

GLOSSARY

COMPETENT AUTHORITY

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

VETERINARY AUTHORITY

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

VETERINARY SERVICES

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

CAPTIVE WILD [ANIMAL]

means an *animal* that has a phenotype not significantly affected by human selection but that is captive or otherwise lives under direct human supervision or control, i.e. population management, regular contacts or handling, feeding, harvesting and slaughter, including zoo *animals* and pets.

EPIDEMIOLOGICAL UNIT

means a group of *animals* with a defined epidemiological relationship that share approximately the same likelihood of exposure to a pathogenic agent. This may be because they share a common environment (e.g. *animals* in a pen), or because of common management practices. Usually, this is a *herd* or a *flock*. However, an *epidemiological unit* may also refer to groups such as *animals* belonging to residents of a village, or *animals* sharing a communal animal handling facility or, in some circumstances, to a single animal. The epidemiological relationship may differ from disease to disease, or even strain to strain of the pathogenic agent.

CHAPTER 1.6.

PROCEDURES FOR PUBLICATION OF A SELF-DECLARATION OF DISEASE FREEDOM, RECOGNITION OF AN OFFICIAL DISEASE STATUS AND FOR ENDORSEMENT OF AN OFFICIAL CONTROL PROGRAMME RECOGNITION BY THE OIE

Article 1.6.1.

General principles Publication by the OIE of a self-declaration of disease freedom by a Member Country

A Member Countryies may wish to make a self-declaration as to of the freedom of a country, zone or compartment from an OIE listed disease or another animal disease. The Member Country may inform the OIE of the its claimed status and the OIE may publish the claim. Publication does not imply endorsement of the claim, and request that the OIE publish the self-declaration for information of OIE Member Countries.

A Member Country requesting the publication of a self-declaration should follow the Standard Operating Procedure (available on the OIE website)[†] for submission of a self-declaration of disease freedom and provide documented information on its compliance with the relevant chapters of the *Terrestrial Code*, including:

- = evidence that the disease is a *notifiable disease* in the entire country;
- = history of absence or eradication of the disease in the country, *zone* or *compartment*;
- = *surveillance* and early warning system for all relevant species in the country, *zone* or *compartment*;
- = measures implemented to maintain freedom in the country, *zone* or *compartment*.

The self-declaration may be published only after all the information provided has been received and an administrative and technical screening has been performed by the OIE. Publication does not imply endorsement of the claim of freedom by the OIE and does not reflect the official opinion of the OIE. Responsibility for the accuracy of the information contained in a self-declaration lies entirely with the OIE Delegate of the Member Country concerned.

The OIE does not publish self-declarations for of freedom for from bovine spongiform encephalopathy (BSE), foot and mouth disease (FMD), contagious bovine pleuropneumonia (CBPP), African horse sickness (AHS), peste des petits ruminants (PPR) and classical swine fever (CSF) diseases listed under point 1) of Article 1.6.24bis.

Article 1.6.24bis.

Official recognition and endorsement by the OIE

A Member Countryies may request:

- 1) official recognition of status by the OIE of as to:
 - a) freedom of a country or zone from African horse sickness (AHS);

[†] <http://www.oie.int/en/animal-health-in-the-world/self-declared-disease-status/>

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- b) risk status of a country or zone with regard to bovine spongiform encephalopathy (BSE);
 - c) freedom of a country or zone from classical swine fever (CSF);
 - d) freedom of a country or zone from contagious bovine pleuropneumonia (CBPP);
 - e) freedom of a country or zone from foot and mouth disease (FMD), with or without vaccination;
 - f) freedom of a country or zone from peste des petits ruminants (PPR);
- 2) endorsement by the OIE of:
- a) an official control programme for contagious bovine pleuropneumonia;
 - b) an official control programme for foot and mouth disease;
 - c) an official control programme for peste des petits ruminants.
- 1) the risk status of a country or zone with regard to BSE;
- 2) the freedom of a country or zone from FMD, with or without vaccination;
- 3) the freedom of a country or zone from CBPP;
- 4) the freedom of a country or zone from AHS;
- 5) the freedom of a country or zone from PPR;
- 6) the freedom of a country or zone from CSF.

The OIE does not grant official recognition of status or endorsement of an official control programme for ~~other~~ diseases other than those listed under points 1) and 2) above.

~~In these cases,~~ Member Countries should present documentation setting out the compliance of their *Veterinary Services* with ~~the applicant country or zone with~~ the provisions of Chapters 1.1., 3.1. and 3.2. of the *Terrestrial Code* and with the provisions of the relevant disease-specific chapters in the *Terrestrial Code* and the *Terrestrial Manual*.

When requesting official recognition of disease status or endorsement by the OIE of an *official control programme*, the Member Country should submit to the OIE ~~Status Department~~ a dossier providing the information requested in the following Chapters (as appropriate): 1.7. (for AHS), 1.8. (for BSE), 1.9. (for CSF), 1.10. (for CBPP), 1.11. (for FMD) or 1.12. (for PPR).

The OIE framework for the official recognition and maintenance of disease status is described in Resolution No. XV (administrative procedures) and Resolution No. XVI (financial obligations) adopted during the 83rd General Session in May 2015, as well as in the Standard Operating Procedures (available on the OIE website)².

The country or the zone, or the country having its official control programme endorsed will be included in the relevant list only after the evidence submitted, based on the provisions of Chapters 1.7. to 1.12., has been adopted by the World Assembly of OIE Delegates.

Retention on the list requires that the information in relevant chapters be re-submitted annually and that changes in the epidemiological situation or other significant events should be reported to the OIE in accordance with the requirements in Chapter 1.1.

² <http://www.oie.int/en/animal-health-in-the-world/official-disease-status/official-recognition-policy-and-procedures/>

CHAPTER 4.Y.

OFFICIAL CONTROL MANAGEMENT OF OUTBREAKS OF LISTED AND EMERGING AND LISTED DISEASES

Article 4.Y.1.

Introduction

When a *listed disease or emerging disease, including a zoonosis*, occurs in a *Member Country*, *Veterinary Services* should implement *a response control measures* proportionate to the likely impact of the disease *and as a result of a risk analysis*, in order to minimise its spread and consequences and, if possible, eradicate it. *These measures can vary from rapid response (e.g. to a new hazard disease) and management of outbreaks, to long-term control (e.g. of an endemic disease) infection or infestation.*

The purposes of this chapter is to provide recommendations to prepare, develop and implement *official control programmes for plans in response to outbreaks occurrence outbreaks of listed and emerging or listed diseases*, including zoonoses. It is not aimed at giving ready-made fit-for-all solutions, but rather at outlining principles to follow when combating animal diseases through organised control programmes plans. *Although this chapter focuses primarily on listed and emerging diseases, the recommendations may also be used by the Veterinary Authorities for any notifiable diseases or diseases against which they have established official control programmes.*

The *Veterinary Authority* should determine which diseases to establish *official control programmes* against and at which regulatory level, according to an evaluation of the actual or likely impact of the disease. *Disease control programmes plans* should be prepared in advance by the *Veterinary Authority* and *Veterinary Services* in close collaboration with the relevant stakeholders and other authorities, as appropriate disposing of the necessary regulatory, technical and financial tools.

Control plans *They Official control programmes* should be justified by rationales developed through *risk analysis and considering taking into account* animal health, public health, and socio-economic, *animal welfare* and environmental aspects. They should preferably be supported by relevant cost-benefit analysis *when possible* and *should* include the necessary regulatory, technical and financial tools.

Official control programmes Control plans should be developed with the aim of achieving defined measurable objectives, in response to a situation in which *purely private action alone* is not sufficient. Depending on the prevailing epidemiological, environmental and socio-economic situation, the goal may vary from the reduction of impact to the eradication of a given *disease infection or infestation*.

The general components of an official control programme include:

- 1) a plan of the programme to control or eradicate the relevant disease in the country or zone;
- 2) regular and prompt animal disease reporting;
- 3) surveillance of the relevant disease in accordance with Chapter 1.4.;
- 4) rapid detection of, and response to, the relevant disease, to reduce the incidence and to eliminate transmission;
- 5) measures implemented to prevent introduction or spread of the relevant disease, including biosecurity and movement control;
- 6) vaccination programme as relevant;
- 7) preparedness and contingency plans;

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8) communication and collaboration with other relevant Competent Authorities.

In any case, the critical components of control plans for management of outbreaks for diseases that are not present in the Member Country are measures to prevent the introduction, an early detection warning system (including a warning procedure), and rapid response and quick and effective action, possibly followed by long-term measures. Plans should always include an exit strategy.

Learning from past outbreaks, and reviewing the response sequence and revising the methods are critical for adaptation to evolving epidemiological situations circumstances and for better performance in future situations. Experiences of the Veterinary Services of other Member Countries may also provide useful lessons. Plans should be tested regularly to ensure that they are fit-for-purpose, practical, feasible and well-understood and that field staff are trained and other stakeholders are fully aware of their respective roles and responsibilities in implementing the response. This is especially important for diseases that are not present in the Member Country.

Article 4.Y.2.

Legal framework and regulatory environment

- 1) In order to be able to effectively control listed diseases and emerging diseases and listed diseases, the *Veterinary Authority* should ensure that:
 - the *Veterinary Services* comply with the principles of Chapter 3.1., especially the services dealing with the prevention and control of contagious infectious transmissible animal diseases, including zoonoses;
 - the *veterinary legislation* complies with the principles of Chapter 3.4.
- 2) In particular, in order for the *Veterinary Services* to be the most effective when combatting animal disease outbreaks, the following should be addressed in the *veterinary legislation or other relevant legal framework*:
 - legal powers and structure of command and responsibilities, including responsible officials with defined powers authority; especially a right of entry to establishments or other related enterprises such as live animal markets, slaughterhouses/abattoirs and animal products processing plants, for regulated purposes of *surveillance* and disease control actions, with the possibility of obliging owners to assist;
 - = sources of financing for dedicated supporting staff;
 - sources of financing for epidemiological enquiries, laboratory diagnostic, disinfectants, insecticides, vaccines and other critical supplies;
 - sources of financing and compensation policy for livestock commodities and property that may be destroyed as part of disease control programmes, or for direct losses incurred due to movement restrictions imposed by the control programme;
 - coordination with other authorities, especially law enforcement and public health authorities.
- 3) Furthermore, the specific regulations, policies, or guidance on disease control activities ~~policies~~ should include the following:
 - *risk analysis* to identify assess and prioritise ~~potential disease risks~~, including a regularly updated list of *notifiable diseases*;
 - definitions and procedures for the reporting and management of a suspected case, or confirmed case, of an listed disease or an emerging disease or a listed disease;
 - procedures for the management of infected establishments, directly or indirectly affected by the disease infected establishment, contact establishment;
 - = procedures for epidemiological investigations of outbreaks including tracing of animals and animal products;

Annex 15 (contd)

- definitions and procedures for the declaration and management of *infected zones* and other zones, such as *free zones*, *protection zones*, *containment zones*, or less specific ones such as *zones of intensified surveillance*;
- procedures for the collection, transport and testing of animal samples;
- procedures for animal identification and the management of animal identification systems ~~the identification of animals~~;
- procedures for the restrictions of movements, including possible standstill or compulsory veterinary certification, of relevant *animals*, ~~and~~ animal products and fomites within, to, or from given *zones* or *establishments* or other related enterprises;
- procedures for the destruction or *slaughter* and safe disposal or processing of infected or potentially infected *animals*, including relevant *wildlife*; ~~and~~
- = procedures for the destruction and safe disposal or processing of contaminated or potentially contaminated animal products and other materials such as fodder, bedding and litter;
- = procedures for cleaning, disinfection and disinsection of establishments and related premises, vehicles/vessels or equipment;
- procedures for compensation for the owners of *animals* or animal products, including defined standards and means of implementing such a compensation;
- ~~procedures for cleaning, disinfection and disinsection of establishments and related premises, vehicles or equipment~~;
- procedures for the compulsory emergency implementation of vaccination programmes or treatment of *animals*, as relevant, and for any other necessary disease control actions; ~~and~~
- = procedures for post-control surveillance and possible gaining or recovery of status, as relevant.

Article 4.Y.3.

Emergency Preparedness

In case of occurrence of a disease that was not present in the country or zone, or of sudden increase of incidence of a disease that is present, rapid and effective response to a new occurrence or emergence of contagious infectious diseases is dependent on the level of preparedness. The Veterinary Authority should integrate preparedness planning and practice within the official control programmes against these diseases as one of its core functions. Rapid, effective response to a new occurrence or emergence of contagious diseases is dependent on the level of preparedness.

Preparedness should be ~~justified~~ supported by *risk analysis*, should be planned in advance, and should include ~~training~~, capacity building and simulation exercises.

