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GLOSSARY

For the purposes of the *Terrestrial Code*:

Communication

means the discipline of informing, influencing, and motivating individual, institutional and public audiences, preferably on the basis of interactive exchanges, about any issue falling under the mandate of the OIE and the competence of the *Veterinary Services*.

Crisis

means a time of great danger, difficulty or uncertainty when problems related to any issue falling under the mandate of the OIE and the competence of the *Veterinary Services* require immediate action.

Crisis Communication

means the process of providing information of potentially incomplete nature within time constraints that allows an individual, affected and/or interested parties, an entire community or the general public to make best possible decisions and be informed of ~~and/or accept~~ policy decisions and rationale behind policy decisions during a crisis.

Outbreak communication

means the process of communicating in the event of an *outbreak*. Outbreak communication includes *notification*.

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Annex XXXIV

CHAPTER 7.X.

USE OF ANIMALS IN RESEARCH, TESTING OR TEACHING

Preamble

The purpose of this Chapter is to provide standards for OIE Members to follow when formulating regulatory requirements for the use of live animals in research, testing or teaching[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.

The OIE recognises the vital role played by the use of live animals in research. The OIE Guiding Principles 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 use of animals in science should cause as little pain and/or distress to animals 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.

A system of animal research 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 national, regional and institutional jurisdictions and both public sector and private sector responsibilities should be clearly defined.

The OIE recognises the central role of veterinarians in animal-based research. Given their unique training and skills, they are an essential member 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 in science leads to high quality scientific outcomes and optimum welfare for the animals used.

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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.

[1] Wherever the term "research" is used, it means "research, testing or teaching".

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.

Biological containment or biocontainment

means the system and procedures designed to prevent the accidental release of biological material. 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 organisms and subsequent infection of animals by human, vermin or other means.

Humane endpoint

means the point at which an experimental animal's pain and/or distress is terminated, minimized or reduced, by taking actions such as giving treatment to relieve pain and/or distress, terminating a painful procedure or humanely killing the animal.

Genetically altered animal (GA animal)

means an animal that has had a random or targeted change in its nuclear or mitochondrial DNA achieved through a deliberate human technological intervention.

Harm-benefit analysis

means the process of weighing the likely adverse effects (harms) 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, should be minimised.

The Three Rs
means the internationally accepted philosophy of Russell and Burch (1959) for the use of animals in research. The Three Rs comprise:

- **replacement** which refers to methods which 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, discomfort or lasting harm and/or enhance animal 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.

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 species-typical behaviours and reduce the expression of aberrant behaviours, as well as provide cognitive stimulation.

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Scope

These standards apply to animals as defined in the *Terrestrial Code* (excluding bees) bred, supplied and/or used in research, testing or teaching. Animals to be 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.

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The Oversight Framework

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

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.

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In providing this oversight, 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 animals.

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

1. Project Proposal Review

Project Proposals should be reviewed and approved prior to commencement of the research and should include a description of the following elements:

a) the scientific aims;

b) the experimental design, including statistics where appropriate;

c) the experimental procedures;

d) methods of handling and restraint and consideration of alternatives 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 physiologic 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 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 anima health or the advancement of biologic knowledge;

j) an assessment for any occupational 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.

2. Facility inspection

There should be regular inspections of the facilities. These inspections should include the following elements:

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

b) husbandry practices;

c) maintenance and cleanliness and security of the facility;

d) type and condition of caging and other equipment;

e) environmental conditions;

f) 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 (ACUP) Review

Critical elements of the Animal Care and Use Programme (ACUP) should be included in relevant regulations to empower the government authority to take appropriate action to ensure compliance. The ACUP should be reviewed regularly to include the following:

a) training and competency of all staff;

b) the programme of veterinary care;

c) husbandry and operational conditions;

d) sourcing and final disposition of animals; and

e) 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.

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Assurance of Training and Competency

An essential component of the ACUP 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. A system (institutional, regional or national) to assure competency should be in place. Continuing professional and paraprofessional education opportunities should be made available to relevant staff.

a) Scientists. 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, institutional policies and ethical considerations. The laboratory animal veterinarian is often a resource for this and other training. Competency in performance of procedures related to the scientist's research (e.g., surgery, anaesthesia, sampling and administration, etc.) should be verified.

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

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

d) Students. Wherever possible, students should learn scientific and ethical principles using non-animal methods (videos, computer models, etc). 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).

