mortem inspections as described in Chapter 6.2.

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Annex XXVII

CHAPTER 11.9.

CONTAGIOUS BOVINE PLEUROPNEUMONIA

Article 11.9.1.

General provisions

For the purposes of the *Terrestrial Code*, the *incubation period* for contagious bovine pleuropneumonia (CBPP) shall be 6 months.

For the purpose of this chapter, a *case* of CBPP means an animal infected with *Mycoplasma mycoides* subsp. *mycoides* SC (*Mmm*SC), and freedom from CBPP means freedom from *Mmm* SC infection.

For the purpose of this chapter, susceptible animals include domestic cattle (*Bos indicus* and *B. taurus*) and water buffalo (*Bubalus bubalis*).

For the purposes of *international trade*, this chapter deals not only with the occurrence of clinical signs caused by MmmSC, but also with the presence of infection with *Mmm*SC in the absence of clinical signs.

The following defines the occurrence of *Mmm*SC infection:

1. *Mmm*SC has been isolated and identified as such from an animal, embryos, oocytes or semen; or

2. antibodies to *Mmm*SC antigens which are not the consequence of vaccination, or *Mmm*SC DNA, have been identified in one or more animals showing pathological lesions consistent with infection with *Mmm*SC with or without clinical signs, and epidemiological links to a confirmed *outbreak* of CBPP in susceptible animals.

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

When authorising import or transit of other *commodities* listed in this chapter, *Veterinary Authorities* should require the conditions prescribed in this chapter relevant to the CBPP status of the domestic cattle and water buffalo population of the *exporting country*, *zone* or *compartment*.

Article 11.9.2.

~~Trade in~~ Safe commodities

When authorising import or transit of the following *commodities*, *Veterinary Authorities* should not require any CBPP related conditions, regardless of the CBPP status of the domestic cattle and water buffalo population of the *exporting country*, *zone* or *compartment*:

1. *milk* and *milk products*;

2. hides and skins;

3. *meat* and *meat products* (excluding lung).

~~When authorising import or transit of other *commodities* listed in this chapter, *Veterinary Authorities* should require the conditions prescribed in this chapter relevant to the CBPP status of the domestic cattle and water buffalo population of the *exporting country*, *zone* or *compartment*.~~

Annex XXVII (contd)

Article 11.9.3.

CBPP free country, zone or compartment

To qualify for inclusion in the existing list of CBPP free countries, a Member should:

1. have a record of regular and prompt animal disease reporting;

2. send a declaration to the OIE stating that:

   a) there has been no *outbreak* of CBPP during the past 24 months;

   b) no evidence of CBPP infection has been found during the past 24 months;

   c) no vaccination against CBPP has been carried out during the past 24 months,

   and supply documented evidence that *surveillance* for CBPP in accordance with this chapter is in operation and that regulatory measures for the prevention and control of CBPP have been implemented;

3. not have imported since the cessation of vaccination any animals vaccinated against CBPP.

The country will be included in the list only after the submitted evidence has been accepted by the OIE. Retention on the list requires that the information 2a), 2b), 2c) and 3 above be re-submitted annually and changes in the epidemiological situation or other significant events should be reported to the OIE according to the requirements in Chapter 1.1.

Article 11.9.4.

Recovery of free status

When a CBPP *outbreak* occurs in a CBPP free country, *zone* or *compartment*, one of the following waiting periods is required to regain the status of CBPP free country, *zone* or *compartment*:

1. 12 months after the last *case* where a *stamping-out policy* and serological *surveillance* and strict movement control are applied in accordance with this chapter;

2. if vaccination was used, 12 months after the *slaughter* of the last vaccinated animal.

Where a *stamping-out policy* is not practised, the above waiting periods do not apply but Article 11.9.3. applies.

Article 11.9.5.

CBPP infected country or zone

When the requirements for acceptance as a CBPP free country or *zone* are not fulfilled, a country or *zone* shall be considered as infected.

Article 11.9.6.

Recommendations for importation from CBPP free countries, zones or compartments

for domestic cattle and water buffaloes

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

Article 11.9.7.

Recommendations for importation from CBPP infected countries or zones

for domestic cattle and water buffaloes for slaughter

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

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

2. originate from an *establishment* where no *case* of CBPP was officially reported for the past 6 months, and

3. are transported directly to the *slaughterhouse* in sealed *vehicles*.

Article 11.9.8.

Recommendations for importation from CBPP free countries, zones or compartments

for bovine semen

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

1. the donor animals:

    a) showed no clinical sign of CBPP on the day of collection of the semen;

    b) were kept in a CBPP free country since birth or for at least the past 6 months;

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

Article 11.9.9.

Recommendations for importation from CBPP infected countries or zones

for bovine semen

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

1. the donor animals:

    a) showed no clinical sign of CBPP on the day of collection of the semen;

    b) were subjected to the complement fixation test for CBPP with negative results, on two occasions, with an interval of not less than 21 days and not more than 30 days between each test, the second test being performed within 14 days prior to collection;

c) were isolated from other domestic bovidae from the day of the first complement fixation test until collection;

d) were kept since birth, or for the past 6 months, in an *establishment* where no *case* of CBPP was reported during that period, and that the *establishment* was not situated in a CBPP *infected zone*;

e) AND EITHER:

i) have not been vaccinated against CBPP;

OR

ii) were vaccinated using a vaccine complying with the standards described in the *Terrestrial Manual* not more than 4 months prior to collection; in this case, the condition laid down in point b) above is not required;

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

Article 11.9.10.

Recommendations for importation from CBPP free countries, zones or compartments

for *in vivo* derived or *in vitro* produced embryos/oocytes of bovidae

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

1. the donor animals:

a) showed no clinical sign of CBPP on the day of collection of the embryos/oocytes;

b) were kept in a CBPP free country since birth or for at least the past 6 months;

2. the oocytes were fertilised with semen meeting the conditions of Article 11.9.8.;

3. the embryos/oocytes was collected, processed and stored in conformity with the provisions of Chapters 4.7., 4.8. and 4.9., as relevant.

Article 11.9.11.

Recommendations for importation from CBPP infected countries or zones

for *in vivo* derived or *in vitro* produced embryos/oocytes of bovidae

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

1. the donor animals:

a) showed no clinical sign of CBPP on the day of collection of the embryos/oocytes;

b) were subjected to the complement fixation test for CBPP with negative results, on two occasions, with an interval of not less than 21 days and not more than 30 days between each test, the second test being performed within 14 days prior to collection;

c) were isolated from other domestic bovidae from the day of the first complement fixation test until collection;

d) were kept since birth, or for the past 6 months, in an *establishment* where no *case* of CBPP was reported during that period, and that the *establishment* was not situated in a CBPP *infected zone*;

e) AND EITHER:

i) have not been vaccinated against CBPP;

OR

ii) were vaccinated using a vaccine complying with the standards described in the *Terrestrial Manual* not more than 4 months prior to collection; in this case, the condition laid down in point b) above is not required;

2. the oocytes were fertilised with semen meeting the conditions of Article 11.9.9.;

3. the embryos/oocytes was collected, processed and stored in conformity with the provisions of Chapters 4.7., 4.8. and 4.9., as relevant.

Article 11.9.12.

Surveillance: introduction

Articles 11.9.12. to 11.9.17. define the principles and provides a guide for the *surveillance* ~~of~~ for CBPP in accordance with Chapter 1.4. applicable to Members seeking establishment of freedom from CBPP. Guidance is provided for Members seeking reestablishment of freedom from CBPP for the entire country or for a *zone* or *compartment*, following an *outbreak* and for the maintenance of CBPP free status.

The impact and epidemiology of CBPP differ widely in different regions of the world and therefore it is impossible to provide specific recommendations for all situations. *Surveillance* strategies employed for demonstrating freedom from CBPP at an acceptable level of confidence will need to be adapted to the local situation. It is incumbent upon the applicant Member to submit a dossier to the OIE in support of its application that not only explains the epidemiology of CBPP in the region concerned but also demonstrates how all the risk factors are managed. This should include provision of scientifically-based supporting data. There is therefore considerable latitude available to OIE Members to provide a well-reasoned argument to prove that the absence of CBPP infection is assured at an acceptable level of confidence.

Surveillance for CBPP should be in the form of a continuing programme designed to establish that the whole territory or part of it is free from CBPP infection.

Article 11.9.13.

Surveillance: general conditions and methods

1. A *surveillance* system in accordance with Chapter 1.4. should be under the responsibility of the *Veterinary Authority*. A procedure should be in place for the rapid collection and transport of samples from suspect *cases* of CBPP to a *laboratory* for CBPP diagnoses as described in the *Terrestrial Manual*.

Annex XXVII (contd)

2. The CBPP *surveillance* programme should:

a) include an early warning system throughout the production, marketing and processing chain for reporting suspicious *cases*. Farmers and workers (such as community animal health workers) who have day-to-day contact with livestock, *meat* inspectors as well as *laboratory* diagnosticians, should report promptly any suspicion of CBPP. They should be integrated directly or indirectly (e.g. through private *veterinarians* or *veterinary para-professionals*) into the *surveillance* system. All suspect *cases* of CBPP should be investigated immediately. Where suspicion cannot be resolved by epidemiological and clinical investigation, samples should be taken and submitted to a *laboratory*. This requires that sampling kits and other equipment are available for those responsible for *surveillance*. Personnel responsible for *surveillance* should be able to call for assistance from a team with expertise in CBPP diagnosis and control;

b) implement, when relevant, regular and frequent clinical inspection and testing of high-risk groups of animals, such as those adjacent to a CBPP infected country or *infected zone* (for example, areas of transhumant production systems);

c) take into consideration additional factors such as animal movement, different production systems, geographical and socio-economic factors that may influence the risk of disease occurrence.

An effective *surveillance* system will periodically identify suspicious *cases* that require follow-up and investigation to confirm or exclude that the cause of the condition is CBPP. The rate at which such suspicious *cases* are likely to occur will differ between epidemiological situations and cannot therefore be predicted reliably. Applications for freedom from CBPP infection should, in consequence, provide details of the occurrence of suspicious *cases* and how they were investigated and dealt with. This should include the results of laboratory testing and the control measures to which the animals concerned were subjected during the investigation (quarantine, movement stand-still orders, etc.).

Article 11.9.14.

Surveillance strategies

1. Introduction

The target population for *surveillance* aimed at identifying *disease* and *infection* should cover all the susceptible species (*Bos taurus*, *B. indicus* and *Bubalus bubalis*) within the country, *zone* or *compartment*.

Given the limitations of the diagnostic tools available, the interpretation of *surveillance* results should be at the *herd* level rather than at the individual animal level.

Randomised *surveillance* may not be the preferred approach given the epidemiology of the *disease* (usually uneven distribution and potential for occult foci of *infection* in small populations) and the limited sensitivity and specificity of currently available tests. Targeted *surveillance* (e.g. based on the increased likelihood of *infection* in particular localities or species, focusing on *slaughter* findings, and active clinical *surveillance*) may be the most appropriate strategy. The applicant Member should justify the *surveillance* strategy chosen as adequate to detect the presence of CBPP infection in accordance with Chapter 1.4. and the epidemiological situation.