1. Risk analysis

Risk analysis, including import *risk analysis*, in accordance with Chapter 2.1., should be used to determine ~~which~~ a list of notifiable diseases that require preparedness planning and to what extent.

A *risk analysis* identifies the pathogenic agents that present the greatest *risk* and for which preparedness is most important and therefore helps to prioritise the range of disease threats and categorise the consequent actions. It also helps to define the best strategies and control options.

The *risk analysis* should be reviewed updated regularly to detect changes (e.g. new pathogenic agents, or changes in distribution and virulence of pathogenic agents previously identified as presenting the major *risk* and changes in possible pathways) and be updated accordingly, taking into account the latest scientific findings.

Annex 15 (contd)2. Planning

Four kinds of plans, describing what governmental or local authorities and all stakeholders should do, comprise any comprehensive preparedness and response system:

- a) a preparedness plan, which outlines what should be done before an *outbreak* of a notifiable disease or an emerging disease or a notifiable disease occurs;
- b) a response or contingency plan, which details what should be done in the event of an occurrence of a notifiable disease or an emerging disease or notifiable disease, beginning from the point when a suspected case is reported;
- c) a comprehensive set of instructions for field staff and other stakeholders on how to undertake specific tasks required by the response or contingency plan;
- d) a recovery plan for the safe restoration of normal activities, including food supply, possibly including procedures and practices modified in light of the experience gained during the management of the outbreak notifiable disease or the emerging disease.

3. Simulation exercises

The *Veterinary Services* and all stakeholders should be made aware of the sequence of measures to be taken in the framework of a contingency plan through the organisation of simulation exercises, mobilising a sufficient number of staff and stakeholders to evaluate the level of preparedness and fill possible gaps in the plan or in staff capacity. Simulation exercises may be organised between the Veterinary Services of neighbouring countries and other relevant agencies.

Article 4.Y.4.

Surveillance and early warning detection systems

- 4) Depending on the priorities identified by the *Veterinary Authority*, *Veterinary Services* should implement adequate *surveillance* for *listed diseases* in accordance with Chapter 1.4. ~~or and listed disease-specific chapters~~, in order to detect suspected cases and either rule them out or confirm them. The *surveillance* should be adapted to the epidemiological and environmental situation. Early warning systems are an integral component of emergency preparedness. They should be in place for diseases infections or infestations for which a rapid response is desired, and should comply with the relevant articles of Chapter 1.4. When used, vector surveillance should be conducted in accordance with Chapter 1.5.

All suspected case investigations should provide a result, either positive or negative. Criteria should be established in advance for a case definition. Confirmation can be made on clinical and post-mortem grounds, epidemiological information, laboratory test results or a combination of these, in accordance with relevant articles of the Terrestrial Code or Terrestrial Manual. Strong suspicion based on supportive, but not definitive, findings should lead to at least the implementation of local control measures as a precaution. When Once a case is confirmed, full sanitary measures should be implemented as planned.

- 2) In order to implement adequate *surveillance*, the *Veterinary Authority* should have access to good diagnostic capacity. This means that the *veterinarians* and other relevant personnel of the *Veterinary Services* have adequate knowledge of the *disease*, its clinical and pathological manifestation and its epidemiology, and that laboratories approved for the testing of animal samples for the relevant *diseases* are available.
- 3) Suspected cases of *notifiable diseases* should be reported without delay to the *Veterinary Authority*, ideally with the following information:
 - the *disease* or pathogenic agent suspected, with brief descriptions of clinical signs or lesions observed, or laboratory test results as relevant;
 - the date when the signs were first noticed at the initial site and any subsequent sites;
 - the names and addresses or geographical locations of suspected infected *establishments* or premises;

Annex 15 (contd)

- the animal species affected, including possible human cases, and the approximate numbers of sick and dead *animals*;
 - initial actions taken, including *biosecurity* and precautionary movement restrictions of *animals*, products, staff, vehicles and equipment;
- 4) Immediately following the report of a suspected case, investigation should be conducted by the *Veterinary Services*, taking into account the following:
- *biosecurity* to be observed when entering and leaving the *establishment*, premises or locality;
 - clinical examinations to be undertaken (number and types of *animals*);
 - samples to be taken from *animals* showing signs or not (number and types of *animals*), with specified sampling and sample handling equipment and sample handling procedures, including for the safety of the investigator and animal owners;
 - procedure for submitting samples for testing;
 - size of the affected *establishment*, premises or locality and possible entry pathways;
 - investigation of the approximate numbers of similar or possibly susceptible *animals* in the *establishment* and its surroundings;
 - details of any recent movements of possibly susceptible *animals* or *vehicles* or people to or from the affected *establishments*, premises or locality;
 - any other relevant epidemiological information, such as presence of the suspected *disease* in *wildlife* or abnormal *vector* activity;

A procedure should be in place for reporting findings to the *Veterinary Authority* and for record keeping.

- 5) All suspected case investigations should provide a result, either positive or negative. Criteria should be established in advance for a case definition. Confirmation can be made on clinical and post-mortem grounds, epidemiological information, laboratory test results or a combination of these, in accordance with relevant articles of the *Terrestrial Code* or *Terrestrial Manual*. Strong suspicion based on supportive, but not definitive, findings should lead to the implementation of local control measures as a precaution. When a case is confirmed, full *sanitary measures* should be implemented as planned.
- 6) When a case of a *listed disease* is detected, *notification* shall be made to the OIE in accordance with Chapter 1.1.

Article 4.Y.5.

General considerations **when managing an for outbreak management**

Upon confirmation of ~~Once an outbreak of a notifiable disease or an emerging disease or a notifiable disease that is subject to an official control programme is confirmed~~ effective *risk management* depends on the application of a combination of measures that are operating at the same time or consecutively, aimed at:

- 1) **epidemiological investigation to trace back and forward animals in contact and potentially infected or contaminated products:**
- 2) eliminating the source of pathogenic agent, through:
 - the *killing* or *slaughter* of *animals* infected or suspected of being infected, as appropriate, and safe disposal of dead *animals* and potentially contaminated products;
 - the cleaning, *disinfection* and, if relevant, *disinsection* of premises and equipment;

Annex 15 (contd)

23) stopping the spread of *infection*, through:

- movement restrictions on *animals* **commodities**, *vehicles*, and equipment and *people*, as appropriate;
- *biosecurity*;
- *vaccination*, treatment or culling of *animals* at risk;
- control of vectors**;
- communication and public awareness.

Different strategies may be chosen depending on the expected outcome of the programme (i.e. eradication, containment or partial control) and the epidemiological, environmental, economic and social situation. The *Veterinary Authority* should assess the situation beforehand and at the time of the *outbreak* detection. For example, the wider the spread of the disease and the more locations affected at the beginning of the implementation of the measures, the less likely it will be that culling as a main eradication tool will be effective, and the more likely it will be that other control tools such as *vaccination* or treatment, either in conjunction with culling or alone, will be needed. The involvement of *vectors* or *wildlife* will also have a major influence on the control strategy and different options chosen. The strategies chosen will, in turn, influence the final objective of the control programme.

In any case, the management plan should consider the costs of the measures in relation to the benefits expected, and should at least integrate the compensation of owners for losses incurred by the measures, as described in regulations, policies or guidance.

In case of highly **contagious transmissible** or high impact disease events, the management plan should be closely coordinated through an inter-sectoral mechanism such as an incident command system.

Article 4.Y.6.

Culling of animals and disposal of dead animals and **animal products other commodities**

Living infected *animals* ~~can be~~ are the greatest source of pathogenic agents. These *animals* may directly transmit the pathogenic agent to other *animals*. They may and also cause lead to indirect **infection transmission of pathogenic agents** through **live organisms (vectors, people) or through** the contamination of fomites, including breeding and handling equipment, bedding, *feed*, *vehicles*, and people's clothing and footwear, or the contamination of the environment. Although carcasses may remain contaminated for a period after death, **active** shedding of the pathogenic agent **effectively** ceases when the *animal* is killed or slaughtered. Thus, culling of *animals* is often a the preferred strategy for the control of **contagious transmissible** diseases.

Veterinary Services should adapt any strategy for culling **of animals, killing or disposal of dead animals and their products other commodities** strategy to the transmission pathways of the *pathogenic* agent. A **stamping-out policy** is should be the preferred strategy for highly **contagious transmissible** diseases and for situations where the country or zone was formerly **previously** free or freedom was impending, while other strategies, such as test and cull, are better suited to less **contagious transmissible** diseases and situations where the disease is endemic.

For control measures, including destruction of *animals* or products, to be most effective, *animal identification* and *animal traceability* should be in place, in accordance with Chapters 4.1. and 4.2.

The *slaughter* or *killing* of *animals* should be performed in accordance with Chapter 7.5. or Chapter 7.6., respectively.

The disposal of dead *animals* and their potentially contaminated products should be performed in accordance with Chapter 4.12.

1. Stamping-out policy

A stamping-out policy consists primarily in ~~of~~ the killing of all the animals affected infected or suspected of being ~~affected infected~~, including those which that have been directly or indirectly exposed to the causal pathogenic agent. This strategy is used for the most contagious transmissible diseases.

A stamping-out policy can be limited to the affected establishments and, where appropriate, other establishments found to be epidemiologically linked with an affected establishment, or be broadened to include all establishments of a defined zone, when pre-emptive depopulation can be used to stop the transmission of a fast spreading pathogenic agent.

A stamping-out policy can be applied to all the animal species present on an affected establishment, or to all susceptible species, or only to the same species as the infected animals, based on the assessment of associated risks.

Depopulation and carcass disposal can be applied to wildlife within a defined zone, based on the assessment of associated risks.

Killing should preferably be performed on site, and the carcasses either disposed of on site or transported directly and safely to a rendering plant or other dedicated site for destruction. If to be killed outside of the establishment or slaughtered, the animals should be transported directly to a dedicated approved rendering plant or slaughterhouse/abattoir respectively, without any possible direct or indirect contacts with other animals. Slaughtered animals and their products should be processed separately from others.

~~Stamping-out can be applied to all the animal species present on affected premises, or to all susceptible species, or only to the same species as the affected animals.~~

Products originating from killed or slaughtered animals, (ranging from carcasses, meat, milk, eggs or genetic material to hair, wool, feathers or manure, slurry) should be destroyed or processed in a way that inactivates the pathogenic agent. The inactivating process should be carried out in accordance with the relevant articles of the listed disease-specific chapters.

Stamping-out policy procedures systematically include the cleaning and disinfection of establishments and vehicles/vessels used for the transport of animals, carcasses or products, as well as of any equipment and material that has been in direct or indirect contact with the animals. The procedures may include disinsection or disinfestation in the case of vector-borne disease or parasitic infestation. These procedures should be conducted in accordance with the relevant articles of Chapter 4.13.

2. Test and cull

This strategy consists primarily of finding the ~~proven~~ infected animals in order to remove them from the population and either slaughter or kill and dispose of them. ~~This strategy is~~ It should be used for less contagious transmissible or slow-spreading diseases. Veterinary Services may apply different test and cull strategies based on the epidemiology of the infection or infestation or on the characteristics of available diagnostic tests. In particular, the design of test and cull strategy will depend on the sensitivity and specificity of the tests. Veterinary Services may adjust test and cull strategies to the changes of the prevalence.

Apart from the selection of animals to be culled, the same principles apply as for stamping-out policy in terms of processing, treatment and disposal of dead or slaughtered animals and their products.

Article 4.Y.7.

Movement control

Disease spread due to the movement of live animals, animal products and contaminated material should be controlled by movement restrictions that are adequately enforced.

These restrictions can be applied to one or more animal species and their associated products, and to people, vehicles/vessels and equipment. They may vary from pre-movement certification to total standstill, and be limited to one or more establishments, or cover specific zones, or the entire country. The restrictions can include the complete isolation of individual animals or group of animals, and specific rules applied to movements, such as protection from vectors.

Annex 15 (contd)

Specific rules covering movement controls should apply to each of any defined *zones*. Physical barriers ~~should~~ may be installed as needed, to ensure the effective application of movement restrictions.

Movement controls should be in place until the end of other disease control operations, ~~e.g. such as a stamping-out policy~~, and after *surveillance* and a revised risk assessment ~~has~~ have demonstrated they are no longer needed.

Veterinary Services should coordinate their movement control actions with other relevant authorities such as local authorities, and law enforcement agencies, and with communication media, as well as with the Veterinary Services of neighbouring countries in the case of transboundary animal diseases.

Article 4.Y.8.

Biosecurity

In order to avoid the spread of the pathogenic agent outside of the affected *establishments* or *infected zones*, and in addition to the management measures described in Articles 4.Y.5. to 4.Y.7., *biosecurity* should be applied, in particular measures to avoid the contamination of people's clothes and shoes, of equipment, of vehicles/vessels, ~~and~~ of the environment or anything capable of acting as a fomite.