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Provision of Veterinary Care

Adequate veterinary care includes responsibility for promoting and monitoring an animal's welfare before, during and after research. Veterinary care includes attention to the physical and behavioural status of the animal. The veterinarian must have the authority and responsibility for making judgements concerning animal welfare.

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 controlled drugs prescribed by the veterinary staff are managed in accordance with applicable regulations.

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

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 minimize 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.

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 monitoring, and providing recommendations concerning, preoperative procedures, aseptic surgical techniques, the qualifications of institutional staff to perform surgery and the provision of postoperative care.

e) Advice on analgesia and anaesthesia. 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 proper use of anaesthetics, analgesics, tranquilizers, and methods of euthanasia for all species.

f) Advice on humane endpoints and euthanasia. 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.

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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.

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Source of animals

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

a) Animal procurement. Animals should 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.

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

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.

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

e) Genetically altered animals. If genetically altered animals are used, such use should be conducted in accordance with relevant regulatory guidance. Consideration should be given to addressing 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.

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.

g) 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.

h) Biosecurity risks. To reduce 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.

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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.

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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.

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.

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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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Annex XXXV

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 ~~can~~ should be ~~separated~~ protected from neighbouring infected countries by ~~a *buffer zone*, or physical or geographical barriers, and~~ 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* ~~should be implemented~~.

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.

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 and 3b) 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 8.5.3.

FMD free country where vaccination is practised

Susceptible animals in the FMD free country where vaccination is practised ~~can~~ should be ~~separated~~ protected from neighbouring infected countries by ~~a *buffer zone*, or physical or geographical barriers, and~~ 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* ~~should be implemented~~.

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 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) *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) routine vaccination is carried out for the purpose of the prevention of FMD;

   c) the vaccine used complies with the standards described in the *Terrestrial Manual*.

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 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.

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 ~~can~~ should be ~~separated~~ protected from the rest of the country and from neighbouring countries ~~by a *buffer zone* or by physical/ geographical barriers from the rest of the country and from neighbouring countries~~ if they are of a different *animal health status*~~, and~~ 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* ~~should be implemented~~.

~~A Member in which a FMD free zone where vaccination is not practised is to be established should~~ 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. describe in detail:

    a) regulatory measures for the prevention and control of both FMD and FMDV infection,

    b) the boundaries of the proposed FMD free zone and, if applicable, the ~~*buffer*~~ *protection zone* or physical or geographical barriers,

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 and 3c) above should be re-submitted annually and changes in the epidemiological situation or other significant events including those relevant to points 3a) and 3b) 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 ~~can~~ should be ~~separated~~ protected from neighbouring countries or *zones* if they are ~~infected~~ of a lesser *animal health status*, by ~~a *buffer zone* or by physical/geographical barriers from the rest of the country and from neighbouring countries if they are of a different *animal health status*, and~~ 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* ~~should be implemented~~.

~~A Member in which a FMD free zone where vaccination is practised is to be established should~~ 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 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 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 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) the boundaries of the proposed FMD free zone where vaccination is practised and, if applicable, the ~~*buffer*~~ *protection zone* or physical or geographical barriers,

c) the system for preventing the entry of the virus into the proposed FMD free zone (in particular if the procedure described in Article 8.5.9. is implemented),

and supply 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 4c) above should be re-submitted annually and changes in the epidemiological situation or other significant events including those relevant to points 4a) 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 Chapter 4.3. and 4.4. should be followed. Susceptible animals in the FMD free *compartment* should be separated from any other animal subpopulations by the application of an effective biosecurity management system.

A Member wishing to establish a FMD free *compartment* should:

1. have a record of regular and prompt animal disease reporting;

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) 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) an *animal identification* and *traceability* system in accordance with Chapters 4.1 and 4.2. is in place;

3. describe the animal subpopulation in detail and the biosecurity 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 ~~a~~ 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* ~~is~~ 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 ~~to~~ prevent the spread of the FMDV ~~*infection* from the containment zone~~ to the rest of the country or *zone*, ~~including~~ taking into consideration physical and geographical barriers, are in place;

6. ongoing *surveillance* in the *containment zone*~~, are~~ is in place;

~~6. *containment zone* should be large enough to contain the *disease* and comprise include both a restricted/*protection zone* and larger *surveillance zone*.~~

The free status of the areas outside the *containment zone* would be suspended pending the establishment of the *containment zone*. The ~~suspension of~~ free status of these areas could be ~~lifted~~ reinstated irrespective of the provisions of Article 8.5.8., once the *containment zone* is clearly established, by complying with points 1 to 5 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.