Targeted *surveillance* may involve testing of the entire target subpopulation or a sample from it. In the latter case the sampling strategy will need to incorporate an epidemiologically appropriate design prevalence. The sample size selected for testing will need to be large enough to detect *infection* if it were to occur at a predetermined minimum rate. The sample size and expected disease prevalence determine the level of confidence in the results of the survey. The applicant Member must justify the choice of design prevalence and confidence level based on the objectives of *surveillance* and the epidemiological situation, in accordance with Chapter 1.4. Selection of the design prevalence in particular clearly needs to be based on the prevailing or historical epidemiological situation.

Irrespective of the survey design selected, the sensitivity and specificity of the diagnostic tests employed are key factors in the design, sample size determination and interpretation of the results obtained. Ideally, the sensitivity and specificity of the tests used should be validated.

Irrespective of the *surveillance* system employed, the 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 needs to be an effective procedure for following-up positives to ultimately determine with a high level of confidence, whether they are indicative of *infection* or not. This should involve follow-up with supplementary tests, clinical investigation and post-mortem examination in the original sampling unit as well as *herds* which may be epidemiologically linked to it.

2. Clinical surveillance

Clinical *surveillance* aims at detecting clinical signs of CBPP in a *herd* by close physical examination of susceptible animals. Clinical inspection will be an important component of CBPP *surveillance* contributing to reach the desired level of confidence of detection of *disease* if a sufficiently large number of clinically susceptible animals is examined.

Clinical *surveillance* and laboratory testing should always be applied in series to clarify the status of CBPP suspects detected by either of these complementary diagnostic approaches. Laboratory testing and post-mortem examination may contribute to confirm clinical suspicion, while clinical *surveillance* may contribute to confirmation of positive serology. Any sampling unit within which suspicious animals are detected should be classified as infected until contrary evidence is produced.

3. Pathological surveillance

Systematic pathological *surveillance* for CBPP is the most effective approach and should be conducted at *slaughterhouses* and other *slaughter* facilities. Suspect pathological findings should be confirmed by agent identification. Training courses for *slaughter* personnel and *meat* inspectors are recommended.

4. Serological testing

Serological *surveillance* is not the preferred strategy for CBPP. However, in the framework of epidemiologic investigations, serological testing may be used.

The limitations of available serological tests for CBPP will make the interpretation of results difficult and useful only at the *herd* level. Positive findings should be followed-up by clinical and pathological investigations and agent identification.

Clustering of seropositive reactions should be expected in CBPP infections and will be usually accompanied by clinical signs. As clustering may signal field strain *infection*, the investigation of all instances must be incorporated in the *surveillance* strategy.

Annex XXVII (contd)

Following the identification of a CBPP infected *herd*, contact *herds* need to be tested serologically. Repeated testing may be necessary to reach an acceptable level of confidence in *herd* classification.

5. Agent surveillance

Agent *surveillance* using tests described in the *Terrestrial Manual* should be conducted to follow-up and confirm or exclude suspect *cases*. Isolates should be typed to confirm *Mmm*SC.

Article 11.9.15.

Countries or zones applying for recognition of freedom from CBPP

In addition to the general conditions described in this chapter, an OIE Member applying for recognition of CBPP freedom for the country or a *zone* should provide evidence for the existence of an effective *surveillance* programme. The strategy and design of the *surveillance* programme will depend on the prevailing epidemiological circumstances and will be planned and implemented according to general conditions and methods in this chapter, to demonstrate absence of CBPP infection, during the preceding 24 months in susceptible populations. This requires the support of a national or other *laboratory* able to undertake identification of CBPP infection using methods described in the *Terrestrial Manual*.

Article 11.9.16.

Compartments seeking recognition of freedom from CBPP

The bilateral recognition of CBPP free *compartments* should follow the principles laid in this chapter, Chapter 4.3. and Chapter 4.4.

Article 11.9.17.

Countries or zones re-applying for recognition of freedom from CBPP following an outbreak

In addition to the general conditions described in this chapter, a Member re-applying for recognition of country or *zone* freedom from CBPP should show evidence of an active *surveillance* programme for CBPP, following the recommendations of this chapter.

Two strategies are recognised by the OIE in a programme to eradicate CBPP infection following an *outbreak*:

1. *slaughter* of all clinically affected and in-contact susceptible animals;

2. vaccination used without subsequent *slaughter* of vaccinated animals.

The time periods before which an application can be made for re-instatement of freedom from CBPP depends on which of these alternatives is followed. The time periods are prescribed in Article 11.9.4.

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Annex XXVIII

CHAPTER 11.11.

ENZOOTIC BOVINE LEUKOSIS

Article 11.11.1.

General provisions

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

For the purpose of this chapter, susceptible animals include domestic cattle (*Bos indicus* and *Bos taurus*).

Article 11.11.2.

Country or zone free from enzootic bovine leukosis

1. Qualification

   To qualify as free from enzootic bovine leukosis (EBL), a country or *zone* ~~must~~ should satisfy the following requirements for at least 3 years:

   a) all tumours, suspected to be lymphosarcoma, are reported to the *Veterinary Authority*, and are examined at a *laboratory* by appropriate diagnostic techniques;

   b) all ~~animals~~ cattle with tumours in which EBL has been confirmed or cannot be ruled out are traced back to the *herds* in which they have been kept since birth; all cattle over 24 months of age in these *herds* are subjected to an individual diagnostic test for EBL;

   c) at least 99.8% of the *herds* are qualified as EBL free.

2. Maintenance of free status

   For a country or *zone* to maintain its EBL free status:

   a) a serological survey ~~must~~ should be carried out annually on a random sample of the cattle population of the country or *zone* sufficient to provide a 99% level of confidence of detecting EBL if it is present at a prevalence rate exceeding 0.2% of the *herds*;

   b) all imported bovines (except for *slaughter*) comply with the provisions of Article 11.11.4.;

   c) all imported bovine semen and embryos/ova fulfil the requirements referred to in Article 11.11.5. and in Article 11.11.6., respectively.

Article 11.11.2.bis

Compartment free from enzootic bovine leukosis

1. Qualification

   To qualify as free from EBL, a *compartment* should satisfy the following requirements:

Annex XXVIII (contd)

All *herds* in the *compartments* have satisfied the requirements of Article 11.11.3.,and;

a) all cattle introduced into the *compartment* come from a free *herd*;

b) all bovine semen and embryos/ova introduced into the *compartment* after the first test have fulfilled the conditions referred to in Article 11.11.5. and in Article 11.11.6., respectively;

c) the *compartment* is managed under a common biosecurity plan complying with Article 4.3.3. and Article 4.4.3., which protects the cattle from contact with EBL virus, which might occur from introduction of infected cattle, cattle products or material and through practices such as vaccinations and other injections, collection of blood and other biological samples, dehorning, ear-tagging, pregnancy diagnosis, etc.;

d) the *compartment* has been approved by the *Veterinary Authority* in accordance with Chapters 4.3. and 4.4.

2. Maintenance of free status

For a *compartment* to maintain its EBL free status, all *herds* in the *compartment* should remain free according to Article 11.11.3. and specific *surveillance* implemented according to Article 4.4.5. has not detected the agent.

3. Revocation and re-approval of free status

If in an EBL free *compartment* any cattle react positively to a diagnostic test for EBL as described in the *Terrestrial Manual,* the status of the *compartment* shall be revoked until all *herds* have recovered their free status according to Article 11.11.3. and the *compartment* has been re-approved according to Chapters 4.3 and 4.4.

Article 11.11.3.

Herd free from enzootic bovine leukosis

1. Qualification

To qualify as free from EBL, a *herd* ~~must~~ should satisfy the following requirements:

a) there has been no evidence of EBL either clinical, post-mortem, or as a result of a diagnostic test for EBL within the previous 2 years;

b) all ~~animals~~ cattle over 24 months of age have been subjected to a diagnostic test for EBL on two occasions with negative results, at an interval of not less than 4 months during the preceding 12 months;

c) ~~animals~~ cattle introduced into the *herd* after the first test have fulfilled the conditions of Article 11.11.4.;

d) all bovine semen and embryos/ova introduced into the *herd* after the first test have fulfilled the conditions referred to in Article 11.11.5. and in Article 11.11.6., respectively.

2. Maintenance of free status

For a *herd* to maintain its EBL free status, the ~~animals~~ cattle in the *herd* over 24 months of age on the day of sampling ~~must~~ should be subjected to a diagnostic test for EBL with negative results at intervals of no more than 36 months and the conditions referred to in points 1a), 1c) and 1d) above continue to be fulfilled.

3. Suspension and restoration of free status

If in an EBL free *herd* any ~~animals~~ cattle react positively to a diagnostic test for EBL as described in the *Terrestrial Manual* ~~or a virological test (under study) for bovine leukosis virus~~, the status of the *herd* shall be suspended until the following measures have been taken:

a) the ~~animals~~ cattle which have reacted positively, and their progeny since the last negative test, ~~must~~ should be removed from the *herd* immediately; however, any ~~animal~~ cattle within the progeny which ~~has~~ have been subjected to a PCR test with negative results (under study) may be retained in the *herd*;

b) the remaining ~~animals~~ cattle ~~must~~ should have been subjected to a diagnostic test for EBL carried out as described in point 1b) above with negative results at least 4 months after removal of the positive ~~animals~~ cattle and their progeny.

Article 11.11.4.

Recommendations for the importation of cattle for breeding or rearing

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

1. come from a country or *zone* free from EBL; or

2. come from an EBL free *herd*; or

3. meet the following three conditions:

a) the ~~animals~~ cattle were kept in a *herd* in which:

i) there has been no evidence of EBL either clinical, post-mortem, or as a result of a diagnostic test for EBL within the previous 2 years;

ii) all ~~animals~~ cattle over 24 months of age have been subjected to a diagnostic test for EBL on a blood sample on two occasions with negative results during the preceding 12 months, at an interval of at least 4 months, or were tested on two occasions while segregated from the *herd* in an isolation unit approved by the *Veterinary Authority* at an interval of at least 4 months;

b) the ~~animals~~ cattle were subjected to a diagnostic test for EBL within 30 days prior to shipment with negative results;

c) if less than 2 years of age, the ~~animals~~ cattle come from 'uterine' dams which have been subjected to a diagnostic test for EBL on a blood sample on two occasions at intervals of at least 4 months within the preceding 12 months, with negative results.

Annex XXVIII (contd)

Article 11.11.5.

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 bull was resident at the time of semen collection in an EBL free *herd*; and

2. if less than 2 years of age, the bull came from a serologically negative 'uterine' dam; or

3. the bull was subjected to diagnostic tests for EBL on blood samples on two occasions with negative results, the first test being carried out at least 30 days before and the second test at least 90 days after collection of the semen;

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

Article 11.11.6.

Recommendations for the importation of bovine embryos/ova

Veterinary Authorities of *importing countries* should require the presentation of an *international veterinary certificate* attesting that the embryos/ova have been collected, processed and stored in conformity with the provisions of Chapters 4.7., 4.8. and 4.9., as relevant.

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Annex XXIX

CHAPTER 11.13.

INFECTIOUS BOVINE RHINOTRACHEITIS/INFECTIOUS PUSTULAR VULVOVAGINITIS

Article 11.13.1.

General provisions

For the purposes of the *Terrestrial Code*, the *incubation period* for infectious bovine rhinotracheitis/infectious pustular vulvovaginitis (IBR/IPV) shall be 21 days.

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

Article 11.13.2.