Disinfection and disinsection should be applied in accordance with Chapter 4.13. When disinfection is applied, specific disinfectant solutions should be used for footbaths or disinfectant baths for vehicles' wheels. Single use material and clothes or material and clothes that can be effectively cleaned and disinfected should be used for the handling of *animals* and animal products; Protection of premises from wildlife and other unwanted animals should be ensured; Wastes, waste-water and other effluents should be collected and treated appropriately.

Article 4.Y.9.

Vaccination and treatment

Vaccination as part of an official control programme ~~in response to a contagious disease outbreak~~ should be conducted in accordance with Chapter 4.17.

Vaccination programmes, especially in response to an *outbreak*, require previous planning to identify potential sources of vaccine, including vaccine banks, and to plan the possible strategies for application, such as emergency barrier, blanket, vaccination or ring or targeted vaccination.

The properties of the vaccines should be well understood, especially the level of protection against *infection* or disease and the possibility to differentiate the immune response produced by the vaccine from that ~~produced~~ induced by *infection* with the pathogenic agent.

Although *vaccination* may hide ongoing *infection* or agent transmission, it can be used to decrease the shedding of the pathogenic agent, hence reduce the reproductive rate of the *infection*. In particular, when stamping-out is not feasible, *vaccination* can be used to reduce the circulation prevalence of the *infection* until its levels are ~~is~~ low enough for the implementation of another strategy ~~ies~~ such as a test and cull strategy.

Vaccination can also be used to minimise the impact of an infection by reducing clinical signs or economic losses.

Whenever *vaccination* is to be used as a tool to control *outbreaks* or spread of disease, the control plan should ~~include~~ consider an exit strategy, i.e. when and how to stop the *vaccination* or whether *vaccination* should become systematic routine.

Article 4.Y.10.

Zoning

The *Veterinary Authority* should use the tool of zoning in official control programmes, in accordance with Chapter 4.3.

Annex 15 (contd)

The use of zoning for disease control and eradication is inherently linked with measures of *killing or slaughter*, movement control, *vaccination* and *surveillance*, which apply differently according to the *zones*. In particular, efforts should be concentrated on those parts of a territory affected by the disease, to prevent the spread of the pathogenic agent and to preserve the status of the parts of the territory not affected by the disease.

~~Zones established defined in response to outbreaks of notifiable diseases or emerging diseases or listed diseases may be~~ are usually infected zones, containment zones and protection zones, and containment zones. However, ~~or~~ other types of zones, e.g. such as zones of intensified surveillance, or zones of intensified vaccination can also be used.

Article 4.Y.11.

Communication ~~in outbreak management~~

For the best implementation of disease control measures, *Veterinary Services* should ensure good communication with all concerned stakeholders, including the general public. This should be part of the official control programme and be carried out, among others, through awareness campaigns targeted at breeders, *veterinarians*, *veterinary paraprofessionals*, local authorities, the media, consumers and general public.

Veterinary Services should communicate before, during and after *outbreaks*, in accordance with Chapter 3.3.

Article 4.Y.12.

Specific post-control surveillance

Specific *surveillance* should be applied in order to monitor the effectiveness of the official control programme plan, and assess the status of the remaining *animal populations* in the different *zones* established by the *Veterinary Services*.

The results of this *surveillance* should be used to reassess the measures applied, including reshaping of the *zones* and re-evaluation of the culling or *vaccination* strategies, and for the eventual recovery of free status, if possible.

This *surveillance* should be conducted in accordance with Chapter 1.4. and with the relevant articles of the listed *disease-specific* chapters.

Article 4.Y.13.

Further outbreak investigation, monitoring, evaluation and review

In order to gather information required for any management information system, *Veterinary Services* should conduct an in-depth epidemiological investigation of each *outbreak* to build up a detailed first-hand, field-based knowledge of how the disease is transmitted, and inform further disease control plans. This requires staff who have been trained in the way to conduct it and the use of the standardised data collection forms.

Information gathered and experience gained should be used to monitor, evaluate and review *disease official control programmes plans*.

CHAPTER 7.Z.

ANIMAL WELFARE AND LAYING HEN
PRODUCTION SYSTEMS

Article 7.Z.1.

Definitions

For the purposes of this chapter:

Laying hens (hens): means sexually mature female birds of the species *Gallus gallus domesticus* kept for the commercial production of eggs for human consumption. ~~Laying hens kept in village or backyard flocks are excluded. Breeding hens are excluded.~~

End-of-lay hens: means laying hens at the end of their productive lives.

Layer pullets (pullets): means female birds of the species *Gallus gallus domesticus* raised for commercial layer production purposes from hatch until the onset of sexual maturity.

Article 7.Z.2.

Scope

~~This chapter addresses the welfare aspects of commercial laying hen production systems. This chapter~~ It covers the production period from the arrival of *day-old birds* on the pullet-rearing farm to the removal of end-of-lay hens from the laying production facilities. ~~Laying hens kept in village or backyard flocks and used for personal consumption are excluded.~~

Commercial production systems involve the confinement of pullets and hensbirds, the application of *biosecurity* and trade in ~~the~~ eggs or pullets. These recommendations cover pullets or laying hens kept in cage or non-cage systems, whether indoors or outdoors.

Commercial pullet or hen production systems include:

1. Indoor systems

Pullets or hens are completely confined in a poultry house, with or without mechanical environmental control and with no designated outdoor area.

2. Outdoor systems

Pullets or hens are kept in premises with or without mechanical environmental control but have access to that include a designated outdoor area.

This chapter should be read in conjunction with Chapters 6.5., 7.1., 7.2., 7.3., 7.4., 7.5. and 7.6.

Article 7.Z.3.

Criteria (or measurables) for the welfare of pullets and ~~or~~ hens

The welfare of pullets and ~~or~~ hens should be assessed using outcome-based measurables, specifically animal-based measurables. ~~Consideration should also be given to the resources provided and the design of the system. Outcome-based measurables, specifically animal-based measurables, can be useful indicators of animal welfare.~~ The use of these measurables ~~indicators~~ and the appropriate thresholds should be adapted to the different situations where pullets and hens are managed, also taking into account the genetics used ~~strain~~ of bird concerned.

Annex 16 (contd)

Consideration should also be given to the resources provided as well as the design and management of the system. Animal-based criteria can be considered as tools to monitor and refine these factors.

Criteria that can be measured in the farm setting include behaviour, body and plumage condition, egg shell condition, mortality and morbidity rates, bone and foot problems, etc. together with other factors such as genetics and environment. The age at which abnormalities of these criteria are observed can help to determine the origin causation of potential problems. ~~Other conditions such as bone and foot problems, disease, infection or infestation can also be assessed at depopulation or during routine sampling. It is recommended that values for welfare measurables be determined with reference to appropriate national, sectorial or regional standards for pullets or hens.~~

Conditions such as bone and foot problems, disease, infection or infestation can be assessed during routine or targeted sampling and at depopulation. It is recommended that target values or thresholds for welfare measurables be determined with reference to current scientific knowledge and appropriate national, sectorial or regional standards for pullets or hens.

The following outcome-based criteria and measurables are can be useful indicators of pullet or hen welfare:

1. Behaviour

The presence or absence of certain ~~chicken~~ behaviours could indicate either good animal welfare or an animal welfare problem, such as including fear, pain or sickness. ~~In addition, chickens have evolved behaviours that they are highly motivated to perform and a good understanding of normal chicken behaviour [Nicol, 2015], including their social interactions [Estevez et al., 2007; Rodríguez-Aurrekoetxea, A. and Estevez, I., 2014], is required. Some behaviours may not be uniquely indicative of one type of problem; they may be exhibited for a variety of reasons. The domestic fowl have evolved behaviours that they are highly motivated to perform and a good understanding of their normal behaviour [Nicol, 2015], including their social interactions [Estevez et al., 2007; Rodríguez-Aurrekoetxea A. and Estevez I., 2014], is required for appropriate management decision making. Opportunities to display these behaviours are influenced by the physical and social environment [Widowski et al., 2016; Lay et al., 2011; O'Connor et al., 2011].~~

a) Dust bathing

Dust bathing is an intricate body maintenance behaviour. During dust bathing, pullets and hens work loose material, such as litter, through their feathers. This behaviour helps remove stale lipids dirt [Van Liere and Bokma, 1987] and parasites [Martin and Mullen, 2012], which contributes to maintaining plumage condition, which in turn helps to maintain body temperature and to protect against skin injury. Reduced dust bathing behaviour in the *flock* may indicate problems with litter or range quality, such as the litter or ground being wet or not friable [Olson and Keeling, 2005; Van Liere and Bokma, 1987]. The presence of complete sequences of dust bathing may indicate good welfare [Widowski and Duncan, 2000].

b) Fear behaviour

Fearful pullets and hens show high reactivity to various stimuli [Jones R. B., 1987; Zeltner and Hirt, 2008]. Fearfulness can lead to traumatic injuries, and suffocation when the pullets and hens pile on top of, and ~~sometimes suffocate,~~ one another. Fearful pullets and hens may be less productive [Barnett J. et al., 1992] and more prone to injurious feather pecking behaviour [Hass et al., 2014]. Methods have been developed for evaluating fearfulness, for example when while animal handlers walk through the poultry house or pullets and hens area [Jones, 1996; Forkman et al., 2007].

c) Feeding and drinking behaviour

~~Reduced~~ Changes in feeding or drinking behaviour can may indicate management problems, including inadequate spaces for, or inappropriate placement of, feeders or drinkers, dietary imbalances, poor feed or water quality, or feed contamination [Garner et al., 2012; Thogerson et al., 2009a; Thogerson et al., 2009b]. Feeding and drinking are often depressed when birds are ill, and intake may also be reduced change during periods of heat [Lara L. J. & Rostagno M. H., 2013; Lin H. et al., 2006] stress and increased or during cold stress [Alves et al., 2012] [Garner et al., 2012; Thogerson et al., 2009a; Thogerson et al., 2009b].

d) Foraging activity

Foraging is the act of searching for food, typically by walking and pecking or scratching the ~~litter~~ substrate. Reduced foraging activity could suggest problems with ~~litter~~ substrate quality or the presence of conditions that decrease pullets and hens' movement [Appleby *et al.*, 2004; Lay *et al.*, 2011; Weeks and Nicol, 2006]. When in the presence of an adequate substrate, laying hens spend a large amount of time foraging even when food is readily accessible [Weeks and Nicol, 2006]. Frequent foraging bouts may indicate good welfare [Dawkins, 1989; Duncan and Hughes, 1972] and reduce the incidence of injurious feather pecking [Blokhuys, 1989].

e) Injurious feather pecking and cannibalism

Injurious feather pecking can result in significant feather loss and may lead to cannibalism. Cannibalism is the tearing of the flesh of another bird, and can result in severe injury or death. These behaviours can have multifactorial causes [Hartcher, 2016; Estevez, 2015; Nicol *et al.*, 2013; Rodenburg, 2013; Lambton, 2013; Newberry, 2004].

f) ~~Locomotory~~ and comfort behaviours

~~Locomotory~~ and comfort behaviours are important for the health of the pullets and hens, allowing for skeletal, body and plumage development and their maintenance. These behaviours and may include walking, running, leaping, turning, stretching legs and wings, wing flapping, feather ruffling and tail wagging and preening [Dawkins and Hardie, 2007; Shipov *et al.*, 2010; Norgaard, 1990].

~~Opportunities to display these behaviours are influenced by housing system and space [Widowski *et al.*, 2016; Lay *et al.*, 2011].~~

g) Nesting

Nesting is a natural and highly motivated behaviour that includes nest site selection, nest formation and egg laying [Cooper and Albertosa, 2003; Weeks and Nicol, 2006; Cronin *et al.*, 2012; Yue and Duncan, 2003]. Uneven nest box utilisation and egg laying outside the nests may be indicative of problems with environmental or social behavioural factors [Cronin *et al.*, 2012; Cooper and Appleby, 1996; Gunnarsson *et al.*, 1999].

h) Perching

Perching is a natural and highly motivated behaviour. ~~Birds~~ Pullets and hens seek elevation during the day; the motivation to seek elevation is particularly strong at night when pullets and hens select a site for resting or sleeping [EFSA, 2015]. Reduced perching behaviour in the *flock* may indicate problems with environmental factors, injuries and pullet rearing experience [Janczak and Riber, 2015; Gunnarsson *et al.*, 1999].

i) Resting and sleeping

Sleeping is a natural behaviour in pullets and hens, including slow-wave and fast-wave sleep states [Blokhuys, 1983]. Sleep is an adaptive state that allows animals to recover from daily stress, conserve energy and consolidate memory [Siegel, 2009]. Pullets and hens display highly synchronized resting and sleeping behaviours, which can be disrupted by light intensity, photoperiod, environmental or social factors [Malleau *et al.*, 2007; Alvino *et al.*, 2009].

ij) Social behaviour

~~Pullets and hens~~ Chickens are a highly social species, engaging in synchronised behaviour [Olsson *et al.*, 2002; Olsson and Keeling, 2005]. Benefits include social learning, protection from predators [Newberry *et al.*, 2001], aiding help in thermoregulation and plumage maintenance. Social behaviour may differ according to the characteristics of the social environment (Estevez *et al.*, 2002; 2007). Problems in social behaviour can be assessed using scoring systems for measuring the degree of aggression damage and competition for resources [Estevez *et al.*, 2002].