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.

Annex XXXV (contd)

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

FMD susceptible animals should only leave the *infected zone* if moved by mechanised transport to the nearest designated *abattoir* located in ~~the~~ a ~~*buffer*~~ *protection zone* directly to *slaughter*.

In the absence of an *abattoir* in ~~the~~ a ~~*buffer*~~ *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 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* ~~since birth or for at least the past 3 months~~;

3. have not been vaccinated.

Article 8.5.11.

Recommendations for importation from FMD free countries or zones where vaccination is practised ~~or from FMD free 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.

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*.

Annex XXXV (contd)

Article 8.5.13.

Recommendations for importation from FMD free countries or zones where vaccination is not practised ~~or FMD free 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* ~~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. or Chapter 4.6., as relevant.

Article 8.5.14.

Recommendations for importation from FMD free countries or zones where vaccination is not practised ~~or FMD free 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. or Chapter 4.6., as relevant.

Article 8.5.15.

Recommendations for importation from FMD free countries or zones where vaccination is practised ~~or from FMD free 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 country or *zone* free from FMD ~~for at least 3 months prior to collection~~;

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. or Chapter 4.6., as relevant;

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. or Chapter 4.6., as relevant;

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 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 ~~free from FMD~~ where vaccination is not practised or a FMD free *compartment* ~~at the time of collection~~;

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 ~~or from FMD free 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 ~~free from FMD~~ where vaccination is practised ~~for at least 3 months prior to collection~~;

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 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 ~~or from FMD free zones where vaccination is practised~~

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.

Annex XXXV (contd)

Article 8.5.22.

Recommendations for importation from FMD free countries or zones where vaccination is practised ~~or from FMD free 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 ~~the~~ 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

for *milk*, cream, milk powder and *milk products*

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

Annex XXXV (contd)

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).

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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 ~~recognition from the OIE for~~ establishment of freedom from FMD, either with or without the use of vaccination. ~~This may be for the entire country or a *zone* within the country.~~ Guidance is provided for Members seeking reestablishment of freedom from FMD for the ~~whole~~ entire country or for a *zone* ~~within the country,~~ either with or without vaccination or a *compartment*, following an *outbreak*, ~~as well as recommendations~~ and for the maintenance of FMD status ~~are provided~~. ~~Applications to the OIE for recognition of freedom should follow the format and answer all the questions posed by the "Questionnaire on FMD" available from the OIE *Central Bureau*.~~

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. ~~It is axiomatic that the s~~*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* ~~to be recognised as free from FMDV *infection*/circulation~~.

   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*.

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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.

~~The principles involved in *surveillance* for *disease*/*infection* are technically well defined. 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.~~

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 dassified 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*.

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.

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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. 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

   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.

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. Antibody titres against NSP 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 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) are present, they could act as sentinels to provide additional serological evidence.

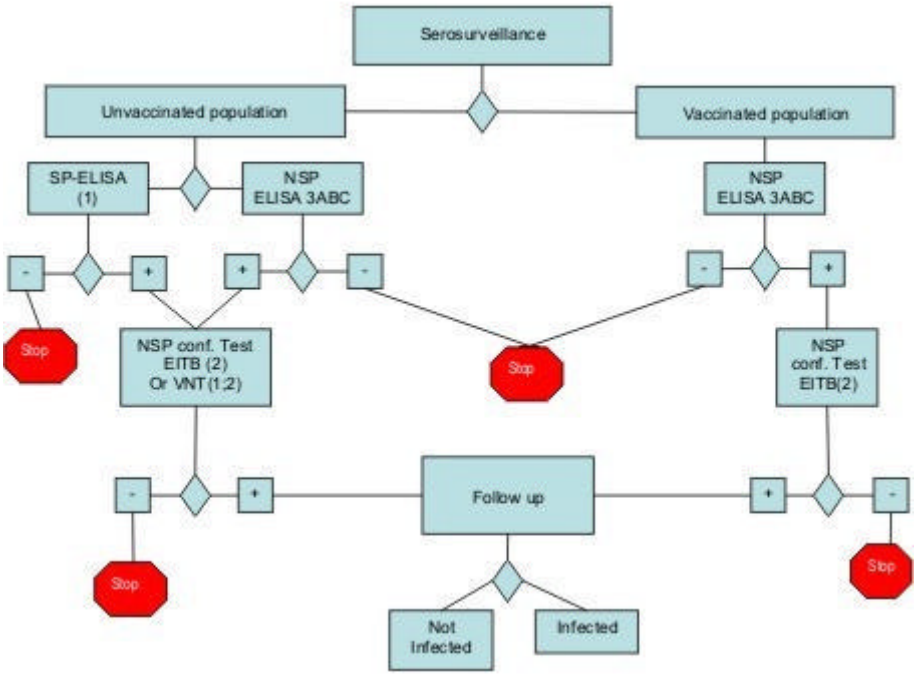
Laboratory results should be examined in the context of the epidemiological situation. Corollary information needed to complement the serological survey and assess the possibility of viral circulation includes but is not limited to:

- 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.

Annex XXXV (contd)

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 XXXVI

CHAPTER 8.1

ANTHRAX

Article 8.1.1.

General provisions

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*.

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.

~~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

Annex XXXVI (contd)

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

OR

3. 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 10 seconds ~~at least equivalent to pasteurisation (under study)~~.

Reference

Sa Xu, Theodore P. Labuza, and Francisco Diez-Gonzalez (2006). Thermal Inactivation of Bacillus anthracis Spores in Cow's Milk. Applied and Environmental Microbiology, June 2006, Vol. 72, No. 6: p. 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;

   b) drying in hot air;

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

References

Böhm, Reinhard. Institut fur Umwelt-und Tierhygiene Sowie Tiermedizin mit Tierklinik, Universität Hohenheim. Personal communication to Dr Wolf-Arno Valder, OIE Terrestrial Animal Health Standards Commission.

Article 8.1.9.

Recommendations for importation of 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:

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.

Annex XXXVI (contd)

References

- Böhm, Reinhard. Institut fur Umwelt-und Tierhygiene Sowie Tiermedizin mit Tierklinik, Universität Hohenheim. Personal communication to Dr Wolf-Arno Valder, OIE Terrestrial Animal Health Standards Commission.

- Turnbull, PCB. (1998) *Guidelines for the Surveillance and Control of Anthrax in Humans and Animals*. 3rd edition. World Health Organization, Geneva: 97 pages.

- Spotts Whitney, EA, Beatty, ME, Taylor, TH, Weyant, R, Sobel, J, Arduino, MJ, Ashford, DA. (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 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

- Böhm, Reinhard. Institut fur Umwelt-und Tierhygiene Sowie Tiermedizin mit Tierklinik, Universität Hohenheim. Personal communication to Dr Wolf-Arno Valder, OIE Terrestrial Animal Health Standards Commission.

- Turnbull, PCB. (1998) *Guidelines for the Surveillance and Control of Anthrax in Humans and Animals*. 3rd edition. World Health Organization, Geneva: 97 pages.

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 45.5 °C;

2. immersion in soap liquor for 10 minutes at 45.5 °C;

3. immersion in 2% formaldehyde solution for 10 minutes at 45.5 °C;

4. a second immersion in 2% formaldehyde solution for 10 minutes at 45.5 °C;

5. rinsing on cold water followed by drying in hot air.

References

- Böhm, Reinhard. Institut fur Umwelt-und Tierhygiene Sowie Tiermedizin mit Tierklinik, Universität Hohenheim. Personal communication to Dr Wolf-Arno Valder, OIE Terrestrial Animal Health Standards Commission.

- Turnbull, PCB. (1998) *Guidelines for the Surveillance and Control of Anthrax in Humans and Animals*. 3rd edition. World Health Organization, Geneva: 97 pages.

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.

References

Böhm, Reinhard. Institut fur Umwelt-und Tierhygiene Sowie Tiermedizin mit Tierklinik, Universität Hohenheim. Personal communication to Dr Wolf-Arno Valder, OIE Terrestrial Animal Health Standards Commission.

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.

Annex XXXVI (contd)

References

- Böhm Reinhard. Institut fur Umwelt-und Tierhygiene Sowie Tiermedizin mit Tierklinik, Universität Hohenheim. Personal communication to Dr Wolf-Arno Valder, OIE Terrestrial Animal Health Standards Commission.

- Turnbull, PCB. (1998) *Guidelines for the Surveillance and Control of Anthrax in Humans and Animals.* 3rd edition. World Health Organization, Geneva: 97 pages.