Country or zone free from IBR/IPV

1. Qualification

   To qualify as free from IBR/IPV, a country or *zone* must satisfy the following requirements:

   a) the *disease* or suspicion of the *disease* is notifiable;

   b) no animal has been vaccinated against IBR/IPV for at least 3 years;

   c) at least 99.8% of the *herds* are qualified as free from IBR/IPV.

2. Maintenance of free status

   For a country or *zone* to maintain its status free from IBR/IPV:

   a) a serological survey should be carried out annually on a random sample of the cattle population of the country or *zone* sufficient to provide a 99% level of confidence of detecting IBR/IPV if it is present at a prevalence rate exceeding 0.2% of the *herds*;

   b) all imported bovines comply with the provisions of Article 11.13.4.;

   c) all imported bovine semen and embryos/ova fulfil the requirements referred to in Articles 11.13.6. or 11.13.7., and in Article 11.13.8., respectively.

Article 11.13.3.

Herd free from IBR/IPV

1. Qualification

   To qualify as free from IBR/IPV, a *herd* of cattle must satisfy the following requirements:

a) all the animals in the *herd* have been subjected to a diagnostic test for IBR/IPV on a blood sample on two occasions with negative results, at an interval of not less than 2 months and not more than 12 months; or

b) if the *herd* contains only dairy cattle of which at least a quarter are lactating cows, each of the latter has been subjected to a diagnostic test on individual milk samples carried out on three occasions at intervals of 2 months with negative results;

c) animals introduced into the *herd* after the first tests referred to in point a) or point b) as relevant have been:

   i) kept in an IBR/IPV free *herd*; or

   ii) placed in isolation for a period of 30 days, and during this period have been subjected to a diagnostic test for IBR/IPV on a blood sample on two occasions with negative results, at an interval of not less than 21 days;

d) all bovine semen and embryos/ova introduced into the *herd* after the first tests referred to in point a) or point b) as relevant have fulfilled the conditions provided in Articles 11.13.6. or 11.13.7. and in Article 11.13.8., respectively.

2. Maintenance of free status

For a *herd* to maintain its status free from IBR/IPV, it must be subjected to the following tests with negative results:

EITHER

a) diagnostic tests for IBR/IPV on blood samples for all the animals repeated at maximum intervals of 12 months; in *herds* composed entirely of fattening animals, blood sampling may be limited to animals sent for *slaughter*;

OR

b) diagnostic tests on individual milk samples from all lactating cows repeated at intervals of 6 months; *Veterinary Authorities* applying an IBR/IPV eradication programme may extend these intervals (under study) if more than 98% of *herds* have been free from the *disease* for at least 3 years; and

c) diagnostic tests on blood samples for IBR/IPV of all breeding bulls repeated at maximum intervals of 12 months;

AND

d) diagnostic tests on blood samples for IBR/IPV of all cattle having aborted after more than 3 months of gestation.

Animals introduced into the *herd* must satisfy the conditions provided in point 1c) above, and semen and embryos/ova used in the *herd* must satisfy the conditions provided in Articles 11.13.6. or 11.13.7. and in Article 11.13.8., respectively.

Article 11.13.4.

Recommendations for the importation of cattle destined for IBR/IPV free herds

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

1. showed no clinical sign of IBR/IPV on the day of shipment;

2. come from an IBR/IPV free *herd*; or

3. were kept in a *quarantine station* for the 30 days prior to shipment and were subjected to a diagnostic test for IBR/IPV on a blood sample on two occasions with negative results, at an interval of not less than 21 days.

Article 11.13.5.

Recommendations for the importation of cattle intended for herds not qualified as free from IBR/IPV

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

1. showed no clinical sign of IBR/IPV on the day of shipment;

2. were vaccinated with an inactivated virus vaccine not less than one month and not more than 6 months prior to shipment.

Article 11.13.6.

Recommendations for the importation of fresh semen

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

1. the donor animals were kept in an IBR/IPV free *herd* at the time of collection of the semen;

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

Article 11.13.7.

Recommendations for the importation of frozen semen

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

1. the donor animals were kept in an IBR/IPV free *herd* at the time of collection of the semen; or

2. the donor animals were held in isolation during the period of collection and for the 30 days following collection and were subjected to a diagnostic test for IBR/IPV on a blood sample taken at least 21 days after collection of the semen, with negative results; or

3. if the serological status of the bull is unknown or if the bull is serologically positive, an aliquot of each semen collection was subjected to a virus isolation test or PCR, performed in accordance with the *Terrestrial Manual*, with negative results; and

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

Article 11.13.8.

Recommendations for the importation of embryos/ova

Veterinary Authorities of *importing countries* should require the presentation of an *international veterinary certificate* attesting that the embryos/ova were collected, processed and stored in conformity with the provisions of Chapters 4.7., 4.8. and 4.9., as relevant.

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Annex XXX

CHAPTER 12.7.

EQUINE INFLUENZA

Article 12.7.1.

General provisions

For the purposes of the *Terrestrial Code*, equine influenza (EI) is defined as an *infection* of domestic horses, donkeys and mules.

For the purposes of *international trade*, this chapter deals not only with the occurrence of clinical signs caused by equine influenza virus (EIV), but also with the presence of *infection* with EIV in the absence of clinical signs.

For the purposes of this chapter, isolation is defined as 'the separation of horses from horses of a different equine influenza health status, utilising appropriate biosecurity measures, with the purpose of preventing the transmission of *infection*'.

For the purposes of the *Terrestrial Code*, the *infective period* for equine influenza is 21 days.

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

When authorising import or transit of other *commodities* listed in this chapter, *Veterinary Authorities* should require the conditions prescribed in this chapter relevant to the EI status of the equine population of the *exporting country*, *zone* or *compartment*.

Article 12.7.2.

~~Trade in~~ Safe commodities

When authorising import or transit of the following *commodities*, *Veterinary Authorities* should not require any EIV related conditions, regardless of the EI status of the equine population of the *exporting country*, *zone* or *compartment*:

1. semen;

2. *in vivo* derived equine embryos collected, processed and stored in conformity with the provisions of Chapter 4.7. or Chapter 4.9. (under study).

~~When authorising import or transit of other *commodities* listed in this chapter, *Veterinary Authorities* should require the conditions prescribed in this chapter relevant to the EI status of the equine population of the *exporting country*, *zone* or *compartment*.~~

Article 12.7.3.

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

The EI status of a country, a *zone* or a *compartment* can be determined on the basis of the following criteria:

1. the outcome of a *risk assessment* identifying all potential factors for EI occurrence and their historic perspective;

2. whether EI is notifiable in the whole country, an on-going EI awareness programme is in place, and all notified suspect occurrences of EI are subjected to field and, where applicable, laboratory investigations;

3. appropriate *surveillance* is in place to demonstrate the presence of *infection* in the absence of clinical signs in horses.

Article 12.7.4.

Equine influenza free country, zone or compartment

A country or a *zone* or a *compartment* may be considered free from EI provided the *disease* is notifiable in the whole country and it shows evidence of an effective *surveillance* programme, planned and implemented according to the general principles in Chapter 1.4. The *surveillance* may need to be adapted to parts of the country, *zone* or *compartment* depending on historical or geographical factors, industry structure, population data, movements of equids into the country, *zone* or *compartment*, wild equid populations or proximity to recent *outbreaks*.

A country, a *zone* or a *compartment* seeking freedom from EI, in which vaccination is practised, should also demonstrate that EIV has not been circulating in the population of domestic and wild equidae during the past 12 months, through *surveillance*, in accordance with Chapter 1.4. In a country in which vaccination is not practised, *surveillance* could be conducted using serological testing. In countries where vaccination is practised, the *surveillance* should include methods of virus detection.

If an *outbreak* of clinical equine influenza occurs in a previously free country, *zone* or *compartment*, free status can be regained 12 months after the last clinical *case*, providing that *surveillance* for evidence of *infection* has been carried out during that 12-month period in accordance with Chapter 1.4.

Article 12.7.5.

Recommendations for the importation of horses for immediate slaughter

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

Article 12.7.6.

Recommendations for the importation of horses for unrestricted movement

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

1. came from an EI free country, *zone* or *compartment* in which they had been resident for at least 21 days; in the case of a vaccinated horse, information on its vaccination status should be included in the veterinary certificate;

OR

2. came from a country, *zone* or *compartment* not known to be free from EI, were subjected to pre-export isolation for 21 days and showed no clinical sign of EI during isolation nor on the day of shipment; and

3. were immunised according to the manufacturer's instructions with a vaccine complying with the standards described in the *Terrestrial Manual* beween 21 and 90 days before shipment either with a primary course or a booster.

For additional security, countries that are free of EI or undertaking an eradication programme may also request that the horses were tested negative for EIV by PCR conducted on nasopharyngeal swabs collected on two occasions at ~~21~~ 7 to 14 days and ~~3~~ less than 5 days before shipment.

Article 12.7.7.

Recommendations for the importation of horses which will be kept in isolation (see Article 12.7.1.)

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

1. came from an EI free country, *zone* or *compartment* in which they had been resident for at least 21 days; in the case of a vaccinated horse, information on its vaccination status should be included in the veterinary certificate;

OR

2. showed no clinical sign of EI in any premises in which the horses had been resident for the 21 days prior to shipment nor on the day of shipment; and

3. were immunised according to the manufacturer's instructions with a vaccine complying with the standards described in the *Terrestrial Manual*.

Article 12.7.8.

Recommendations for the importation of fresh meat of horses, mules or donkeys

Veterinary Authorities should require the presentation of an *international veterinary certificate* attesting that the *fresh meat* came from horses, mules or donkeys which had been subjected to ante-mortem and post-mortem inspections as described in Chapter 6.2.

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CHAPTER 12.10.

EQUINE VIRAL ARTERITIS

Article 12.10.1.

General provisions

The *infective period* for equine viral arteritis (EVA) shall be 28 days for all categories of equine except sexually mature stallion where the *infective period* may be for the life of the animal. Because the *infective period* may be extended in the case of virus shedding in semen, the status of seropositive stallions should be checked to ensure that they do not shed virus in their semen.

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

Article 12.10.2.

Recommendations for the importation of uncastrated male equines

Veterinary Authorities of *importing countries* should require the presentation of an *international veterinary certificate* attesting that the animals showed no clinical sign of EVA on the day of shipment and during the 28 days prior to shipment and met one of the following requirements:

1. were isolated for the 28 days prior to shipment and were subjected, to a test for EVA, as prescribed in the *Terrestrial Manual*, carried out on a single blood sample collected during the 21 days prior to shipment with negative result; or

2. were subjected between 6 and 9 months of age to a test for EVA, as prescribed in the *Terrestrial Manual*, carried out on two blood samples collected at least 14 days apart with stable or decreasing titre, immediately vaccinated for EVA and regularly revaccinated according to the manufacturer's instructions; or

3. met the following requirements:

    a) were isolated ~~for 28 days~~; and

    b) not earlier than 7 days of commencing isolation were tested, with negative results, with a test for EVA as prescribed in the *Terrestrial Manual*; and

    c) were then immediately vaccinated; and

    d) were kept separated from other equidae for 21 days following vaccination; and

    e) were revaccinated regularly according to the manufacturer's instructions; or

4. have been subjected to a test for EVA, as prescribed in the *Terrestrial Manual*, carried out on a blood sample with positive results and then: either

    a) were subsequently test mated to two mares within ~~12~~ 6 months prior to shipment which were subjected to two tests for EVA as prescribed in the *Terrestrial Manual* with negative results on blood samples collected at the time of test mating and again 28 days after the mating; or

b) were subjected to a test for equine arteritis virus as prescribed in the *Terrestrial Manual* with negative results, carried out on semen collected during the ~~28 days~~ 6 months prior to shipment;or

c) were subjected to a test for equine arteritis virus as prescribed in the *Terrestrial Manual* with negative results, carried out on semen collected within 6 months after the blood sample was tested, then immediately vaccinated, and revaccinated regularly.