Annex 16 (contd)j/k) Spatial distribution

Uneven spatial distribution of the birds may indicate thermal discomfort or uneven availability or use of resources, such as light, food or water, shelter, nesting area and comfortable resting locations. [Rodríguez-Aurrekoetxea and Estevez, 2016; ~~Cornetto and Estevez, 2004~~; Bright and Johnson, 2011].

k/l) Thermoregulatory behaviour

Prolonged or excessive panting and wing spreading are observed during heat stress [Mack, 2013; Lara and Rostagno, 2013]. Indicators of cold stress include feather ruffling, rigid posture, trembling, huddling and ~~piling on top of each other and~~ distress vocalisations.

m) Vocalisation

Vocalisation can indicate emotional states, both positive and negative. A good understanding of *flock* vocalisations is useful for good animal care [Zimmerman *et al.*, 2000; Bright, 2008; Koshiba *et al.*, 2013].

2. Body condition

Poor body condition is reflective of ~~poor~~ animal welfare outcomes problems for individual birds. At *flock* level, uneven body condition may be an indicator of ~~potential poor~~ animal welfare problems. Body condition can be evaluated using on-farm sampling methods for body weight or body condition scores [Gregory and Robins, 1998; Craig and Muir, 1996; Elson and Croxall, 2006; Keeling *et al.*, 2003]. The choice of sampling methods should take into account feather cover that can mask actual body condition.

3. Eye conditions

Conjunctivitis can indicate disease or the presence of irritants such as dust and ammonia. High ammonia levels can also cause corneal burns and eventual blindness. Abnormal eye development ~~can~~ may be associated with low light intensity [Jenkins *et al.*, 1979; Lewis and Gous, 2009; Prescott *et al.*, 2003].

4. Foot problems

Hyperkeratosis, ~~and~~ bumblefoot, excessive claw growth, broken claws and toe injuries are painful conditions associated with inappropriate flooring, poorly designed perches or poorly maintained litter [EFSA, 2005; Lay *et al.*, 2001; Abrahamsson and Tauson, 1995; Abrahamsson and Tauson, 1997].

~~Excessive claw growth, broken claws and toe injuries affect locomotion and may be associated with pain [EFSA, 2005].~~

Contact dermatitis affects skin surfaces that have prolonged contact with wet litter, manure or other wet flooring surfaces [Tauson and Abrahamson, 1996].

Foot problems are usually manifested as blackened skin progressing to erosion and fibrosis on the lower surface of the footpads and at the back of the hocks. If severe, the foot and hock lesions may contribute to locomotion problems and lead to secondary *infections*. Scoring systems for foot problems have been developed [Blatchford *et al.*, 2016].

5. Incidence of diseases, infections, metabolic disorders and infestations

Ill-health, regardless of the cause, is a welfare concern, and may be exacerbated by poor environmental or husbandry management.

6. Injury rate and severity

Injuries are associated with pain and risk of infection. The rate and severity of injuries ~~can~~ indicate health and welfare problems, in the flock during production. They can be a consequence of the actions of ~~Injuries include those caused by~~ other birds (e.g. scratches, feather loss or wounding), management (e.g. nutrition), ~~by~~ environmental conditions, (e.g. fractures and keel bone deformation), ~~and or by~~ human intervention (e.g. during handling and catching).

7. Mortality, culling and morbidity rates

Daily, weekly and cumulative mortality, culling and morbidity rates should be within expected ranges. Any unforeseen increase in these rates could reflect an *animal welfare* problem.

8. Performance

Daily, weekly and cumulative performance should be within expected ranges. Any unforeseen reduction ~~decreases~~ in these rates ~~could~~ may be reflective of the welfare status of the individual birds or the *flocks*.

- a) Pullet growth rate measures average daily mass gain per average pullet and *flock* uniformity.
- b) Pullet feed conversion measures ~~the~~ quantity of feed consumed by a *flock* relative to the total live mass produced, expressed as the mass of feed consumed per unit of body mass.
- c) Hen feed conversion measures ~~the~~ mass of feed consumed by a *flock* relative to the unit of egg production.
- d) Egg production, ~~such as when~~ measured by e.g. the number of eggs per hen housed.
- e) Egg quality and downgrades, ~~such as when~~ measured by e.g. grade percentage, shell strength ~~and~~ Haugh units, abnormalities and mis-laid or floor eggs.

9. Plumage condition

Evaluation of ~~the~~ plumage condition of ~~pullets and hens~~ provides useful information about aspects of welfare. Feather loss and damage can result from injurious feather pecking behaviour, nutritional problems, external parasites and abrasions ~~resulting from faults in the equipment housing system~~ [Rodriguez-Aurrekoetxea and Estevez, 2016; Drake *et al.*, 2010]. Plumage dirtiness may be associated with illness, ~~the~~ environmental conditions ~~and or~~ production system. Plumage scoring systems have been developed for these purposes [Blokhuys, 2007].

10. Water and feed consumption

Monitoring daily water and feed consumption is a useful tool ~~to~~ which may indicate thermal stress, disease, *infection* or *infestation* and other welfare conditions, taking into consideration ambient temperature, relative humidity and other related factors. ~~Problems with the water or feed quality and supply can result in~~ Changes in intake, crowding at feeders and drinkers and wet litter and diarrhoea, dermatitis, dehydration, changes in egg quality or quantity, production and body condition may be associated with problems with the water or feed quality and supply.

Article 7.Z.4.

Recommendations

Ensuring good welfare of pullets and hens is contingent on several management factors, including system design, environmental and animal management practices which include responsible husbandry and provision of appropriate care. Serious problems can arise in any system if one or more of these elements are lacking.

Articles 7.Z.5. to 7.Z.29. provide recommendations for measures applied to pullets and hens.

Each recommendation in Article 7.Z.5. to 7.Z.29. includes a list of relevant animal-based criteria and measurables derived from Article 7.Z.3. This does not exclude other criteria and measurables being used where or when appropriate. The suitability of some of these criteria and measurables will be determined by the system in which the pullets and hens are housed.

~~Each recommendation includes a list of relevant outcome-based measurables derived from Article 7.Z.3. This does not exclude other measures being used when appropriate.~~

Annex 16 (contd)

Article 7.Z.5.

Location, design, construction and equipment of establishments

The location of pullets and hen *establishments* should be chosen to be safe from the effects of fires and floods and other natural disasters to the extent practicable. In addition, *establishments* should be located or designed to avoid or minimise disease risks, exposure of pullets and hens to chemical and physical contaminants, noise and adverse climatic conditions.

Pullet and layer houses, outdoor areas and accessible equipment should be designed, after consideration of ~~bird~~ the opportunities for pullets and hens to perform highly motivated behaviours (e.g. perching and nesting), to promote good *animal welfare* and be maintained to avoid injury or discomfort ~~pain to the birds.~~

Pullet and layer houses should be constructed with materials and electrical and fuel installations that minimise the risk of fire and other hazards.

Producers should have a maintenance programme in place for all equipment and contingency plans in place to deal with, the failures of which could jeopardise ~~bird~~ pullet and hen welfare.

~~Outcome~~Animal-based measurables include: culling and morbidity rates, fear behaviour, feeding, and drinking behaviour, and foraging activity, foot problems, incidence of diseases, *infections* and *infestations*, injury rates and severity, locomotion and comfort behaviours, mortality rates, performance, plumage condition, resting and sleeping, social behaviour and spatial distribution, thermoregulatory behaviour, vocalisations.

Article 7.Z.6.

Matching the birds and the housing and production system

Welfare and health considerations should balance any decisions on performance when choosing a layer strain for a particular location, housing and production system. The pullet rearing system should pre-adapt ~~prepare~~ the bird for the intended ~~layer~~ production system [*Aerni et al., 2005*].

~~Animal~~Outcome-based measurables include: dust bathing, feeding, and drinking behaviours, foraging activity, incidence of diseases, injurious feather pecking and cannibalism, injury rate and severity, locomotory ~~ion~~ and comfort behaviours, mortality rate, nesting, *infestations*, perching, performance, plumage condition, resting and sleeping, social behaviour, spatial distribution.

Article 7.Z.7.

Stocking density Space allowance

Pullets and hens should be housed with at a space allowance ~~stocking density~~ that allows them to have adequate access to resources and to express locomotory ~~ion~~ and comfort behaviours. The following factors should be taken into account:

- management capabilities,
- ambient conditions,
- housing design ~~system~~
- usable space,
- production system,
- litter quality,
- ventilation,
- *biosecurity* strategy,
- genetics ~~strain~~,
- age and bird mass.

Annex 16 (contd)

~~Animal Outcome~~-based measurables include: dust bathing, feeding and drinking and foraging behaviour, foraging activity, feeding, incidence of diseases, *infections* and *infestations*, injury rate and severity, locomotory and comfort behaviours, mortality rate, nesting, perching, performance, plumage condition, resting and sleeping, social behaviour, spatial distribution.

Article 7.Z.8.

Nutrition

Pullets and hens should always be fed a diet appropriate to their age, production stage and genetics strain, which contains adequate nutrients to meet their requirements for good health and welfare.

The form and quality of feed and water should be acceptable to the birds and free from contaminants, debris and microorganisms hazardous to bird health.

The feeding and watering systems should be inspected regularly and cleaned as needed regularly to prevent the growth of hazardous microorganisms.

~~Birds~~ Pullets and hens should be provided with adequate access to feed on a daily basis. Water should be continuously available except under veterinary advice. Special provision should be made to enable newly hatched pullets chicks to access appropriate feed and water.

~~Animal Outcome~~-based measurables include: aggression, body condition, performance (egg quality), water and feed consumption, foraging activity behaviour, incidence of disease, *infections* and *infestations*, injurious feather pecking, injury rate and severity, metabolic disorders, mortality rate, performance, plumage condition, vocalisations.

Article 7.Z.9.

Flooring

~~The flooring for the birds should be easy to clean and disinfect and not cause harm or damage to them.~~

The slope, and design and construction of the floor should allow birds pullets and hens to express normal locomotory and comfort behaviours. The floors should provide adequate support the birds adequately, prevent injuries, entrapments and ensure good health and that manure does not contaminate other birds pullets and hens. Changes of flooring types from pullet to layer housing should be avoided. The flooring should be easy to clean and disinfect and should not cause harm.

~~The provision of loose and dry litter material is desirable to encourage dust bathing and foraging by pullets and hens. When litter is provided it should be managed to minimise any detrimental effects on welfare and health. Litter should be managed to remain dry and friable, replaced or adequately treated or replaced when required to prevent diseases and minimise any detrimental effects on welfare, infections and infestations.~~

~~Animal Outcome~~-based measurables include: comfort behaviour, dust bathing, foot problems, foraging, incidence of diseases, *infections* and *infestations*, injury rates and severity, locomotory, performance, plumage condition, resting and sleeping.

Article 7.Z.10.

Dust bathing areas

The provision of friable, dry litter material is desirable to encourage dust bathing by pullets and hens.

~~When dust bathing areas are offered, they should be provide suitable friable materials, designed and positioned to encourage dust bathing, allow synchronised behaviour, prevent undue competition and not cause damage or injuries. Dust bathing areas should be easy to inspect and maintain clean [Lentfer et al., 2014] [Weeks and Nicol, 2006].~~

~~Animal Outcome~~-based measurables include: dust bathing, injury rate and severity, plumage condition, spatial distribution.

Annex 16 (contd)

Article 7.Z.11.

Foraging areas

The provision of friable, dry litter material is desirable to encourage foraging activity by pullets and hens.

~~When foraging areas are offered, they~~ should provide suitable materials, and be designed and positioned to encourage foraging activity, allow synchronised behaviour, prevent undue competition and not cause damage or injuries. Foraging areas should be easy to inspect and maintain clean.

~~Animal Outcome~~-based measurables include: foraging activity, injurious feather pecking and cannibalism, injury rate and severity, spatial distribution.

Article 7.Z.12.

Nesting areas

~~When nesting areas should be provided are offered, they and should~~ be built of suitable materials, designed and positioned to encourage nesting, prevent undue competition and not cause damage or injuries. Nesting areas should be easy to inspect, clean and maintain disinfect.