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

- Turnbull, PCB. (1998) *Guidelines for the Surveillance and Control of Anthrax in Humans and Animals.* 3rd edition. World Health Organization, Geneva: 97 pages.

- Spotts Whitney, EA, Beatty, ME, Taylor, TH, Weyant, R, Sobel, J, Arduino, MJ, Ashford, DA. (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 m³, 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

Turnbull, PCB. (1998) *Guidelines for the Surveillance and Control of Anthrax in Humans and Animals.* 3rd edition. World Health Organization, Geneva: 97 pages.

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Annex XXXVII

CHAPTER 8.16.

SWINE VESICULAR DISEASE

Article 8.16.1.

For the purposes of the *Terrestrial Code*, the *incubation period* for swine vesicular disease (SVD) shall be 28 days.

For the purposes of this Chapter, susceptible animals include domestic and wild pigs.

For the purposes of this Chapter, a case includes an animal infected with SVD virus (SVDV).

For the purposes of *international trade*, this Chapter deals not only with the occurrence of clinical signs caused by SVDV, but also with the presence of infection with SVDV in the absence of clinical signs.

For the purposes of this Chapter, virus infection means presence of SVDV as demonstrated by:

1. virus isolation, or detection of virus antigen or virus nucleic acid, or

2. seroconversion, or

3. clinical signs associated with serological evidence, or

4. clinical signs or serological evidence associated with epidemiological link.

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

Article 8.16.2.

SVD free country, *zone* or *compartment*

Susceptible animals in the SVD free country or *zone* or *compartment* should be separated from neighbouring infected countries or *zones* by animal health measures (bio-security measures, which may include a *buffer zone*) that effectively prevent the entry of the virus, or by physical barriers.

The SVD status of a country, *zone* or *compartment* can only be determined by applying *surveillance* recommendations described in Chapter 1.4. according to two possibilities:

1. Historically free status

   A country or *zone* may be considered free from the *disease* without formally applying a specific *surveillance* programme if the provisions of Article 1.4.6. are complied with.

2. Free status as a result of a specific surveillance programme

   A country, *zone* or *compartment* which does not meet the conditions of point 1 above may be considered free from SVD when:

a) *surveillance* for both SVD and SVDV infection in accordance with Chapter 1.4. has been in place for at least 3 years;

b) no *outbreak* of SVD and no evidence of SVDV circulation has been found during the past 3 years;

c) regulatory measures for the prevention and control of SVD have been implemented, including the control of the movement of susceptible animals and other relevant measures for preventing the entry of the virus.

If a *stamping-out policy* was applied in respect of the most recent *outbreak*, the requirement of 3 years in points a) and b) above is shortened to 12 months.

Article 8.16.3.

SVD infected country or zone

An SVD infected country or *zone* is a country or *zone* that does not fulfill the requirements to be considered as free.

Article 8.16.4.

Establishment of a containment zone within an SVD free country or SVD free zone

In the event of a limited *outbreak* within an SVD free country or SVD free *zone*, 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 be able to provide documented evidence that:

1. the *outbreak* is 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 source of the *outbreak* has been identified;

   e) all *cases* have been shown to be epidemiologically linked;

2. *surveillance* in accordance with Chapter 1.4. demonstrates that there are no undetected *cases* in the *containment zone*;

3. a *stamping-out policy* has been applied;

4. increased passive and targeted *surveillance* in accordance with Chapter 1.4. in the rest of the country or *zone* has been carried out and has not detected any evidence of *infection*;

5. measures to prevent spread of the *infection* from the *containment zone* to the rest of the country or *zone*, are in place.

The free status of the area outside the *containment zone* would be suspended pending the establishment of the *containment zone.* The suspension of free status of this area could be lifted irrespective of the provisions of Article 8.16.5., once the *containment zone* is clearly established, by complying with points 1 to 5 above.

The recovery of the SVD free status of the *containment zone* should follow the provisions of Article 8.16.5.

When importing from *containment zones*, provisions of Articles 8.16.6., 8.16.9., 8.16.11. and 8.16.13., concerning the importation from countries or *zones* considered infected with SVD, should be applied.

Article 8.16.5.