Article 12.10.3.

Recommendations for the importation of equines other than uncastrated males

Veterinary Authorities of *importing countries* should require the presentation of an *international veterinary certificate* attesting that the animals showed no clinical sign of EVA on the day of shipment and

EITHER

1. were kept in an *establishment* where no animals have shown any signs of EVA for the 28 days prior to shipment; and ~~either~~

~~1~~a) ~~were isolated for the 28 days prior to shipment and~~ were subjected to a test for EVA, as prescribed in the *Terrestrial Manual*, carried out ~~either:~~

~~a.~~ on a single blood sample collected during the 28 days prior to shipment with negative results, or

~~b.~~ on blood samples collected on two occasions at least 14 days apart within 28 days prior to shipment, which demonstrated stable or declining antibody titres; or

b) regularly vaccinated according to the manufacturer's instructions;

OR

2. were isolated for the 28 days prior to shipment and during this period the animals showed no signs of EVA and were subjected~~, between 6 and 9 months of age,~~ to a diagnostic test for EVA, as prescribed in the *Terrestrial Manual*~~, carried out on two blood samples collected at least 14 days apart,~~ on a single blood sample with negative results ~~or stable or declining titre, and immediately vaccinated for EVA and regularly revaccinated according to the manufacturer's instructions.~~

Article 12.10.4.

Recommendations for the importation of semen

Veterinary Authorities of *importing countries* should require the presentation of an *international veterinary certificate* attesting that the animal donors were kept for the 28 days prior to semen collection in an *establishment* where no equine has shown any clinical sign of EVA during that period and showed no clinical sign of EVA on the day of semen collection; and

1. were subjected between 6 and 9 months of age to a test for EVA as prescribed in the *Terrestrial Manual* on two blood samples with stable or decreasing titre, immediately vaccinated for EVA and regularly revaccinated according to the manufacturer's instructions; or

2. were isolated and not earlier than 7 days of commencing isolation were subjected to a test for EVA as prescribed in the *Terrestrial Manual* on a blood sample with negative results, immediately vaccinated for EVA, kept for 21 days following vaccination separated from other equidae and regularly revaccinated according to the manufacturer's instructions; or

3. were subjected to a test for EVA as prescribed in the *Terrestrial Manual* on a blood sample with negative results within 14 days prior to semen collection, and had been separated from other equidae not of an equivalent EVA status for 14 days prior to blood sampling from the time of the taking of the blood sample until the end of semen collection; or

4. have been subjected to a test for EVA as prescribed in the *Terrestrial Manual* carried out on a blood sample with positive results and then: either

   a) were subsequently test mated to two mares within ~~12~~ 6 months prior to semen collection, which were subjected to two tests for EVA as prescribed in the *Terrestrial Manual* with negative results on blood samples collected at the time of test mating and again ~~28 days~~ 6 months after the test mating, or

   b) were subjected to a test for equine arteritis virus as prescribed in the *Terrestrial Manual* with negative results, carried out on semen collected within ~~one year~~ 6 months prior to collection of the semen to be exported; or

   c) were subjected to a test for equine arteritis virus as prescribed in the *Terrestrial Manual* with negative results, carried out on semen collected within 6 months after the blood sample was tested, then immediately vaccinated, and revaccinated regularly; or

5. were, for frozen semen, subjected with negative results either:

   a) to a test for EVA as prescribed in the *Terrestrial Manual* carried out on a blood sample taken not earlier than 14 days and not later than 12 months after the collection of the semen for export; or

   b) to a test for equine arteritis virus as prescribed in the *Terrestrial Manual* carried out on an aliquot of the semen collected immediately prior to processing or on an aliquot of semen collected within 14 to 30 days after the first collection of the semen to be exported.

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Annex XXXI

CHAPTER 14.9.

SCRAPIE

Article 14.9.1.

General provisions and safe commodities

Scrapie is a neurodegenerative *disease* of sheep and goats. The main mode of transmission is from mother to offspring immediately after birth and to other susceptible neonates exposed to the birth fluids and tissues of an infected animal. Transmission occurs at a much lower frequency to adults exposed to the birth fluids and tissues of an infected animal. A variation in genetic susceptibility of sheep has been recognised. The *incubation period* of the *disease* is variable; however, it is usually measured in years. The duration in *incubation period* can be influenced by a number of factors including host genetics and strain of agent.

Scrapie ~~is~~ does not ~~considered to~~ pose a risk to human health. The recommendations in this chapter are intended to manage the animal health risks associated with the presence of the scrapie agent in sheep and goats. The chapter does not cover so-called 'atypical' scrapie which is clinically, pathologically, biochemically and epidemiologically unrelated to 'classical' scrapie, may not be contagious and may, in fact, be a spontaneous degenerative condition of older sheep.

1. When authorising import or transit of the following *commodities* derived from sheep or goats and any products made from these *commodities* and containing no other tissues from sheep or goats derived, *Veterinary Authorities* should not require any scrapie-related conditions, regardless of the scrapie risk status of the sheep and goat populations of the *exporting country*, *zone* or *compartment*:

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

   b) *meat* (excluding materials as referred to in Article 14.9.12.);

   ~~b~~c) hides and skins;

   ~~c~~d) gelatine;

   ~~d~~e) collagen prepared from hides or skins;

   ~~e~~f) tallow (maximum level of insoluble impurities of 0.15% in weight) and derivatives made from this tallow;

   ~~f~~g) dicalcium phosphate (with no trace of protein or fat);

   ~~g~~h) wool or fibre.

2. When authorising import or transit of other *commodities* listed in this chapter, *Veterinary Authorities* should require the conditions prescribed in this chapter relevant to the scrapie risk status of the sheep and goat populations of the *exporting country*, *zone* or *compartment*.

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

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Article 14.9.2.

Determination of the scrapie status of a country, zone, compartment or establishment

The scrapie status of the sheep and goat populations of a country, *zone*, *compartment* or *establishment* should be determined on the basis of the following criteria:

1. the outcome of a *risk assessment* identifying all potential factors for scrapie occurrence and their historic perspective, in particular the:

    a) importation or introduction of sheep and goats or their ~~semen or~~ their embryos/oocytes potentially infected with scrapie;

    b) extent of knowledge of the population structure and husbandry practices of sheep and goats;

    c) feeding practices, including consumption of *meat-and-bone meal* or *greaves* derived from ruminants;

    d) importation of *milk* and *milk products* of sheep or goats origin intended for use in feeding of sheep and goats;

2. an on-going awareness programme for *veterinarians*, farmers, and workers involved in transportation, marketing and *slaughter* of sheep and goats to facilitate recognition and encourage reporting of all animals with clinical signs compatible with scrapie;

3. a *surveillance* and monitoring system including the following:

    a) official veterinary *surveillance*, reporting and regulatory control in accordance with the provisions of Chapter 1.4.;

    b) a *Veterinary Authority* with current knowledge of, and authority over, all *establishments* which contain sheep and goats in the whole country;

    c) compulsory notification and clinical investigation of sheep and goats showing clinical signs compatible with scrapie;

    d) examination, in accordance with the *Terrestrial Manual*, in a *laboratory* of appropriate material from sheep and goats older than 18 months displaying clinical signs compatible with scrapie;

    e) maintenance of records including the number and results of all investigations for at least 7 years.

Article 14.9.3.

Scrapie free country or zone

Countries or *zones* may be considered free from scrapie if within the said territory:

1. a *risk assessment*, as described in point 1 of Article 14.9.2., has been conducted, and it has been demonstrated that appropriate measures are currently in place and have been taken for the relevant period of time to manage any *risk* identified and points 2 and 3 have been complied with for the preceding 7 years;

AND

2. one of the following conditions should be met:

   a) the country or the *zone* have demonstrated historical freedom taking into account the recommendations in Articles 14.9.14. and 14.9.15. ~~(under study)~~; or

   b) for at least 7 years, a sufficient number of representative mature ~~culled~~ sheep and goats over 18 months of age culled and/or dead on farm have been tested annually, to provide a 95% level of confidence of detecting scrapie if it is present at a prevalence rate exceeding 0.1% out of the total number of all chronic wasting conditions in the population of sheep and goats older than 18 months of age and no *case* of scrapie has been reported during this period; it is assumed that the occurrence rate of chronic wasting conditions within the population of sheep and goats older than 18 months of age is at least 1% ~~(under study)~~; or

   c) all *establishments* containing sheep or goats have been accredited free as described in Article 14.9.5.;

AND

3. the feeding to sheep and goats of *meat-and-bone meal* or *greaves* of ruminant origin has been banned and effectively enforced in the whole country for at least 7 years;

AND

4. introductions of sheep and goats or their ~~semen or~~ their embryos/oocytes from countries or *zones* not free from scrapie are carried out in accordance with Articles 14.9.6., 14.9.7.~~, 14.9.8.~~ or 14.9.9., as relevant.

Article 14.9.4.

Scrapie free compartment

A *compartment* may be considered free from scrapie if the following conditions are fulfilled:

1. all *establishments* within the *compartment* are free from scrapie according to Article 14.9.5.;

2. all *establishments* within the *compartment* are managed under a common *biosecurity plan* protecting them from introduction of scrapie, and the *compartment* has been approved by the *Veterinary Authority* in accordance with Chapters 4.3. and 4.4.;

3. introductions of sheep and goats are allowed only from accredited free *establishments*;

4. introductions of sheep and goat embryos are allowed either from accredited free *establishments* or in accordance with Article 14.9.9.;

5. sheep and goat semen introduced into the *compartment* should have been collected, processed and stored in conformity with the provisions of Chapters 4.5. and 4.6.;

6. sheep and goats in the *compartment* should have no direct or indirect contact, including shared grazing, with sheep or goats from *establishments* not within the *compartment*.

~~One or more *establishments* may be considered eligible for accreditation as a scrapie free *compartment* if:~~

Annex XXXI (contd)

1. in the country or *zone* where the *establishments* are situated, the following conditions are fulfilled:

   a. the *disease* is compulsorily notifiable;

   b. an awareness, *surveillance* and monitoring system as referred to in Article 14.9.2. is in place;

   c. affected sheep and goats are slaughtered and completely destroyed;

   d. the feeding to sheep and goats of *meat-and-bone meal* or *greaves* of ruminant origin has been banned and effectively enforced in the whole country;

   e. an official accreditation scheme is in operation under the supervision of the *Veterinary Authority*, including the measures described in point 2 below;

2. in the *establishments* the following conditions have been complied with for at least 7 years:

   a. sheep and goats are permanently identified and records maintained, to enable trace back to their *establishment* of birth;

   b. records of movements of sheep and goats in and out of the *establishment* are maintained;

   c. introductions of sheep and goats are allowed only from free *establishments* of an equal or higher stage in the process of accreditation; however, rams and bucks complying with the provisions in point 1 of Article 14.9.8. may also be introduced;

   d. an *Official Veterinarian* inspects sheep and goats in the *establishments* and audits the records at least once a year;

   e. no *case* of scrapie has been reported;

   f. sheep and goats of the *establishments* should have no direct or indirect contact, including shared grazing, with sheep or goats from *establishments* of a lower status;

   g. all culled sheep and goats over 18 months of age are inspected by an *Official Veterinarian*, and a proportion of those exhibiting wasting signs and all those exhibiting neurological signs are tested in a *laboratory* for scrapie. The selection of the sheep and goats to be tested should be made by the *Official Veterinarian*. Sheep and goats over 18 months of age that have died or have been killed for reasons other than routine *slaughter* should also be tested (including 'fallen' stock and those sent for emergency *slaughter*).