~~Animal Outcome~~-based measurables include: injurious feather pecking and cannibalism, injury rate and severity, nesting, performance, (mis-laid or floor eggs), spatial distribution.

Article 7.Z.13.

Perches

~~When perches should be provided are offered, they and should~~ be built of suitable materials, designed, elevated and positioned to encourage perching for all pullets and hens, to prevent keel bone deformation ~~or~~ foot problems or other harms, and to maintain stability ~~of the birds~~ during perching. In the absence of designated perches, platforms, grids and slats that are perceived by the pullets and hens ~~birds~~ as elevated and that do not cause damage or injuries, may be a suitable alternative. Perches or their alternatives should be easy to clean and maintain, disinfect and positioned to minimise faecal fouling [Hester, 2014; EFSA, 2015].

~~Perch elevation should be carefully considered to minimise injurious feather pecking, cannibalism, keel deformities and fractures.~~

~~Animal Outcome~~-based measurables include: foot problems, injurious feather pecking and cannibalism, injury rate and severity, perching, plumage condition, resting and sleeping, spatial distribution.

Article 7.Z.14.

Outdoor areas

Pullets and hens can be given access to outdoor areas ~~as soon as when~~ they have sufficient feather cover and ~~are old enough to can~~ range safely. There should be sufficient appropriately designed ~~exit areas~~ openings to allow them to leave and re-enter the poultry house freely.

Management of outdoor areas is important. Land and pasture management measures should be taken to reduce the risk of birds becoming infected by pathogenic agents, infested by parasites or being injured. This might include limiting the stocking density or using several pieces of land consecutively in rotation.

Outdoor areas should be located on well-drained ground and managed to minimise ~~swampy conditions~~ standing water and mud. The outdoor area should be able to contain the Pullets and hens ~~birds~~ and prevent them escaping. Outdoor areas should allow pullets and hens to feel safe outdoors and be encouraged to optimise utilisation of the range, while mitigating predation and disease risks [Gilani *et al.*, 2014; Hegelund *et al.*, 2005; Nagle and Glatz, 2012]. Hens should be habituated early to the outdoor area [Rodriguez-Aurrekoetxea and Estevez, 2016]. Outdoor areas should provide shelter for the birds and be free from ~~poisonous~~ harmful plants and contaminants.

Annex 16 (contd)

Animal Outcome-based measurables include: fear behaviour, foot problems, foraging activity, incidence of diseases, injury rate and severity, locomotory ~~ion~~ and comfort behaviours, morbidity rate, mortality rate, infestations, performance, plumage condition, social behaviour, spatial distribution, thermoregulatory behaviour, vocalisation.

Article 7.Z.15.

Thermal environment

Thermal conditions for pullets and hens should be maintained within a range that is appropriate for their stage of life, and extremes of heat, humidity and cold should be avoided. A heat index can assist in identifying the thermal comfort zones for the pullets and hens at varying temperature, air velocity and relative humidity levels, and can be found in management guidelines provided by primary laying hen genetics companies [Xin and Harmon, 1998].

When environmental conditions move outside of these zones, strategies should be used to mitigate the adverse effects on the pullets and hens birds. These may include adjusting air speed, provision of heat or evaporative cooling [Yahav, 2009].

Control of the thermal environment should be monitored frequently enough so that failure of the system will be noticed detected and corrected before it causes a welfare problem.

Animal Outcome-based measurables include: morbidity rate, mortality rate, performance, spatial distribution, thermoregulatory behaviours, water and feed consumption.

Article 7.Z.16.

Air quality

Ventilation, housing, and manure management can affect air quality. Actions are required to maintain air quality at all times, including the removal or mitigation of noxious ~~of waste~~ gases such as carbon dioxide and ammonia, dust and excess moisture ~~content from in~~ the environment.

~~The a~~Ammonia concentration should not routinely exceed 25 ppm at bird level [David *et al.*, 2015; Milles *et al.*, 2006; Olanrewaiu, 2007].

Dust levels should be kept to a minimum [David, 2015]. ~~Where the health and welfare of birds depend on an artificial ventilation system, provision should be made for an appropriate back-up power and alarm system.~~

Animal Outcome-based measurables include: eye conditions, incidence of respiratory diseases, plumage condition, performance.

Article 7.Z.17.

Lighting

There should be an adequate period of continuous light.

The light intensity during the light period should be sufficient and homogeneously distributed to promote ~~for~~ normal development ~~of the birds~~, for finding feed and water, to stimulate activity, to stimulate onset of lay, minimise likelihood of feather pecking and cannibalism and to allow adequate inspection [Prescott *et al.*, 2003; Prescott and Wathes, 1999; Green *et al.*, 2000].

There should also be an adequate period of ~~light and~~ darkness during each 24-hour cycle to allow pullets and hens ~~the birds~~ to rest, to reduce stress and to promote circadian rhythms [Malleau *et al.*, 2007].

When changes in lighting are needed, they should be performed in a step-wise fashion, except during induced moulting ~~(if practised)~~ when rapid adjustments to lighting should be considered ~~are desired~~.

Animal Outcome-based measurables include: eye conditions, injurious feather pecking and cannibalism, injury rate and severity, locomotory ~~ion~~-behaviours, nesting, perching, performance, plumage condition, resting and sleeping, spatial distribution.

Annex 16 (contd)

Article 7.Z.18.

Noise

Pullets and hens are adaptable to different levels and types of noise. ~~However, Exposure of birds pullets and hens to unfamiliar noises, particularly those that are sudden or loud, should be minimised wherever possible to prevent stress and fear reactions, such as piling up [Bright and Johnson, 2001].~~ Ventilation fans, machinery or other indoor or outdoor equipment should be constructed, placed, operated and maintained in such a way ~~that it~~ causes the least possible amount of noise [Chloupek *et al.*, 2009].

Location of establishments should, where possible, take into account existing local sources of noise. Strategies should be implemented to habituate the birds to the conditions [Candland *et al.*, 1963; Morris, 2009].

~~Animal Outcome~~-based measurables include: fear behaviours, injury rate and severity, mortality rate, performance, resting and sleeping, vocalisation.

Article 7.Z.19.

Prevention and control of injurious feather pecking and cannibalism

Injurious feather pecking and cannibalism are challenges in pullet and hen production.

Management methods that may reduce the risk of occurrence include:

- managing light in rearing and lay [Nicol *et al.*, 2013; van Niekerk *et al.*, 2013],
- choosing genetics strain with a low propensity to injurious feather pecking [Craig and Muir, 1996; Kjaer and Hocking, 2004],
- influencing age of onset of lay [Green *et al.*, 2010],
- providing foraging or other manipulable materials in rearing and lay [Huber-Eicher and Wechsler, 1998; de Jong *et al.*, 2010; Daigle *et al.*, 2014],
- adapting diet and form of feed in rearing and lay [Lambton *et al.*, 2010],
- ~~reducing stocking density~~ [Zimmerman *et al.*, 2006];
- reducing group size in rearing and lay [Bilcik and Keeling, 1999],
- providing elevated perches in rearing and lay [Green *et al.*, 2010],
- treating beaks in chicks [Gentle and Hughes, 1997], especially by using new non-invasive beak treatments that are being developed,
- minimising fear-related stimuli [Uitdehaag K. A. *et al.*, 2009].
- ~~introducing males~~ [Bestman and Wagenaar, 2003].

Management methods to control the occurrence include the above list, where applicable, and prompt removal of affected pullets and hens to a hospital area or euthanasia.

If these management strategies fail, therapeutic beak treatment ~~trimming is the last resort.~~ may be considered as a final course of action.

~~Animal Outcome~~-based measurables include: injurious feather pecking and cannibalism, injury rate and severity, mortality and culling rate, plumage condition, vocalisation.

Article 7.Z.20.

Moulting

Induced moulting can lead to animal welfare problems if not well managed. When induced moulting is practised, techniques that do not involve withdrawal of feed ~~should be used~~ and are consistent with Article 7.Z.8. should be used. Hens should have light and have access to water at all times. Only hens in good body condition and health should be moulted. During the moulting period, body mass loss should not compromise hen welfare, including welfare during the subsequent laying period. Total mortality and culling rate during the moult period should not exceed normal variations in *flock* mortality and culling rate.

Annex 16 (contd)

~~Animal Outcome~~-based measurables include: body condition, feeding and drinking, foraging activity [Biggs *et al.*, 2004; Saiozkan *et al.*, 2016; Petek and Alpay, 2008], injurious feather pecking and cannibalism, injury rate and severity, morbidity rate, mortality and culling rate, performance, plumage condition, social behaviour.

Article 7.Z.21.

Painful interventions

Painful interventions, such as beak ~~treatment~~trimming, should not be practised unless ~~absolutely~~ necessary and pain mitigation interventions should be used. Beak trimming at a mature age can cause chronic pain. Other mutilations (e.g. dubbing and toe trimming) should not be performed in pullets and hens. Pain-free alternatives should be favoured ~~are preferred~~. If preventive beak ~~treatment~~trimming is required, it should be carried out by ~~trained and skilled personnel~~ at the earliest age possible and care should be taken to remove the minimum amount of beak necessary using a method, which minimises pain and controls bleeding. ~~Current methods include infrared treatment or hot blade cutting. Beak trimming at a mature age can cause chronic pain.~~ If management strategies to control injurious feather pecking and cannibalism fail, therapeutic beak treatment may be considered as a final course of action [Gentle *et al.*, 1991; Marchand-Forde *et al.*, 2008; Marchand-Forde *et al.*, 2010; McKeegan and Philbey, 2012; Freire *et al.*, 2011; Glatz *et al.*, 1998]. Other mutilations (e.g. dubbing and toe trimming) should not be performed in pullets and hens.

~~Beak trimming at a mature age can cause chronic pain.~~ If therapeutic beak trimming is required, at whatever age, it should be carried out by ~~trained and skilled personnel~~ and care should be taken to remove the minimum amount of beak necessary using a method which minimises pain and controls bleeding.

~~Animal Outcome~~-based measurables include: feeding and drinking behaviour and foraging activity, feeding, injurious feather pecking and cannibalism, locomotory and comfort behaviours, mortality rate, morbidity rate, performance, plumage condition, vocalisations.

Article 7.Z.22.

Animal health management, preventive medicine and veterinary treatment

Animal handlers responsible for the care of pullets and hens should have ~~be knowledge aware~~ of normal pullet and hen behaviour, ~~the~~ and be able to detect signs of ill-health or distress, such as a change in feed and water intake, reduced production, changes in behaviour, abnormal plumage condition ~~appearance of feathers~~, faeces, or other physical features.

If they are ~~not~~ unable to identify the causes of disease, ill-health or distress, or unable to correct these, or if they suspect the presence of a *notifiable disease*, they should seek advice from *veterinarians* or other qualified advisers. Veterinary treatments should be prescribed by a *veterinarian*.

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

Vaccinations and treatments should be administered by personnel skilled in the procedures and with consideration for the welfare of the pullets and hens.

Sick or injured pullets and hens should be placed in a hospital area for observation and treatment or humanely killed in accordance with Chapter 7.6. as soon as possible.

~~Animal Outcome~~-based measurables include: body condition, incidence of diseases, injury rate and severity, metabolic disorders and *infestations*, morbidity rate, mortality rate, performance.

Article 7.Z.23.

Biosecurity

Biosecurity plans should be designed and implemented, commensurate with the best possible pullets and hens ~~birds~~ health status and current disease *risk* (endemic and exotic or transboundary) that is specific to each epidemiological group of pullets and hens and in accordance with relevant recommendations in the *Terrestrial Code*.

Annex 16 (contd)

These programmes should address the control of the major routes for *infection* and *infestation* such as:

- direct transmission from other *poultry*, domestic *animals* and *wildlife* and humans,
- fomites, such as equipment, facilities and vehicles,
- *vectors* (e.g. arthropods and rodents),
- aerosols,
- water supply,
- feed,
- the practice of partially restocking the house (back filling), due to catastrophe or incomplete *flock* placement, which should only be performed with due consideration to *biosecurity* and in a manner that prevents commingling of *flocks*.

~~Animal Outcome-based~~ measurable-based measurables include: incidence of diseases, ~~infestations, morbidity rate, mortality rate, culling and~~ morbidity rates, ~~mortality rate,~~ performance.

Article 7.Z.24.

Humane killing of individual birds or flocks

Individual sick or injured pullets or hens requiring euthanasia should be humanely killed as soon as possible. When an individual or groups of pullets or hens birds are killed for euthanasia, diagnostic purposes, depopulation of end-of-lay *flocks* or for purposes of disease control, the techniques used should be performed in a humane manner in accordance with Chapter 7.6.

Article 7.Z.25.