Recovery of free status

When an SVD *outbreak* or SVDV infection occurs in an SVD free country or *zone*, one of the following waiting periods is required to regain the status of SVD free country or *zone*:

1. 2 months after the *stamping-out* of the last *case*, where a *containment zone* and serological *surveillance* have been applied in accordance with Chapter 1.4.; or

2. 12 months after the *stamping-out* of the last *case*, where the conditions for the establishment of a *containment zone* are not fulfilled, a *stamping-out policy* and serological *surveillance* have been applied in accordance with Chapter 1.4.

Where both a *stamping-out policy* and serological *surveillance* in accordance with Chapter X.X. have not been practiced, the above waiting periods do not apply, and Article 8.16.2. applies.

Article 8.16.6.

Transfer directly to slaughter of SVD susceptible animals from an infected zone to a free zone within a country

SVD susceptible animals should only leave the *infected zone* if moved by mechanised transport to the nearest designated *abattoir*, located in the *buffer zone* (if established), directly to *slaughter*.

In the absence of an *abattoir* in the *buffer zone*, or in the absence of a *buffer zone*, live SVD susceptible animals can be transported to the nearest *abattoir* in a free *zone* directly to *slaughter* only under the following conditions:

1. no SVD susceptible animal has been introduced into the *establishment* of origin and no animal in the *establishment* of origin has shown clinical signs of SVD for at least 60 days prior to movement;

2. a representative sample of animals of the *herd* of origin, including all animals to be moved for *slaughter* has been serologically tested with negative findings;

3. the animals were kept in the *establishment* of origin for at least 2 months prior to movement;

4. SVD has not occurred within a 1-kilometre radius of the *establishment* of origin for at least 2 months prior to movement;

5. 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;

6. 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* and, to be re-approved, must apply *disinfections* able to destroy any residual infectivity;

7. *vehicles* and the *abattoir* must be subjected to thorough cleansing and *disinfection* able to destroy any residual *infectivity* immediately after use.

All products obtained from the animals and any products coming into contact with them must be identified and traded only on domestic market.

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 8.16.9.

Article 8.16.7

Recommendations for importation from SVD free countries, zones or compartment

for domestic pigs

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

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

2. were kept in an SVD free country, *zone* or *compartment* since birth or for at least the past 60 days.

Article 8.16.8.

Recommendations for importation from SVD free countries or zones

for wild pigs

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

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

2. come from an SVD free country or *zone*;

if the country or *zone* of origin has a common border with a country or *zone* considered infected with SVD:

3. were kept in a *quarantine station* for the 60 days prior to shipment and were subjected to a prescribed serological test for SVD with negative results during that period.

Article 8.16.9.

Recommendations for importation from countries or zones considered infected with SVD

for domestic and wild pigs

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

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

2. were kept in a *quarantine station* for the 60 days prior to shipment and were subjected to a prescribed serological test for SVD with negative findings during that period.

Article 8.16.10.

Recommendations for importation from SVD free countries or zones or compartments

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 SVD on the day of collection of the semen;

   b) were kept in an SVD free country or *zone* or *compartment* for not less than 60 days prior to collection;

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

Article 8.16.11.

Recommendations for importation from countries or zones considered infected with SVD

for semen of pigs

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

1. the donor animals showed no clinical sign of SVD on the day of collection of the semen and were subjected to a prescribed serological test for SVD with negative findings;

2. the donor animals were kept in the *exporting country* or *zone* for the 60 days prior to collection, in an *establishment* or *artificial* insemination *centre* where no *case* of SVD was officially reported during that period, and that the *establishment* or *artificial insemination centre* was not situated within one km from an *outbreak* occurring in the last 60 days;

3. a representative sample of animals of the *herd* of origin has been serologically tested with negative findings;

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

Article 8.16.12.

Recommendations for importation from SVD free countries, zones or compartments

for *fresh meat* of pigs

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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 an SVD free country, *zone* or *compartment* since birth or for at least the past 60 days;

2. which have been slaughtered in an *approved abattoir* and have been subjected to ante-mortem and post-mortem inspections for SVD with favourable outcome.

Article 8.16.13

Recommendations for the importation of *meat products* of pigs (either domestic or wild), or for products of animal origin (from *fresh meat* of pigs) intended for use in animal feeding, for agricultural or industrial use, or for pharmaceutical or surgical use, or for trophies derived from wild pigs

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 8.16.12, as relevant;

   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 8.16.12, as relevant;

OR

2. have been processed in an establishment approved by the *Veterinary Authority* for export purposes so as to ensure the destruction of the SVD virus.

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