3. cattle, water buffalo and wood bison in a *compartment* free from bovine tuberculosis are protected from contact with wildlife reservoirs of bovine tuberculosis and are managed under a common biosecurity plan protecting them from contamination with *M. bovis*, and the *compartment* has been approved by the *Veterinary Authority* in accordance with Chapters 4.3. and 4.4.

Article 14.9.5.

Scrapie free establishment

An *establishment* may be considered eligible for accreditation as a scrapie free *establishment* if:

1. in the country or *zone* where the *establishment* is situated, the following conditions are fulfilled:

   a) the *disease* is compulsorily notifiable;

b) an awareness, *surveillance* and monitoring system as referred to in Article 14.9.2. is in place;

c) affected sheep and goats are slaughtered and completely destroyed;

d) the feeding to sheep and goats of *meat-and-bone meal* or *greaves* of ruminant origin has been banned and effectively enforced in the whole country;

e) an official accreditation scheme is in operation under the supervision of the *Veterinary Authority*, including the measures described in point 2 below;

2. in the *establishment* the following conditions have been complied with for at least 7 years:

a) sheep and goats are permanently identified and records maintained, to enable trace back to their *establishment* of birth;

b) records of movements of sheep and goats in and out of the *establishment* are maintained;

c) introductions of sheep and goats are allowed only from free *establishments*;

d) introduction of sheep and goat embryos should comply with Article 14.9.9.;

e) sheep and goat semen introduced into the *establishment* should have been collected, processed and stored in conformity with the provisions of Chapters 4.5. and 4.6.;

~~d~~f) an *Official Veterinarian* inspects sheep and goats in the *establishments* and audits the records at least once a year;

~~e~~g) no *case* of scrapie has been reported;

~~f~~h) sheep and goats of the *establishments* should have no direct or indirect contact, including shared grazing, with sheep or goats from *establishments* of a lower status;

~~g~~i) all culled sheep and goats over 18 months of age are inspected by an *Official Veterinarian*, and a proportion of those exhibiting wasting signs and all those exhibiting neurological signs are tested in a *laboratory* for scrapie. The selection of the sheep and goats to be tested should be made by the *Official Veterinarian*. Sheep and goats over 18 months of age that have died or have been killed for reasons other than routine *slaughter* should also be tested (including 'fallen' stock and those sent for emergency *slaughter*).

Article 14.9.6.

Recommendations for importation from countries or zones not considered free from scrapie

for sheep and goats for breeding or rearing

Veterinary Authorities should require the presentation of an *international veterinary certificate* attesting that the animals come from an *establishment* free from scrapie as described in Article 14.9.5.

~~OR~~

~~In cases where the animals do not come from an *establishment* free from scrapie as described in Article 14.9.5., the *importing country* may require the placing of the animals in a *quarantine station* located on its territory, in conformity with the conditions stipulated in its animal health legislation.~~

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Article 14.9.7.

Recommendations for importation from countries or zones not considered free from scrapie

for sheep and goats for slaughter

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

1. in the country or *zone*:
    a) the *disease* is compulsorily notifiable;
    b) an awareness, *surveillance* and monitoring system as referred to in Article 14.9.2. is in place;
    c) affected sheep and goats are slaughtered and completely destroyed;
2. the sheep and goats selected for export showed no clinical sign of scrapie on the day of shipment.

~~Article 14.9.8.~~

~~**Recommendations for importation from countries or zones not considered free from scrapie**~~

~~for semen of sheep and goats~~

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

~~1. the donor animals:~~
    ~~a) are permanently identified to enable trace back to their *establishment* of origin;~~
    ~~b) have been kept since birth in *establishments* in which no *case* of scrapie had been confirmed during their residency;~~
    ~~c) showed no clinical sign of scrapie at the time of semen collection;~~
~~2. the semen was collected, processed and stored in conformity with the provisions of Chapter 4.5. and Chapter 4.6.~~

Article 14.9.9.

Recommendations for importation from countries or zones not considered free from scrapie

for embryos/oocytes of sheep and goats

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

1. in the country or *zone*:
    a) the *disease* is compulsorily notifiable;
    b) an awareness, *surveillance* and monitoring system as referred to in Article 14.9.2. is in place;

c) affected sheep and goats are slaughtered and completely destroyed;

d) the feeding to sheep and goats of *meat-and-bone meal* or *greaves* of ruminant origin has been banned and effectively enforced in the whole country;

2. the donor animals either have been kept since birth in a free *establishment*, or meet the following conditions:

a) are permanently identified to enable trace back to their *establishment* of origin;

b) have been kept since birth in *establishments* in which no *case* of scrapie had been confirmed during their residency;

c) showed no clinical sign of scrapie at the time of embryo/oocyte collection;

3. the embryos/oocytes were collected, processed and stored in conformity with the provisions of Chapter 4.7.

Article 14.9.10.

Recommendations for importation from countries or zones not considered free from scrapie

for milk and milk products of sheep or goat origin intended for use in feeding of sheep and goats

Veterinary Authorities should require the presentation of an *international veterinary certificate* attesting that the *milk* and *milk products* come from scrapie free *establishments*.

Article 14.9.11.

Recommendations on meat-and-bone meal

Meat-and-bone meal containing any sheep or goat protein, or any feedstuffs containing that type of *meat-and-bone meal*, which originate from countries not considered free of scrapie should not be traded between countries for ruminant feeding.

Article 14.9.12.

Recommendations for importation from countries or zones not considered free from scrapie

for skulls including brains, ganglia and eyes, vertebral column including ganglia and spinal cord, tonsils, thymus, spleen, intestine, adrenal gland, pancreas, or liver, and protein products derived therefrom, from sheep and goats

1. these *commodities* should not be traded for use in ruminant feeds;

2. for purposes other than ruminant feeding, *Veterinary Authorities* should require the presentation of an *international veterinary certificate* attesting that:

~~1~~a) in the country or *zone*:

~~A~~i) the *disease* is compulsorily notifiable;

Annex XXXI (contd)

~~B~~ii) an awareness, *surveillance* and monitoring system as referred to in Article 14.9.2. is in place;

~~c~~iii) affected sheep and goats are slaughtered and completely destroyed;

~~2~~b) the materials come from sheep and goats that showed no clinical sign of scrapie on the day of *slaughter*.

Article 14.9.13.

Recommendations for the importation of ovine and caprine materials destined for the preparation of biologicals

Veterinary Authorities of *importing countries* should require the presentation of an *international veterinary certificate* attesting that the products originate from sheep and goats born and raised in a scrapie free country, *zone* or *establishment*.

Article 14.9.14.

Principles for declaring a country or zone historically free from scrapie

Articles 14.9.14. and 14.9.15. outline principles for declaring a country or *zone* free from scrapie.

An essential prerequisite to provide the guarantees required for the recognition of freedom from *disease/infection* is that the *Veterinary Services* of the Member comply with the provisions of Chapter 3.1. on evaluation of *Veterinary Services*, and, if relevant, with the provisions of Chapter 4.3. on zoning and compartmentalisation.

The provisions of the above-mentioned articles are based on the principles developed in Chapter 1.4. and the following premises:

~~1. the sheep population of the country or *zone* includes a range of genotypes known to be susceptible to scrapie;~~

~~2~~1. the *Veterinary Services* have the competence, capacity and mandate to investigate, diagnose and report scrapie, if present;

~~3~~2. the absence of scrapie over a long period of time can be substantiated by effective *disease* investigation and reporting by the *Veterinary Services* of an OIE Member.

Article 14.9.15.

Requirements to declare a country or zone historically free from scrapie

A country or *zone* may be recognised free from scrapie without having applied the requirements of Article 14.9.3. when:

1. scrapie has been notifiable for at least 25 years; and

2. a formal programme of targeted *surveillance* and monitoring, which includes clinical suspects, animals dead on farm and aged sheep and goats, can be documented as having been in place for at least 10 years; and

~~3. the presence of a range of scrapie susceptible genotypes in this sheep population can be documented; and~~

~~4~~3. appropriate measures to prevent scrapie introduction can be documented as having been in place for at least 25 years; and

a) either scrapie has never been reported; or

b) no *case* of scrapie has been reported for at least 25 years.

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Annex XXXII

CHAPTER 15.3.

CLASSICAL SWINE FEVER

Article 15.3.1.

General provisions

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

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

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

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

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

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

Article 15.3.2.

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

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

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

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

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

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

5. for domestic pigs, appropriate *surveillance*, capable of detecting the presence of *infection* even in the absence of clinical signs, and the risk posed by wild pigs, is in place; this may be achieved through a *surveillance* programme in accordance with Articles 15.3.23. to 15.3.28.

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

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

Article 15.3.3.

CSF free country, zone or compartment

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

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

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

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

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

Article 15.3.4.

Recovery of free status

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

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

OR

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

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

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

OR

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

Article 15.3.5.

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

for domestic pigs

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

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

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

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

Article 15.3.6.

Recommendations for importation from CSF infected countries or zones

for domestic pigs

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

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

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

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

Article 15.3.7.

Recommendations for the importation of wild pigs

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

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

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

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

Article 15.3.8.

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

for semen of domestic pigs

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

Annex XXXII (contd)

1. the donor animals:

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

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

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

Article 15.3.9.

Recommendations for importation from CSF infected countries or zones

for semen of domestic pigs

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

1. the donor animals:

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

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

    c) met one of the following conditions:

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

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

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

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

Article 15.3.10.

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

for *in vivo* derived embryos of domestic pigs

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

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

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

Article 15.3.11.

Recommendations for importation from CSF infected countries or zones

for *in vivo* derived embryos of domestic pigs

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

1. the donor females:

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

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

    c) and either:

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

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

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

Article 15.3.12.

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

for fresh meat of domestic pigs

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

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

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

Article 15.3.13.

Recommendations for the importation of fresh meat of wild pigs

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

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

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

Article 15.3.14.

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

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

1. have been prepared:

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

    b) in a processing establishment:

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

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

OR

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

Article 15.3.15.

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

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

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

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

Article 15.3.16.

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

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

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

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

Article 15.3.17.

Recommendations for the importation of bristles

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

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

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

Article 15.3.18.

Recommendations for the importation of litter and manure

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

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

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

Article 15.3.19.

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

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

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

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

Annex XXXII (contd)

Article 15.3.20.

Procedures for the inactivation of the CSF virus in swill

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

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

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

Article 15.3.21.

Procedures for the inactivation of the CSF virus in meat

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

1. Heat treatment

   Meat shall be subjected to one of the following treatments:

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

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

2. Natural fermentation and maturation

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

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

   b) a pH value of not more than 6.0.

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

3. Dry cured pork meat

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

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

Article 15.3.22.