Depopulation of pullet and layer hen facilities

This article refers to removal of pullets and laying hens from facilities for whatever reason and should be read in conjunction with Article 7.Z.24.

Pullets and hens should not be subjected to an excessive period of feed withdrawal prior to ~~the expected~~ depopulation ~~time~~ [Webster, 2003].

Water should be available up to the time of depopulation.

~~Birds~~ Pullets and hens that are not fit for *loading* or transport ~~because they are sick or injured~~ should be humanely killed.

Catching should be carried out by competent *animal handlers* in accordance with the condition of Article 7.Z.28. and every attempt should be made to minimise stress, fear reactions and injuries. If a pullet or hen bird is injured during catching, it should be humanely killed.

~~Birds~~ Pullets and hens should be handled and placed into the transport *container* according to Chapter 7.3. Article 7.Z.14.

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

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

Stocking density in transport *containers* should comply with Chapters 7.2., 7.3. and 7.4.

~~Animal Outcome-based~~ measurable-based measurables include: fear behaviour, injury rate and severity, mortality ~~at depopulation and on arrival at the destination~~, spatial distribution, vocalisation.

Article 7.Z.26.

Emergency Contingency plans

Pullet and hen producers should have ~~emergency contingency~~ plans to minimise and mitigate the consequences of natural disasters, disease *outbreaks* and the failure of mechanical equipment. Planning should include a fire safety plan and where relevant, may include the provision, maintenance and testing of fail-safe alarm devices to detect malfunctions, backup generators, access to maintenance providers, alternative heating or cooling arrangements, ability to store water on farm, access to water cartage services, adequate on-farm storage of feed and alternative feed supply, a fire safety plan and a plan for managing ventilation emergencies.

The ~~emergency contingency~~ plans should be consistent with national programmes established or recommended by *Veterinary Services*. Humane emergency *killing* procedures should be a part of the plan according to the methods recommended in Chapter 7.6.

~~Animal Outcome~~-based measurables include: culling, morbidity and mortality rates.

Article 7.Z.27.

Personnel competency

All *animal handlers* responsible for the pullets and hens should have received appropriate training or be able to demonstrate that they are competent to carry out their responsibilities and should have sufficient knowledge of pullet and hen~~bird~~ behaviour, handling techniques, emergency killing procedures, *biosecurity*, general signs of diseases, and indicators of poor *animal welfare* and procedures for their alleviation.

~~Animal Outcome~~-based measurables include: fear behaviour, incidence of diseases, locomotory~~ion~~ and comfort behaviours, performance, ~~morbidity rate~~, mortality, culling and morbidity rate, spatial distribution, vocalisation.

Article 7.Z.28.

Inspection and handling

Pullets and hens and facilities and equipment within their premises should be inspected at least daily. Inspection should have the following three main objectives: to identify sick or injured birds to treat or cull them, to detect and correct any welfare or health problem in the flock and to pick up dead birds.

- = to identify sick or injured pullets and hens and to treat or cull them;
- = to pick up dead pullets and hens;
- = to detect and correct any welfare or health problem in the flock; and
- = to detect and correct malfunctioning equipment and other facility problems.

Inspection should be done in such a way that ~~birds~~ pullets and hens are not unnecessarily disturbed, for example *animal handlers* should move quietly and slowly through the *flock*.

When pullets and hens are handled, particularly when ~~birds are~~ placed into or removed from the house, they should not be injured, and should be held in postures that minimise fear and stress unnecessarily frightened or stressed (e.g. should be restrained in an upright posture) [Gregory & Wilkins, 1989; Gross & Siegel, 2007; Kannan & Mench, 1996]. The distances pullets and hens are carried should be minimised. Laying hens are prone to bone fractures when not handled properly.

~~Animal Outcome~~-based measurables include: fear behaviour, injury rate and severity, ~~morbidity rate~~, mortality, culling and morbidity rates, performance, spatial distribution, vocalisation.

Annex 16 (contd)

Article 7.Z.29.

Protection from predators

Pullets and hens should be protected from predators in indoor and outdoor areas. All production systems should be designed and maintained to prevent access by predators and wild birds.

Animal Outcome-based measurables include: fear behaviour, ~~mortality~~, injury rate and severity, locomotion and comfort behaviours, mortality, culling and morbidity rates, performance, spatial distribution, vocalisation.

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CHAPTER 15.2.

INFECTION WITH CLASSICAL SWINE FEVER VIRUS

Article 15.2.1.

General provisions

The pig (*Sus scrofa*, both domestic and wild) is the only natural host for classical swine fever virus (CSFV). For the purposes of this chapter, a distinction is made between:

- ≡ domestic and captive wild pigs, whether permanently housed or free ranging, used for the production of meat, or other commercial products or purposes use, or for breeding; and
- ≡ wild and feral pigs.

For the purposes of the *Terrestrial Code*, classical swine fever (CSF) is defined as an *infection* of pigs with classical swine fever virus (CSFV).

The following defines the occurrence of infection with CSFV:

- 1) a strain of CSFV (excluding vaccine strains) has been isolated from samples from a pig;

OR

- 2) ~~viral antigen or nucleic acid specific to CSFV~~ (excluding vaccine strains) has been identified detected, or ~~viral ribonucleic acid (RNA) specific to a strain of CSFV has been demonstrated to be present~~, in samples from ~~one or more a pigs showing clinical signs or pathological lesions suggestive of CSF, or epidemiologically linked to a suspected or confirmed or suspected outbreak case~~ of CSF, or giving cause for suspicion of previous association or contact with CSFV, ~~with or without clinical signs consistent with CSF;~~

OR

- 3) ~~virus specific antibodies specific to CSFV that are not a consequence of vaccination or infection with other pestiviruses~~, have been identified detected in samples from ~~one or more a pigs in a herd showing clinical signs or pathological lesions consistent with CSF, or epidemiologically linked to a suspected or confirmed or suspected outbreak case~~ of CSF, or giving cause for suspicion of previous association or contact with CSFV.

~~The pig is the only natural host for CSFV. The definition of pig includes all varieties of *Sus scrofa*, both domestic and wild. For the purposes of this chapter, a distinction is made between:~~

- ~~– domestic and captive wild pigs, permanently captive or farmed free range, used for the production of meat, or other commercial products or use, or for breeding these categories of pigs;~~
- ~~– wild and feral pigs.~~

~~For the purposes of the *Terrestrial Code*, the incubation period shall be 14 days. Pigs exposed to CSFV prenatally may not show clinical signs at birth and be persistently infected throughout life and may have an incubation period of several months before showing signs of disease. Pigs exposed postnatally have an incubation period of 2-14 days, and are usually infective between post-infection days 5 and 14, but up to 3 months in cases of chronic infections.~~ Pigs exposed to CSFV postnatally have an infective period of up to three months.

~~A Member Country should not impose bans on the trade in commodities of domestic and captive wild pigs in response to a notification of infection with CSFV in wild and feral pigs provided that Article 15.2.2. is implemented.~~

Commodities of domestic or captive wild pigs can be traded safely in accordance with the relevant articles of this chapter from countries complying with the provisions of Article 15.2.2, even if they notify infection with CSFV in wild or feral pigs.

Annex 17 (contd)

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

Article 15.2.1bis.Safe commodities

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

1) meat in a hermetically sealed container with a F-value of 3 or above;

2) gelatine.

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

Article 15.2.2.

General criteria for the determination of the ~~classical swine fever~~ CSF status of a country, zone or compartment

- 1) CSF ~~should be~~ is notifiable in the whole territory, and all pigs showing clinical signs or pathological lesions suggestive of CSF ~~should be~~ are subjected to appropriate field or *laboratory* investigations;
- 2) an on-going awareness programme ~~should be~~ is in place to encourage reporting of all cases pigs showing signs suggestive of CSF;
- 3) the *Veterinary Authority* ~~should have~~ has current knowledge of, and authority over, all domestic and *captive wild pig herds* in the country, zone or compartment;
- 4) the *Veterinary Authority* ~~should have~~ has current knowledge about of the population distribution and habitat of *wild* and *feral* pigs in the country or zone;
- 5) for domestic and *captive wild* pigs, appropriate *surveillance* in accordance with Articles 15.2.26. to 15.2.32. is in place;
- 6) for *wild* and *feral* pigs, if present in the country or zone, a *surveillance* programme is in place according to Article 15.2.31., taking into account the presence of natural and artificial boundaries, the ecology of the *wild* and *feral* pig population, and an assessment of the *risks* of disease spread;
- 7) based on the assessed *risk* of spread within the *wild* and *feral* pig population, and according to Article 15.2.29., the domestic and *captive wild* pig population ~~should be~~ is separated from the *wild* and *feral* pig population by appropriate measures.

Article 15.2.3.

Country or zone free from CSF ~~Classical swine fever free country or zone~~

A country or zone may be considered free from CSF when Article 15.2.2. is complied with, and when:

- 1) *surveillance* in accordance with Articles 15.2.26. to 15.2.32. has been in place for at least 12 months;
- 2) there has been no *outbreak* of CSF in domestic and *captive wild* pigs during the past 12 months;
- 3) no evidence of *infection* with CSFV has been found in domestic and *captive wild* pigs during the past 12 months;

Annex 17 (contd)

- 4) no *vaccination* against CSF has been carried out in domestic and *captive wild* pigs during the past 12 months unless there are means, validated according to Chapter 2.8.3. of the *Terrestrial Manual*, of distinguishing between vaccinated and infected pigs;
- 5) imported pigs and pig *commodities* comply with the requirements in Articles 15.2.7. to 15.2.21bis.

The proposed free country or ~~the proposed free zone~~ will be included in the list of CSF free countries or *zones* only after the submitted evidence, based on the provisions of Article 1.6.910, Chapter 1.9, has been accepted by the OIE.

Retention on the list requires that the information in points 1), 2) to or 53), 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 15.2.4.

Compartment free from CSF Classical swine fever free compartment

The bilateral recognition of a compartment free from CSF ~~free compartment~~ should follow the relevant requirements of this chapter and the principles laid down in Chapters 4.3. and 4.4. Pigs in a the compartment free from CSF should be separated from any other pigs by the application of effective biosecurity.

Article 15.2.5.

Establishment of a containment zone within a classical swine fever free country or zone free from CSF

In the event of limited *outbreaks* or *cases* of CSF within a ~~CSF free~~ country or *zone* previously free from CSF, including within a *protection zone*, a *containment zone*, which includes all *outbreaks*, can be established for the purpose of minimising the impact on the entire country or *zone*.

For this to be achieved and for the Member Country to take full advantage of this process, the *Veterinary Authority* should submit documented evidence as soon as possible to the OIE.

In addition to the requirements for the establishment of a *containment zone* outlined in Article 4.3.7, point 3 of Article 4.3.3, the *surveillance* programme should take into consideration the involvement of *wild* and *feral* pigs and measures to avoid their dispersion.

The free status of the areas outside the *containment zone* is suspended while the *containment zone* is being established. The free status of these areas may be reinstated irrespective of the provisions of Article 15.2.6., once the *containment zone* is clearly established. It should be demonstrated that *commodities* for *international trade* have originated outside the *containment zone*.

In the event of the recurrence of CSF in the *containment zone*, the approval of the *containment zone* is withdrawn, and the free status of the country or zone is suspended until the relevant requirements of Article 15.2.36, have been fulfilled.

The recovery of the CSF free status of the *containment zone* should follow the provisions of Article 15.2.6 and be achieved within 12 months of its approval.

Article 15.2.6.

Recovery of free status

Should an outbreak of CSF occur in a previously a CSF outbreak occur in a free country or zone, the free its status may be restored when where surveillance in accordance with Articles 15.2.2630- to 15.2.32. has been carried out with negative results either:

- 1) three months after the disposal of the last case where a *stamping-out policy* without *vaccination* is practised;

Annex 17 (contd)

OR

- 2) when where a *stamping-out policy* with emergency vaccination is practised:
- a) three months after the disposal of the last case and or the *slaughter* of all vaccinated animals, whichever occurred last; or
 - b) three months after the disposal of the last case without the *slaughter* of vaccinated animals when where there are means, validated according to Chapter 2.8.3. of the *Terrestrial Manual*, of distinguishing between vaccinated and infected pigs;

OR

- 3) when where a *stamping-out policy* is not practised, the provisions of Article 15.2.3. should be followed.

The country or zone will regain CSF free status only after the submitted evidence, based on the provisions of Article 1.6.9-Chapter 1.9., has been accepted by the OIE.

~~The country or zone will regain CSF free status only after the submitted evidence, based on the provisions of Article 1.6.10., has been accepted by the OIE.~~

Article 15.2.6bis.**Direct transfer of pigs within a country from an infected zone to a free zone for slaughter**

In order not to jeopardise the status of a free zone, pigs should only leave the infected zone if transported by mechanised vehicle directly for slaughter in the nearest designated slaughterhouse/abattoir under the following conditions:

- 1) no pig has been introduced into the establishment of origin and no pig in the establishment of origin has shown clinical signs of CSF for at least 30 days prior to slaughter.
- 2) the pigs were kept in the establishment of origin for at least three months prior to movement for slaughter.
- 3) CSF has not occurred within a 10-kilometre radius of the establishment of origin for at least three months prior to movement;
- 4) the pigs should be transported under the supervision of the Veterinary Services in a vehicle, which was cleaned and disinfected before loading, directly from the establishment of origin to the slaughterhouse/abattoir without coming into contact with other pigs;
- 5) such a slaughterhouse/abattoir is not approved for the export of fresh meat during from the time the pigs arrived from the infected zone until it is handling the meat of those pigs have left the premises from the infected zone;
- 6) vehicles and the slaughterhouse/abattoir should be subjected to disinfection immediately after use.

The pigs should be subjected to ante- and post-mortem inspections in accordance with Chapter 6.2. with favourable results and the meat should be treated according to in accordance with Article 15.2.23. The fresh meat from those pigs should be identified and kept separate from other pig products until treated.

Any other products obtained from the pigs, and any products coming into contact with them, should be considered contaminated and treated in accordance with Article 15.2.22. or Articles 15.2.24. to 15.2.24.ter to destroy any residual virus-CSFV potentially present.

Article 15.2.6ter.

Direct transfer of pigs within a country from a containment zone to a free zone for slaughter

In order not to jeopardise the status of a free zone, pigs should only leave the containment zone if transported by mechanised vehicle directly to for slaughter in the nearest designated slaughterhouse/abattoir under the following conditions:

- 1) the containment zone has been officially established according to the requirements in Article 15.2.5.;
- 2) the pigs should be transported under the supervision of the Veterinary Services in a vehicle, which was cleaned and disinfected before loading, directly from the establishment of origin to the slaughterhouse/abattoir without coming into contact with other pigs;
- 3) such a slaughterhouse/abattoir is not approved for the export of fresh meat during from the time the pigs arrived from the containment zone until the meat of those pigs have left the premises the time it is handling the meat of pigs from the containment zone;
- 4) vehicles and the slaughterhouse/abattoir should be subjected to disinfection immediately after use.

The pigs should be subjected to ante- and post-mortem inspections in accordance with Chapter 6.2. with favourable results and the meat should be treated according to in accordance with Article 15.2.23. The fresh meat from those pigs should be identified and kept separate from other pig products until treated.

Any other products obtained from the pigs, and any products coming into contact with them, should be considered contaminated and treated in accordance with Article 15.2.22. or Articles 15.2.24. to 15.2.24ter. to destroy any residual virus CSFV potentially present.

Article 15.2.7.

Recommendations for importation from countries, zones or compartments free from ~~classical swine fever~~ CSF

For domestic and captive wild pigs

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

- 1) showed no clinical sign of CSF on the day of shipment;
- 2) were kept ~~in a country, zone or compartment free from CSF~~ since birth or for at least the past three months in a country, zone or compartment free from CSF;
- 3) ~~have~~ were not been vaccinated against CSF, nor are they the progeny of vaccinated sows, unless there are means, validated according to in accordance with Chapter 2.8.3. of the *Terrestrial Manual*, of distinguishing between vaccinated and infected pigs.

Article 15.2.8.

Recommendations for importation from countries or zones ~~considered infected with classical swine fever virus~~ not free from CSF

For domestic and captive wild pigs

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

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

Annex 17 (contd)

- 2) and either:
- a) were kept since birth or for the past three months in a CSF free compartment, or
 - b) were isolated for 28 days prior to shipment in a quarantine station, and were subjected to a virological test and a serological test performed on a sample collected at least 21 days after entry into the quarantine station, with negative results;
- 3) ~~have were~~ not been vaccinated against CSF, nor are they the progeny of vaccinated sows, unless there are means, validated according to in accordance with Chapter 2.8.3. of the *Terrestrial Manual*, of distinguishing between vaccinated and infected pigs.

Article 15.2.9.**Recommendations for the importation of wild and feral pigs**

Regardless of the CSF status of the country of origin, ~~Veterinary Authorities~~ should require the presentation of an international veterinary certificate attesting that the animals pigs:

- 1) showed no clinical sign of CSF on the day of shipment;
- 2) were kept isolated in a quarantine station for 40 28 days prior to shipment, and were subjected to a virological test and a serological test performed on a sample collected at least 21 days after entry into the quarantine station, with negative results;
- 3) have were not been vaccinated against CSF, unless there are means, validated according to Chapter 2.8.3. of the Terrestrial Manual, of distinguishing between vaccinated and infected pigs.

Article 15.2.10.**Recommendations for importation from countries, zones or compartments free from ~~classical swine fever~~ CSF**For semen of domestic and captive wild pigs

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

- 1) the donor animals males:
 - a) ~~were kept in a country, zone or compartment free from CSF~~ since birth or for at least three months prior to collection in a country, zone or compartment free from CSF;
 - b) showed no clinical sign of CSF on the day of collection of the semen;
- 2) the semen was collected, processed and stored in conformity accordance with the provisions of Chapters 4.5. and 4.6.

Article 15.2.11.**Recommendations for importation from countries or zones ~~considered infected with classical swine fever virus~~ not free from CSF**For semen of domestic and captive wild pigs

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

- 1) the donor animals males:
 - a) ~~were kept in a compartment free from CSF since birth~~ or for at least three months prior to collection in an establishment in which surveillance, in accordance with Articles 15.2.26. to 15.2.32., demonstrated that no case of CSF occurred in the past 12 months;

Annex 17 (contd)

- b) showed no clinical sign of CSF on the day of collection of the semen ~~and for the following 40 days;~~
- c) met one of the following conditions:
 - i) were subjected to a virological test performed on a blood sample taken on the day of collection, with negative results; or
 - ii) were not been vaccinated against CSF and were subjected to a serological test performed on a sample taken at least 21 days after collection, with negative results; or
 - iii) have been vaccinated against CSF and were subjected to a serological test performed on a sample taken at least 21 days after collection, which and it has been conclusively demonstrated that any antibody is due to was caused by the vaccine; or
 - iiii) ~~have been vaccinated against CSF and were subjected to a virological test performed on a sample taken on the day of collection and it has been conclusively demonstrated that the bear is negative for virus genome;~~
- 2) the semen was collected, processed and stored in ~~conformity~~ accordance with the provisions of Chapters 4.5. and 4.6.

Article 15.2.12.

Recommendations for importation from countries, zones or compartments free from ~~classical swine fever~~ CSFFor in vivo derived embryos of domestic pigs

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

- 1) the donor females: ~~showed no clinical sign of CSF on the day of collection of the embryos;~~
 - a) were kept since birth or for at least three months prior to collection in a country, zone or compartment free from CSF;
 - b) showed no clinical sign of CSF on the day of collection of the embryos;
- 2) the semen used to fertilise the oocytes complied with the conditions in Articles 15.2.10. or Article 15.2.11., as relevant;
- 3) the embryos were collected, processed and stored in accordance with Chapters 4.7. and 4.9., as relevant.

Article 15.2.13.

Recommendations for importation from countries or zones ~~considered infected with classical swine fever virus~~ not free from CSFFor in vivo derived embryos of domestic pigs

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

- 1) the donor females:
 - a) ~~were kept in a compartment free from CSF since birth or for at least three months prior to collection in~~ an establishment in which surveillance, in accordance with Articles 15.2.26. to 15.2.32., demonstrated that no case of CSF occurred in the past three months;
 - b) showed no clinical sign of CSF on the day of collection of the embryos ~~and for the following 40 days;~~

Annex 17 (contd)

- c) ~~and either~~ met one of the following conditions:
- i) were subjected to a virological test performed on a blood sample taken on the day of collection, with negative results; or
 - ii) ~~have~~ were not been vaccinated against CSF and were subjected, with negative results, to a serological test performed at least 21 days after collection; or
 - iii) ~~have been~~ were vaccinated against CSF and were subjected to a serological test performed on a sample taken at least 21 days after collection, which ~~and it has been conclusively demonstrated by means, validated according to Chapter 2.8.3. of the *Terrestrial Manual*, that any antibody is due to~~ was caused elicited by the vaccine;
- 2) the embryos were collected, processed and stored in accordance with Chapters 4.7. and 4.9., as relevant.

Article 15.2.14.

Recommendations for importation from countries, zones or compartments free from ~~classical swine fever~~ CSF

For fresh meat of domestic and captive wild pigs

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

- 1) have been kept in a country, *zone* or *compartment* free from CSF, or which have been imported in accordance with Article 15.2.7. or Article 15.2.8.;
- 2) have been slaughtered in an approved *slaughterhouse/abattoir*, where they have been subjected to ante- and post-mortem inspections in accordance with Chapter 6.2. with favourable results ~~and have been found free from any sign suggestive of CSF.~~

Article 15. 2.14 bis.

Recommendations for importation from countries or zones not free from CSF, where an official control programme exists

For fresh meat of domestic pigs and captive wild pigs

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

- 1) the meat comes from pigs from which the meat comes complying complied complying with Article 15.2.8.;
- 2) the pigs were transported under the supervision of the *Veterinary Services*, in a *vehicle* which was cleaned and disinfected before the pigs were loaded;
- 3) the pigs were transported directly to the approved *slaughterhouse/abattoir* without coming into contact either during transport or at the *slaughterhouse/abattoir* with other pigs which do not fulfil the conditions of Article 15.2.8. required for export;
- 4) the pigs were slaughtered in an approved *slaughterhouse/abattoir*:
 - a) which is officially approved designated for export by the *Veterinary Authority*;
 - b) in which no case of CSF was detected during the period between the last *disinfection* carried out before *slaughter* and the shipment for export has been dispatched from the *slaughterhouse/abattoir*;

Annex 17 (contd)

- 5) the pigs were subjected to ante- and post-mortem inspections in accordance with Chapter 6.2. with favourable results;
- 6) appropriate precautions have been taken after slaughter to avoid contact cross-contamination of the fresh meat with any source of CSFV.

Article 15.2.15.

Recommendations for the importation of fresh meat of wild and feral pigs

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

- 1) that were killed in a country or zone free from CSF in accordance with point 1) or point 2) of Article 15.2.3.;
- 42) that which have been were subjected with favourable results to a post-mortem inspection in accordance with Chapter 6.2. in an approved examination centre facility approved by the Veterinary Authority for export purposes, with favourable results and have been found free from any sign suggestive of CSF;
- 2) from each of which a sample has been was collected and has been subjected to a virological test and a serological test for CSF, with negative results.

Article 15.2.16.

Recommendations for the importation of ~~meat and meat products of pigs intended for use in animal feeding, for agricultural or industrial use, or for pharmaceutical or surgical use~~

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

- 1) ~~have been were~~ prepared:
 - a) exclusively from *fresh meat* meeting the conditions laid down in Articles 15.2.14., 15.2.14bis. or 15.2.15.;
 - b) in a processing establishment facility that, at the time of processing:
 - i) is approved for export by the *Veterinary Authority* for export purposes;
 - ii) processing processes only meat of pigs meeting satisfying the conditions laid down in Articles 15.2.14., 15.2.14bis. or 15.2.15.;

OR

- 2) ~~have been were~~ processed in accordance with one of the processes in Article 15.2.23. in an establishment a facility approved by the *Veterinary Authority* for export purposes ~~so as to ensure the destruction of the CSFV in conformity with one of the procedures referred to in Article 15.2.23., and that the necessary appropriate~~ precautions were taken after processing to avoid contact cross-contamination of the product with any source of CSFV.

Article 15.2.17.

~~Recommendations for the importation of pig products not derived from fresh meat intended for use in animal feeding~~

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

Annex 17 (contd)

- 1)- ~~originated from domestic and captive wild pigs in a CSF free country, zone or compartment and have been prepared in a processing establishment approved by the Veterinary Authority for export purposes; or~~
- 2)- ~~have been processed in an establishment approved by the Veterinary Authority for export purposes so as to ensure the destruction of the CSFV in accordance with Article 15.2.22., and that the necessary precautions were taken after processing to avoid contact of the product with any source of CSFV.~~

~~Article 15.2.18.~~

~~Recommendations for the importation of pig products not derived from fresh meat intended for agricultural or industrial use~~

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

- 1)- ~~originated from domestic and captive wild pigs in a CSF free country, zone or compartment and have been prepared in a processing establishment approved by the Veterinary Authority for export purposes; or~~
- 2)- ~~have been processed in an establishment approved by the Veterinary Authority for export purposes so as to ensure the destruction of the CSFV, and that the necessary precautions were taken after processing to avoid contact of the product with any source of CSFV.~~

Article 15.2.19.