Procedures for the inactivation of the CSF virus in trophies

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

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

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

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

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

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

Article 15.3.23.

Surveillance: introduction

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

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

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

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

Annex XXXII (contd)

Article 15.3.24.

Surveillance: general conditions and methods

1. A *surveillance* system in accordance with Chapter 1.4. should be under the responsibility of the *Veterinary Authority*. A procedure should be in place for the rapid collection and transport of samples to an accredited *laboratory* as described in the *Terrestrial Manual.*

2. The CSF *surveillance* programme should:

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

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

   An effective *surveillance* system will periodically identify suspicious *cases* that require follow-up and investigation to confirm or exclude that the cause of the condition is CSFV. The rate at which such suspicious *cases* are likely to occur will differ between epidemiological situations and cannot, therefore, be reliably predicted. Recognitions for freedom from CSFV infection should, as a consequence, provide details of the occurrence of suspicious *cases* and how they were investigated and dealt with. This should include the results of *laboratory* testing and the control measures to which the animals concerned were subjected during the investigation (quarantine, movement standstill orders, etc.).

Article 15.3.25.

Surveillance strategies

1. Introduction

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

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

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

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

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

For random surveys, the design of the sampling strategy will need to incorporate epidemiologically appropriate design prevalence. The sample size selected for testing will need to be large enough to detect *infection* if it were to occur at a predetermined minimum rate. The sample size and expected *disease* prevalence determine the level of confidence in the results of the survey. The Member must justify the choice of design prevalence and confidence level based on the objectives of *surveillance* and the epidemiological situation, in accordance with Chapter 1.4. Selection of the design prevalence in particular clearly needs to be based on the prevailing or historical epidemiological situation.

Irrespective of the survey design selected, the sensitivity and specificity of the diagnostic tests employed are factors in the design, sample size determination and interpretation of the results obtained. Ideally, the sensitivity and specificity of the tests used should be validated for the vaccination/*infection* history and production class of animals in the target population.

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

2. Clinical and virological surveillance

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

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

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

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

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

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

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

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

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

3. Serological surveillance

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

a) natural *infection* with CSFV;

b) legal or illegal vaccination against CSF;

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

d) cross-reactions with other pestiviruses;

e) non-specific reactors.

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

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

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

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

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

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

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

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

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

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

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

Article 15.3.26.

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

1. Country or zone free of CSF

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

2. Compartment free of CSF

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

a) proper containment of domestic pigs;

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

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

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

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

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

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

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

h) *herd* registration;

i) official accreditation of *biosecurity plans*;

j) periodic monitoring and review.

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

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

Article 15.3.27.

Recovery of free status: additional surveillance procedures

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

Populations under this *surveillance* programme should include:

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

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

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

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

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

Article 15.3.28.

Surveillance for CSF in wild pigs

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

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

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

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

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

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

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

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

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

a) areas with past history of CSF;

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

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

d) interface between wild and domestic pig populations;

e) picnic and camping areas;

f) farms with free-ranging pigs;

g) garbage dumps;

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

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Annex XXXIII

CHAPTER 11.4.

BOVINE CYSTICERCOSIS

Article 11.4.1.

General provisions

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

Article 11.4.2.

Recommendations for the importation of fresh meat of cattle

Veterinary Authorities of *importing countries* should require the presentation of an *international veterinary certificate* attesting that the entire consignment of *meat* comes from animals which have been subjected to ante-mortem and post-mortem inspections as described in Chapter 6.2.

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~~CHAPTER 11.10.~~

~~DERMATOPHILOSIS~~

~~Article 11.10.1.~~

~~General provisions~~

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

~~Article 11.10.2.~~

~~Recommendations for importation from countries considered infected with dermatophilosis~~

~~for ruminants and equines~~

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

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

~~2. were treated with acaricides prior to shipment and were completely free of ticks.~~

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CHAPTER 12.4.

EPIZOOTIC LYMPHANGITIS

Article 12.4.1.

General provisions

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

Article 12.4.2.

Recommendations for the importation of domestic horses

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

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

2. were kept in *establishments* in which no *case* of epizootic lymphangitis was officially reported during the 2 months prior to shipment.

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~~CHAPTER 12.12.~~

~~HORSE MANGE~~

~~Article 12.12.1.~~

~~General provisions~~

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

~~Article 12.12.2.~~

~~Recommendations for the importation of equines~~

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

~~1. showed no clinical sign of horse mange on the day of shipment;~~

~~2. were kept for the 3 months prior to shipment in an *establishment* where no *case* of horse mange was officially reported during that period.~~

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~~CHAPTER 12.13.~~

~~HORSE POX~~

~~Article 12.13.1.~~

~~Recommendations for the importation of equines~~

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

~~1. showed no clinical sign of horse pox on the day of shipment;~~

~~2. were kept for the 3 months prior to shipment in an *establishment* where no *case* of horse pox was officially reported during that period.~~

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CHAPTER 15.2.

ATROPHIC RHINITIS OF SWINE

Article 15.2.1.

General provisions

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

Article 15.2.2.

Recommendations for the importation of pigs for breeding or rearing

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

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

2. were kept in the *exporting country*, since birth or for the 6 months prior to shipment, in an *establishment* where no *case* of atrophic rhinitis was officially reported during the past year.

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CHAPTER 15.6.

TESCHOVIRUS ENCEPHALOMYELITIS
(previously enterovirus encephalomyelitis, Teschen disease, Talfan disease)

Article 15.6.1.

General provisions

For the purposes of the *Terrestrial Code*, the *incubation period* for Teschovirus encephalomyelitis shall be 40 days.

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

Article 15.6.2.

Teschovirus encephalomyelitis free country

A country may be considered free from Teschovirus encephalomyelitis when it has been shown that Teschovirus encephalomyelitis has not been present for at least the past 3 years.

This period shall be 6 months after the *slaughter* of the last affected animal for countries in which a *stamping-out policy* is practised with or without vaccination against Teschovirus encephalomyelitis.

Article 15.6.3.

Teschovirus encephalomyelitis infected zone

A zone shall be considered as infected with Teschovirus encephalomyelitis until:

1. at least 40 days have elapsed after the confirmation of the last *case* and the completion of a *stamping-out policy* and *disinfection* procedures, or

2. 6 months have elapsed after the clinical recovery or death of the last affected animal if a *stamping-out policy* was not practised.

Article 15.6.4.

Recommendations for importation from Teschovirus encephalomyelitis free countries

for domestic pigs

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

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

2. were kept in a country free from Teschovirus encephalomyelitis since birth or for at least the past 40 days.

Annex XXXIII (contd)

~~Article 15.6.5.~~

~~**Recommendations for importation from Teschovirus encephalomyelitis free countries**~~

~~for wild pigs~~

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

~~1. showed no clinical sign of Teschovirus encephalomyelitis on the day of shipment;~~

~~2. come from a country free from Teschovirus encephalomyelitis;~~

~~if the country of origin has a common border with a country considered infected with Teschovirus encephalomyelitis:~~

~~3. were kept in a *quarantine station* for the 40 days prior to shipment.~~

~~Article 15.6.6.~~

~~**Recommendations for importation from countries considered infected with Teschovirus encephalomyelitis**~~

~~for domestic pigs~~

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

~~1. showed no clinical sign of Teschovirus encephalomyelitis on the day of shipment;~~

~~2. were kept since birth, or for the past 40 days, in an *establishment* where no *case* of Teschovirus encephalomyelitis was officially reported during that period, and that the *establishment* of origin was not situated in an Teschovirus encephalomyelitis *infected zone*; or~~

~~3. were kept in a *quarantine station* for the 40 days prior to shipment;~~

~~4. have not been vaccinated against Teschovirus encephalomyelitis; or~~

~~5. were vaccinated against Teschovirus encephalomyelitis, not less than 30 days and not more than one year prior to shipment (the nature of the vaccine used, whether inactivated or modified live virus, and the virus types and strains included shall also be stated in the certificate).~~

~~Article 15.6.7.~~

~~**Recommendations for importation from countries considered infected with Teschovirus encephalomyelitis**~~

~~for wild pigs~~

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

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

2. were kept in a *quarantine station* for the 40 days prior to shipment;

3. have not been vaccinated against Teschovirus encephalomyelitis; or

4. were vaccinated against Teschovirus encephalomyelitis, not less than 30 days and not more than one year prior to shipment (the nature of the vaccine used, whether inactivated or modified live virus, and the virus types and strains included shall also be stated in the certificate).

Article 15.6.8.

Recommendations for importation from Teschovirus encephalomyelitis free countries

for semen of pigs

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

1. showed no clinical sign of Teschovirus encephalomyelitis on the day of collection of the semen;

2. were kept in a country free from Teschovirus encephalomyelitis for not less than 40 days prior to collection.

Article 15.6.9.

Recommendations for importation from countries considered infected with Teschovirus encephalomyelitis

for semen of pigs

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

1. showed no clinical sign of Teschovirus encephalomyelitis on the day of collection of the semen;

2. were kept in the *exporting country*, for the 40 days prior to collection, in an *establishment* or *artificial insemination centre* where no *case* of Teschovirus encephalomyelitis was officially reported during that period, and that the *establishment* or *artificial insemination centre* was not situated in an Teschovirus encephalomyelitis *infected zone.*

Article 15.6.10.

Recommendations for importation from Teschovirus encephalomyelitis free countries

for fresh meat of pigs

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

1. which have been kept in a country free from Teschovirus encephalomyelitis since birth or for at least the past 40 days;

2. which have been slaughtered in an approved *abattoir* and have been subjected to ante-mortem and post-mortem inspections for Teschovirus encephalomyelitis with favourable results.

Annex XXXIII (contd)

~~Article 15.6.11.~~

~~Recommendations for importation from countries considered infected with Teschovirus encephalomyelitis~~

~~for fresh meat of pigs~~

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

1. ~~which have not been kept in an Teschovirus encephalomyelitis *infected zone*;~~

2. ~~which have been slaughtered in an approved *abattoir* not situated in an Teschovirus encephalomyelitis *infected zone* and have been subjected to ante-mortem and post-mortem inspections for Teschovirus encephalomyelitis with favourable results.~~

~~Article 15.6.12.~~

~~Recommendations for importation from countries considered infected with Teschovirus encephalomyelitis~~

~~for meat products of pigs~~

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

1. ~~the entire consignment of *meat products* comes from animals which have been slaughtered in an approved *abattoir* and have been subjected to ante-mortem and post-mortem inspections for Teschovirus encephalomyelitis with favourable results;~~

2. ~~the *meat products* have been processed to ensure the destruction of the Teschovirus encephalomyelitis virus;~~

3. ~~the necessary precautions were taken after processing to avoid contact of the meat with any source of Teschovirus encephalomyelitis virus.~~

~~Article 15.6.13.~~

~~Recommendations for importation from Teschovirus encephalomyelitis free countries~~

~~for products of animal origin (from pigs) intended for use in animal feeding or for agricultural or industrial use~~

~~*Veterinary Authorities* should require the presentation of an *international veterinary certificate* attesting that these products come from animals which have been kept in a country free from Teschovirus encephalomyelitis since birth or for at least the past 40 days.~~

~~Article 15.6.14.~~

~~Recommendations for importation from countries considered infected with Teschovirus encephalomyelitis~~

~~for meal and flour from blood, meat, defatted bones, hooves and claws (from pigs)~~

~~*Veterinary Authorities* should require the presentation of an *international veterinary certificate* attesting that these products have been processed using heat treatment to ensure the destruction of Teschovirus encephalomyelitis virus.~~

~~Article 15.6.15.~~

~~Recommendations for importation from countries considered infected with Teschovirus encephalomyelitis~~

~~for bristles~~

~~*Veterinary Authorities* should require the presentation of an *international veterinary certificate* attesting that these products have been processed to ensure the destruction of Teschovirus encephalomyelitis virus, in premises controlled and approved by the *Veterinary Authority* of the *exporting country*.~~

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Annex XXXIV

CHAPTER 8.2.

AUJESZKY'S DISEASE

Article 8.2.1.

General provisions

The Aujeszky's disease (AD) free or provisionally free status of a country or *zone* can only be determined if the following conditions are fulfilled:

1. a *risk assessment* has been conducted identifying all potential factors for AD occurrence and their historic perspective;

2. AD is notifiable in the whole country, and all clinical cases suggestive of AD are subjected to field and laboratory investigations;

3. an on-going awareness programme is in place to encourage reporting of all cases suggestive of AD in susceptible species;

4. the *Veterinary Authority* has current knowledge of, and authority over, all *establishments* containing pigs in the whole country;

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

An AD infected *establishment* means an *establishment* in which the virus has been isolated or identified, or a positive serological result (total or gE antibodies) has been confirmed in a *laboratory*.

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

When authorising import or transit of other *commodities* listed in this chapter, *Veterinary Authorities* should require the conditions prescribed in this chapter relevant to the AD status of the *exporting country* or *zone*.

Article 8.2.1.bis

Safe commodities

When authorising import or transit of the following *commodities* and any products made from these, *Veterinary Authorities* should not require any AD related conditions, regardless of the AD status of the *exporting country* or *zone*:

1. *fresh meat* of domestic and wild pigs not containing offal (head, and thoracic and abdominal viscera);

2. *meat products* of domestic and wild pigs not containing offal (head, and thoracic and abdominal viscera);

3. products of animal origin not containing offal (head, and thoracic and abdominal viscera).

Annex XXXIV (contd)

Article 8.2.2.

AD free country or zone

1. Qualification

A country or *zone* may be considered free from the *disease* without formally applying a specific *surveillance* programme (historical freedom) if the *disease* has not been reported for at least 25 years, and if for at least the past 10 years:

a) it has been a *notifiable disease*;

b) an early detection system has been in place;

c) measures to prevent the introduction of the AD virus into the country or *zone* have been in place;

d) no vaccination against the *disease* has been carried out;

e) *infection* is not known to be established in wild swine, or measures have been implemented to prevent any transmission of the AD virus from wild swine to domestic pigs.

A country or *zone* which does not meet the conditions of the above paragraph may be considered free from AD when:

f) animal health regulations to control the movement of *commodities* listed in Article 8.2.6. in order to prevent the introduction of *infection* into the *establishments* of the country or *zone* have been in place for at least 2 years;

g) vaccination against AD has been banned for all domestic pigs in the country or *zone* for at least 2 years;

h) if AD has never been reported in the country or *zone*, serological surveys, with negative results, have been conducted on a representative sample of all pig *establishments* in conformity with the recommendations in Chapter X.X. (under study) no more than 3 years prior to qualification; the serological surveys should be directed at the detection of antibodies to the whole virus, and based on the breeding pig population or, for *establishments* that contain no breeding pigs, on a comparable number of fattening pigs; or

i) if AD has been reported in the country or *zone*, a *surveillance* and control programme has been in place to detect every infected *establishment* and eradicate AD from it; the *surveillance* programme should be carried out in conformity with the recommendations in Chapter X.X. (under study) and demonstrate that no *establishments* within the country or *zone* have had any clinical, virological or serological evidence of AD for at least 2 years.

In order for a country to reach free status, all of its *zones* must have reached AD free status.

In countries or *zones* with wild swine, measures should be implemented to prevent any transmission of the AD virus from wild swine to domestic pigs.

2. Maintenance of free status

In order to maintain its free status, a country or *zone* should comply with the following requirements:

a) periodic serological surveys directed at the detection of antibodies to the whole AD virus should be carried out on a statistically significant number of breeding pigs, in conformity with the recommendations in Chapter X.X. (under study);

b) the importation of the *commodities* listed in Article 8.2.6. into the country or *zone* is carried out in conformity with the import conditions contained in the relevant Articles of the present chapter;

c) the ban on AD vaccination remains in force;

d) measures aimed at preventing the transmission of the AD virus from wild swine to domestic pigs remain in force.

3. Recovery of free status

Should an AD *outbreak* occur in an *establishment* of a free country or zone, the status of the country or *zone* may be restored if either:

a) all the pigs in the *outbreak* have been slaughtered; and, during and after the application of this measure, an epidemiological investigation including clinical examination, and serological and/or virological testing has been carried out in all pig *establishments* which have been directly or indirectly in contact with the infected *establishment* and in all pig *establishments* located within a 5-kilometre radius of the *outbreak*, demonstrating that these *establishments* are not infected; or

b) vaccination with gE- deleted vaccines has been applied and:

i) a serological testing procedure (differential ELISA) has been implemented in the *establishments* where vaccination has been applied to demonstrate the absence of *infection*;

ii) the movement of pigs from these *establishments* has been banned, except for immediate *slaughter*, until the above procedure has demonstrated the absence of *infection*;

iii) all vaccinated animals have been slaughtered;

iv) during and after the application of the measures described in points i) to iii) above, a thorough epidemiological investigation including clinical examination and serological and/or virological testing has been carried out in all pig *establishments* which have been directly or indirectly in contact with the infected *establishment* and in all pig *establishments* located within a 5-kilometre radius of the *outbreak*, demonstrating that these *establishments* are not infected.

Article 8.2.3.

AD provisionally free country or zone

1. Qualification

A country or *zone* may be considered as provisionally free from AD if the following conditions are complied with:

a) animal health regulations to control the movement of *commodities* listed in Article 8.2.6. in order to prevent the introduction of *infection* into the *establishments* of the country or *zone* have been in place for at least 2 years;

b) if AD has never been reported in the country or *zone*, a serological survey, with negative results, has been conducted on a representative sample of all pig *establishments* in conformity with the recommendations in Chapter X.X. (under study) (at a level of confidence not sufficient to meet requirements for freedom); the serological survey should be directed at the detection of antibodies to the whole virus, and based on the breeding pig population or, for *establishments* that contain no breeding pigs, on a comparable number of fattening pigs; or

c) if AD has been reported in the country or *zone*, a *surveillance* and control programme has been in place to detect infected *establishments* and eradicate AD from these *establishments*, the *herd* prevalence rate in the country or *zone* has not exceeded 1% for at least 3 years (the sampling procedure described in point 1e) of the definition of 'AD free establishment' should be applied within the *establishments* of the country or *zone*), and at least 90% of the *establishments* in the country or *zone* are qualified free;

d) in countries or *zones* with wild swine, measures should be taken to prevent any transmission of the AD virus between wild swine and domestic pigs.

2. Maintenance of provisionally free status

In order to maintain its provisionally free status, a country or *zone* should comply with the following requirements:

a) the measures described in points 1b) and 1d) above should be continued;

b) the percentage of infected *establishments* remains $\leq$1%;

c) the importation of the *commodities* listed in Article 8.2.6. into the country or *zone* is carried out in conformity with the import conditions contained in the relevant Articles of the present chapter.

3. Recovery of provisionally free status

Should the percentage of infected *establishments* exceed 1% in a provisionally free country or zone, the status of the country or *zone* is cancelled and may be restored only once the percentage of infected *establishments* has remained $\leq$1% for at least 6 months, and this result is confirmed by a serological survey conducted in conformity with point 1c) above.

Article 8.2.4.

AD infected country or zone

Countries and *zones* which do not fulfil the conditions to be considered free or provisionally free of AD should be considered as infected.

Article 8.2.5.

AD free establishment

1. Qualification

To qualify as free from AD, an *establishment* should satisfy the following conditions:

a) it is under the control of the *Veterinary Authority*;

b) no clinical, virological or serological evidence of AD has been found for at least one year;

c) the introduction of pigs, semen and embryos/ova into the *establishment* is carried out in conformity with the import conditions for these *commodities* contained in the relevant articles of the present chapter;

d) vaccination against AD has not been carried out in the *establishment* for at least 12 months, and any previously vaccinated pigs are free from gE antibodies;

e) a number of breeding pigs from the *establishment* has been subjected, with negative results, to serological tests to the whole AD virus, applying a sampling procedure set out in conformity with the recommendations in Chapter X.X. (under study); these tests must have been carried out on two occasions, at an interval of 2 months; for *establishments* that contain no breeding pigs, the tests should be carried out only once on a comparable number of fattening or weaning pigs;

f) a *surveillance* and control programme has been in place to detect infected *establishments* located within a 5-kilometre radius of the *establishment* and no *establishment* is known to be infected within this *zone*.

2. Maintenance of free status

For *establishments* located in an infected country or *infected zone*, the testing procedure described in point 1e) above should be carried out every 4 months.

For *establishments* located in a provisionally free country or zone, the testing procedure described in point 1e) above should be carried out every year.

3. Recovery of free status

Should a free *establishment* become infected, or should an *outbreak* occur within a 5-kilometre radius of a free *establishment*, the free status of the *establishment* should be suspended until the following conditions are met:

a) in the infected *establishment*:

i) all the pigs in the *establishment* have been slaughtered, or

ii) at least 30 days after removal of all infected animals, all breeding animals have been subjected to a serological test to the whole AD virus, with negative results, on two occasions, at an interval of 2 months;

b) in other *establishments* located in the 5-kilometre radius *zone*: a number of breeding pigs from each *establishment* has been subjected, with negative results, to serological tests to the whole AD virus (non vaccinated *establishments*) or to gE antibodies (vaccinated *establishments*), applying the sampling procedure described in point 1e above.

~~Article 8.2.6.~~

~~**Trade in commodities**~~

~~*Commodities* other than those listed below are not considered to have the potential to spread AD when they are the subject of *international trade*.~~

~~*Veterinary Authorities* of countries shall consider whether there is a risk with regard to AD in accepting importation or transit through their territory, from other countries, of the following *commodities*:~~

Annex XXXIV (contd)

~~1. domestic and wild swine;~~

~~2. semen of domestic and wild swine;~~

~~3. embryos/ova of domestic and wild swine;~~

~~4. offal (head, and thoracic and abdominal viscera) of swine and products containing swine offal;~~

~~5. *pathological material* and biological products (see Chapter 5.8.).~~

Article 8.2.7.

Recommendations for importation from AD free countries or zones

for domestic pigs

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

1. showed no clinical sign of AD on the day of shipment;
2. come from an *establishment* located in an AD free country or zone;
3. have not been vaccinated against AD.

Article 8.2.8.

Recommendations for importation from AD provisionally free countries or zones

for domestic pigs for breeding or rearing

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

1. showed no clinical sign of AD on the day of shipment;
2. have been kept exclusively in AD free *establishments* since birth;
3. have not been vaccinated against AD;
4. were subjected to a serological test to the whole AD virus, with negative results, within 15 days prior to shipment.

Article 8.2.9.

Recommendations for importation from AD infected countries or zones

for domestic pigs for breeding or rearing

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

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

2. were kept exclusively in AD free *establishments* since birth;

3. have not been vaccinated against AD;

4. were isolated in the *establishment* of origin or a *quarantine station*, and were subjected to a serological test to the whole AD virus, with negative results, on two occasions, at an interval of not less than 30 days between each test, the second test being performed during the 15 days prior to shipment.

Article 8.2.10.

Recommendations for importation from AD provisionally free countries or zones or AD infected countries or zones

for domestic pigs for slaughter

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

1. a *surveillance* and control programme is in place in the country or *zone* to detect infected *establishments* and eradicate AD;

2. the animals:

   a) are not being eliminated as part of an eradication programme;

   b) showed no clinical sign of AD on the day of shipment;

   c) have been kept exclusively in AD free *establishments* since birth; or

   d) have been vaccinated against AD at least 15 days prior to shipment.

[Note: Appropriate precautions should be taken both by the exporting country *and the* importing country *to ensure that the pigs are transported directly from the* place of shipment *to the* abattoir *for immediate* slaughter.*]*

Article 8.2.11.

Recommendations for importation from AD free countries or zones

for wild swine

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

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

2. were captured in an AD free country or zone;

3. have not been vaccinated against the *disease*;

4. were isolated in a *quarantine station*, and were subjected to a serological test to the whole AD virus, with negative results, on two occasions, at an interval of not less than 30 days between each test, the second test being performed during the 15 days prior to shipment.

Annex XXXIV (contd)

Article 8.2.12.

Recommendations for importation from AD free countries or zones

for semen of pigs

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

1. the donor animals:

   a) showed no clinical sign of AD on the day of collection of the semen;

   b) were kept in an *establishment* or *artificial insemination centre* located in an AD free country or zone at the time of semen collection;

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

Article 8.2.13.

Recommendations for importation from AD provisionally free countries or zones

for semen of pigs

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

1. the donor animals:

   a) have been kept for at least 4 months prior to semen collection in an *artificial insemination centre* which has the status of AD free *establishment*, and where all boars are subjected to a serological test to the whole AD virus, with negative results, every 4 months;

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

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

Article 8.2.14.

Recommendations for importation from AD infected countries or zones

for semen of pigs

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

1. the donor animals:

   a) were kept in an AD free *establishment* for at least 6 months prior to entering the *artificial insemination centre*;

   b) have been kept for at least 4 months prior to semen collection in the *artificial insemination centre* which has the status of AD free *establishment*, and where all boars are subjected to a serological test to the whole AD virus, with negative results, every 4 months;

c) were subjected to a serological test to the whole AD virus, with negative results, within 10 days prior to or 21 days after semen collection;

d) showed no clinical sign of AD on the day of collection;

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

Article 8.2.15.

Recommendations for importation from AD free countries or zones

for *in vivo* derived embryos of pigs

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

1. the donor females:

   a) showed no clinical sign of AD on the day of collection of the embryos;

   b) were kept in an *establishment* located in an AD free country or zone prior to collection;

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

Article 8.2.16.

Recommendations for importation from AD provisionally free countries or zones

for *in vivo* derived embryos of pigs

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

1. the donor females:

   a) showed no clinical sign of AD on the day of collection of the embryos;

   b) were kept in an AD free *establishment* for at least 3 months prior to collection;

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

Article 8.2.17.

Recommendations for importation from AD infected countries or zones

for *in vivo* derived embryos of pigs

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

1. the donor females:

   a) showed no clinical sign of AD on the day of collection of the embryos;

b) were kept in an AD free *establishment* for at least 3 months prior to collection;

c) were subjected to a serological test to the whole AD virus, with negative results, within 10 days prior to collection;

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

Article 8.2.18.

Recommendations for importation from AD free countries or zones

for offal (head, and thoracic and abdominal viscera) of pigs or products containing pig offal

Veterinary Authorities should require the presentation of an *international veterinary certificate* attesting that the entire consignment of offal or products containing pig offal comes from animals which come from *establishments* located in an AD free country or zone.

Article 8.2.19.

Recommendations for importation from AD provisionally free countries or zones or from AD infected countries or zones

for offal (head, and thoracic and abdominal viscera) of pigs

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

1. which have been kept in an AD free *establishment* since birth;

2. which have not been in contact with animals from *establishments* not considered free from AD during their transport to the approved *abattoir* and therein.

Article 8.2.20.

Recommendations for importation from AD provisionally free countries or zones or from AD infected countries or zones

for products containing pig offal (head, and thoracic and abdominal viscera)

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

1. either the entire consignment of offal used to prepare the products complied with the conditions referred to in Article 8.2.19.; or

2. the products have been processed to ensure the destruction of the AD virus; and

3. the necessary precautions were taken after processing to avoid contact of the products with any source of AD virus.

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CHAPTER 8.11.

RIFT VALLEY FEVER

Article 8.11.1.

General provisions

For the purposes of the *Terrestrial Code*, the *infective period* for Rift Valley fever (RVF) shall be 30 days.

For the purposes of this chapter, ruminants include camels.

The historic distribution of RVF is the sub-Saharian African continent, Madagascar and the Arabian Peninsula.

Countries or *zones* within the historic distribution of RVF or adjacent to those that are historically infected should be subjected to *surveillance*.

Epidemics of RVF may occur in infected areas after flooding. They are separated by inter-epidemic periods that may last for several decades in arid areas and, during these periods, the prevalence of *infection* in humans, animals and mosquitoes can be difficult to detect.

In the absence of clinical *disease*, the RVF status of a country or *zone* within the historically infected regions of the world should be determined by a *surveillance* programme (carried out in accordance with Chapter 1.4.) focusing on mosquitoes and serology of susceptible mammals. The programme should concentrate on parts of the country or *zone* at high risk because of historical, geographic and climatic factors, ruminant and mosquito population distribution, and proximity to areas where epidemics have recently occurred.

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

When authorising import or transit of other *commodities* listed in this chapter, *Veterinary Authorities* should require the conditions prescribed in this chapter relevant to the RVF status of the ruminant population of the *exporting country* or *zone.*

Article 8.11.2.

~~Trade in~~ Safe commodities

When authorising import or transit of the following *commodities* and any products made from them, *Veterinary Authorities* should not require any RVF related conditions, regardless of the RVF status of the ruminant population of the *exporting country* or *zone*:

1. hides and skins;

2. wool and fiber.

~~When authorising import or transit of other *commodities* listed in this chapter, *Veterinary Authorities* should require the conditions prescribed in this chapter relevant to the RVF status of the ruminant population of the *exporting country* or *zone.*~~

Annex XXXIV (contd)

Article 8.11.3.

RVF infection free country or zone

A country or a *zone* may be considered free from RVF infection when the *disease* is notifiable in animals throughout the country and either:

1. the country or *zone* lies outside the historically infected regions, and not adjacent to historically infections; or

2. a *surveillance* programme as described in Article 8.11.1. has demonstrated no evidence of RVF infection in humans, animals or mosquitoes in the country or *zone* during the past 4 years following a RVF epidemic.

The provisions of the last paragraph of Article 8.11.1. may need to be complied with on a continuous basis in order to maintain freedom from *infection*, depending on the geographical location of the country or *zone*.

A RVF infection free country or *zone* in which *surveillance* and monitoring has found no evidence that RVF infection is present will not lose its free status through the importation of permanently marked seropositive animals or those destined for direct *slaughter*.

Article 8.11.4.

RVF infected country or zone without disease

A RVF *disease* free country or *zone* is a country or *zone* that is not *infection* free (see Article 8.11.3.) but in which *disease* has not occurred in humans or animals in the past 6 months provided that climatic changes predisposing to *outbreaks* of RVF have not occurred during this time.

Article 8.11.5.

RVF infected country or zone with disease

A RVF infected country or *zone* with *disease* is one in which clinical *disease* in humans or animals has occurred within the past 6 months.

Article 8.11.6.

Recommendations for importation from RVF infection free countries or zones

for ruminants

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

1. were kept in a RVF free country or *zone* since birth or for at least 30 days prior to shipment; and

2. if the animals were exported from a free *zone*, either:

   a) did not transit through an *infected zone* during transportation to the *place of shipment*; or

   b) were protected from mosquito attack at all times when transiting through an *infected zone*.

Article 8.11.7.

Recommendations for importation from RVF infection free countries or zones

for meat and meat products of domestic and wild ruminants

Veterinary Authorities should require the presentation of an *international veterinary certificate* attesting that the products are derived from animals which remained in the RVF infection free country/free *zone* since birth or for the last 30 days.

Article 8.11.8.

Recommendations for importation from RVF infected countries/zones without disease

for ruminants

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

1. showed no evidence of RVF on the day of shipment;

2. met one of the following conditions:

    a) were kept in a RVF infected country/*zone* free of *disease* since birth or for the last 6 months providing that climatic changes predisposing to *outbreaks* of RVF have not occurred during this time; or

    b) were vaccinated against RVF at least 21 days prior to shipment with a modified live virus vaccine; or

    c) were held in a mosquito-proof *quarantine station* for at least 30 days prior to shipment during which the animals showed no clinical signs of RVF and were protected from mosquitoes between quarantine and the *place of shipment* as well as at the *place of shipment*;

AND

3. did not transit through an *infected zone* with *disease* during transportation of the *place of shipment*.

Article 8.11.9.

Recommendations for importation from RVF infected countries or zones without disease

for meat and meat products of domestic and wild ruminants

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

1. the products are derived from animals which:

    a) remained in the RVF infected country or *zone* without *disease* since birth or for the last 30 days;

    b) were slaughtered in an approved *abattoir* and were subjected to ante-mortem and post-mortem inspections for RVF with favourable results;

2. the carcasses from which the products were derived were submitted to maturation at a temperature above +2°C for a minimum period of 24 hours following *slaughter*.

Article 8.11.10.

Recommendations for importation from RVF infected countries or zones with disease

for ruminants

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

1. showed no evidence of RVF on the day of shipment;

2. were vaccinated against RVF at least 21 days prior to shipment with a modified live virus vaccine;

OR

3. were held in a mosquito-proof *quarantine station* for at least 30 days prior to shipment during which the animals showed no clinical signs of RVF and were protected from mosquito attack between quarantine and the *place of shipment* as well as at the *place of shipment*.

Article 8.11.11.

Recommendations for importation from RVF infected countries or zones with disease

for meat and meat products of domestic and wild ruminants

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

1. are from animals which have been slaughtered in an approved *abattoir* and have been subjected to ante-mortem and post-mortem inspections for RVF with favourable results; and

2. have been fully eviscerated and submitted to maturation at a temperature above +2°C for a minimum period of 24 hours following *slaughter*.

Article 8.11.12.

Recommendations for importation from RVF infected countries or zones with disease

for *in vivo* derived embryos of ruminants

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

1. showed no evidence of RVF within the period from 28 days prior to 28 days following collection of the embryos;

2. were vaccinated against RVF at least 21 days prior to collection with a modified live virus vaccine;

OR

3. were serologically tested on the day of collection and at least 14 days following collection and showed no significant rise in titre.

Article 8.11.13.

(Under study) Recommendations for importation from RVF infected countries or zones with disease or from RVF infected countries or zones without disease

for milk and milk products

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

1. was subjected to pasteurization; or

2. was subjected to a combination of control measures with equivalent performance as described in the Codex Alimentarius Code of Hygienic Practice for Milk and Milk Products.

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