Recommendations for the importation of bristles

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

- 1) originated from domestic and or captive wild pigs in a CSF free country, zone or compartment free from CSF and have been were prepared processed in a processing establishment facility approved by the Veterinary Authority for export purposes; or
- 2) have been were processed in accordance with one of the processes in Article 15.2.24bis, in an establishment a facility approved by the Veterinary Authority for export purposes so as to ensure the destruction of the CSFV, and that the necessary appropriate precautions were taken after processing to avoid contact cross-contamination of the product with any source of CSFV.

Article 15.2.20.

Recommendations for the importation of litter and manure from pigs

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

- 1) originated from domestic and or captive wild pigs in a CSF free country, zone or compartment free from CSF and have been prepared were processed in a processing establishment facility approved by the Veterinary Authority for export purposes; or
- 2) have been were processed in accordance with one of the procedures in Article 15.2.24ter, in an establishment a facility approved by the Veterinary Authority for export purposes so as to ensure the destruction of the CSFV, and that the necessary appropriate precautions were taken after processing to avoid contact cross-contamination of the product with any source of CSFV.

Article 15.2.21.

Recommendations for the importation of skins and trophies from pigs

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

- 1) originated from domestic ~~and or~~ captive wild pigs in a CSF-free country, zone or compartment free from CSF and ~~have been prepared were processed~~ in a processing establishment facility approved by the *Veterinary Authority* for export purposes; or
- 2) ~~have been were processed in accordance with one of the procedures in Article 15.2.25. in an establishment a facility approved by the Veterinary Authority for export purposes so as to ensure the destruction of the CSFV in conformity with one of the procedures referred to in Article 15.2.25., and that the necessary appropriate precautions were taken after processing to avoid~~ contact cross-contamination of the product with any source of CSFV.

Article 15.2.21bis.

Recommendations for the importation of other pig products

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

- 1) originated from domestic or captive wild pigs in a country, zone or compartment free from CSF and were processed in a facility approved by the Veterinary Authority for export purposes; or
- 2) were processed in a manner to ensure the destruction of CSFV in a facility approved by the Veterinary Authority for export purposes, and that appropriate precautions were taken after processing to avoid contact cross-contamination of the product with any source of CSFV.

Article 15.2.22.

Procedures for the inactivation of ~~the classical swine fever virus~~ CSFV in swill

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

- 1) the swill ~~should be~~ is maintained at a temperature of at least 90°C for at least 60 minutes, with continuous stirring; or
- 2) the swill ~~should be~~ is maintained at a temperature of at least 121°C for at least 10 minutes at an absolute pressure of 3 bar, ~~or~~
- 3) the swill is subjected to an equivalent treatment that has been demonstrated to inactivate CSFV.

Article 15.2.23.

Procedures for the inactivation of ~~the classical swine fever virus~~ CSFV in meat

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

1. Heat treatment

Meat should be subjected to ~~one of~~ the following treatments:

- a) heat treatment in a hermetically sealed container with a F0 value of 3.00 or more;

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- b) heat treatment for at least 30 minutes at a minimum temperature of 70°C, which should be reached throughout the *meat*.
2. Natural fermentation and maturation
- The *meat* should be subjected to a treatment consisting of natural fermentation and maturation having resulting in the following characteristics:
- an A_w a_w value of not more than 0.93, or
 - a pH value of not more than 6.0.
- ~~Hams should be subjected to a natural fermentation and maturation process for at least 190 days and loins for 140 days.~~
3. Dry cured ~~perk pig meat~~
- ~~Italian style hams with bone-in should be cured with salt and dried for a minimum of 313 days.~~
 - ~~Spanish style pork *meat* with bone-in should be cured with salt and dried for a minimum of 252 days for Iberian hams, 140 days for Iberian shoulders, 126 days for Iberian loin, and 140 days for Serrano hams.~~

Meat should be cured with salt and dried for a minimum of six months.

Article 15.2.24.

Procedures for the inactivation of ~~the classical swine fever virus~~ CSFV in casings of pigs

For the inactivation of CSFV in casings of pigs, the following procedures should be used: ~~salting~~ treating for at least 30 days either with phosphate supplemented dry salt or saturated brine (A_w a_w < 0.80) containing 86.5% NaCl, 10.7% Na_2HPO_4 and 2.8% Na_3PO_4 (weight/weight/weight), ~~and kept~~ and at a temperature of ~~greater than 20°C or above~~ during this entire period.

Article 15.2.24bis.

Procedures for the inactivation of CSFV in bristles

For the inactivation of CSFV in bristles for industrial use, they should be boiled for at least 30 minutes.

Article 15.2.24ter.

Procedures for the inactivation of CSFV in litter and manure from pigs

For the inactivation of CSFV in litter and manure from pigs, one of the following procedures should be used:

- 1) moist heat treatment for at least one hour at a minimum temperature of 55°C; or
- 2) moist heat treatment for at least 30 minutes at a minimum temperature of 70°C.

Article 15.2.25.

Procedures for the inactivation of ~~the classical swine fever virus~~ CSFV in skins and trophies

For the inactivation of CSFV in skins and trophies, one of the following procedures should be used:

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

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- 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 percent % (w/v) solution of washing soda (sodium carbonate [Na₂CO₃]) 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 percent % washing soda (sodium carbonate [Na₂CO₃]).

Article 15.2.25bis.Procedures for the inactivation of CSFV in bristles

For the inactivation of CSFV in bristles for industrial use, they should be boiled for at least 30 minutes.

Article 15.2.25ter.Procedures for the inactivation of CSFV in litter and manure from pigs

For the inactivation of CSFV in litter and manure from pigs, one of the following procedures should be used:

- 1) moist heat treatment for at least one hour at a minimum temperature of 55°C; or
- 2) moist heat treatment for at least 30 minutes at a minimum temperature of 70°C.

Article 15.2.26.

Introduction to surveillance: introduction

Articles 15.2.26. to 15.2.32. define the principles and provide a guide on the *surveillance* for CSF, complementary to Chapter 1.4., applicable to Member Countries seeking the OIE recognition of CSF status. This may be for the entire country or a *zone*. Guidance is also provided for Member Countries seeking recovery of CSF status for the entire country or for a *zone* following an *outbreak* and for the maintenance of CSF status.

The impact and epidemiology of CSF may vary in different regions of the world. The *surveillance* strategies employed for demonstrating freedom from CSF at an acceptable level of confidence should be adapted to the local situation. For example, the approach should be tailored in order to prove freedom from CSF for a country or *zone* where *wild* and *feral* pigs provide a potential reservoir of *infection*, or where CSF is present in adjacent neighbouring countries. The method should examine the epidemiology of CSF in the region concerned and adapt to the specific risk factors encountered. This should include provision of scientifically based supporting data. There is, therefore, latitude available to Member Countries to provide a well-reasoned argument to prove that absence of *infection* with CSFV is assured at an acceptable level of confidence.

Surveillance for CSF should be in the form of a continuing programme designed to establish that susceptible populations in a country, *zone* or *compartment* are free from *infection* with CSFV or to detect the introduction of CSFV into a population already defined as free. Consideration should be given to the specific characteristics of CSF epidemiology which include:

- the role of swill feeding, the impact of different production systems and the role of *wild* and *feral* pigs on disease spread;
- the role of semen in transmission of the virus;
- the lack of pathognomonic gross lesions and clinical signs;
- the frequency of clinically inapparent *infections*;

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- the occurrence of persistent and chronic *infections*;
- the genotypic, antigenic, and virulence variability exhibited by different strains of CSFV.

Article 15.2.27.

General conditions and methods for surveillance: ~~general conditions and methods~~

- 1) A *surveillance* system in accordance with Chapter 1.4. and under the responsibility of the *Veterinary Authority* should address the following aspects:
 - a) formal and ongoing system for detecting and investigating *outbreaks* of disease or CSFV *infection* should be in place;
 - b) a procedure should be in place for the rapid collection and transport of samples from suspected cases to a laboratory ~~for CSF diagnosis~~;
 - c) appropriate laboratory testing capability for CSF diagnosis;
 - d) a system for recording, managing and analysing diagnostic and *surveillance* data should be in place.
- 2) The CSF *surveillance* programme should:
 - a) include an early warning detection system throughout the production, marketing and processing chain for reporting suspected cases. Diagnosticians and those with regular contact with pigs should report promptly any suspicion of CSF to the *Veterinary Authority*. The ~~notification reporting~~ system under the *Veterinary Authority* should be supported directly or indirectly (e.g. through private *veterinarians* or *veterinary paraprofessionals*) by government information programmes. Since many strains of CSFV do not induce pathognomonic gross lesions or clinical signs, cases in which CSF cannot be ruled out should be immediately investigated. Other important diseases such as African swine fever should also be considered in any differential diagnosis. As part of the contingency plan, personnel responsible for *surveillance* should be able to call for assistance from a team with expertise in CSF diagnosis, epidemiological evaluation, and control;
 - b) implement, when relevant, regular and frequent clinical inspections and laboratory testing of high-risk groups (for example, where swill feeding is practised), or those adjacent-neighbouring to a CSF infected country or *zone* (for example, bordering areas where infected *wild* and *feral* pigs are present).

An effective *surveillance* system will periodically identify suspected cases that require follow-up and investigation to confirm or exclude *infection* with CSFV. The rate at which such suspected cases are likely to occur will differ between epidemiological situations and cannot, therefore, be reliably predicted. Applications for recognition of CSF status should, as a consequence, provide details in accordance with Article 1.6.10. of the occurrence of suspected cases and how they were investigated and dealt with.

Member Countries should review their *surveillance* strategies whenever an increase in the likelihood of incursion of CSFV is perceived identified. Such changes include but are not limited to:

- a) an emergence or an increase in the prevalence of CSF in countries or *zones* from which live pigs or products are imported;
- b) an increase in the prevalence of CSF in *wild* or *feral* pigs in the country or *zone*;
- c) an increase in the prevalence of CSF in adjacent-neighbouring countries or *zones*;
- d) an increased entry from, or exposure to, infected *wild* or *feral* pig populations of adjacent-neighbouring countries or *zones*.

Article 15.2.28.

Surveillance strategies1. Introduction

The population covered by *surveillance* aimed at detecting disease and *infection* should include domestic and *wild* pig populations within the country or *zone* to be recognised as free from *infection* with CSFV.

The strategy employed to ~~establish~~ estimate the prevalence or ~~demonstrate~~ the absence of *infection with CSFV* may be based on clinical investigation or on randomised or targeted ~~clinical investigation or~~ sampling at an acceptable level of statistical confidence. If an increased likelihood of *infection* in particular localities or subpopulations can be identified, targeted sampling may be an appropriate strategy. This may include:

- a) swill fed farms;
- b) pigs reared outdoors;
- c) specific high-risk *wild* and *feral* pig subpopulations and their proximity.

Risk factors may include, among others, temporal and spatial distribution of past *outbreaks*, pig movements and demographics, ~~etc~~ and types of production systems.

~~Serology in unvaccinated populations is often the most effective and efficient surveillance methodology, for reasons of cost, persistence extended duration of antibody levels and the existence of clinically inapparent infections; serology in unvaccinated populations is often the most effective and efficient surveillance methodology. In some circumstances, such as differential diagnosis of other diseases, clinical and virological surveillance may also have value.~~

The *surveillance* strategy chosen should be justified as adequate to detect the presence of *infection* with CSFV in accordance with Chapter 1.4. and the epidemiological situation. Cumulative survey results in combination with the results of routine *surveillance*, over time, will increase the level of confidence in the *surveillance* strategy.

When applying randomised sampling, either at the level of the entire population or within targeted subpopulations, the design of the sampling strategy should incorporate epidemiologically appropriate design prevalences for the selected populations. The sample size selected for testing should be large enough to detect *infection* if it were to occur at a predefined minimum rate. The choice of design prevalence and confidence level should be justified based on the objectives of *surveillance* and the epidemiological situation, in accordance with Chapter 1.4. Selection of the design prevalence in particular, needs to be based on the prevailing or historical epidemiological situation.

Irrespective of the approach selected, the sensitivity and specificity of the diagnostic tests should be considered in the survey design, the sample size determination and the interpretation of the results obtained.

The *surveillance* system design should anticipate the occurrence of false positive reactions. This is especially true of the serological diagnosis of CSF because of the recognised cross-reactivity with ruminant pestiviruses, among other factors mentioned in point 4. There needs to be an effective procedure for following up positives to ultimately determine with a high level of confidence, whether or not they are indicative of *infection* with CSFV. This should involve confirmatory and differential tests for pestiviruses, as well as further investigations concerning the original sampling unit as well as *animals* which may be epidemiologically linked.

2. Clinical surveillance

Clinical *surveillance* continues to be the cornerstone of CSF detection. However, due to the low virulence of some CSFV strains and the spread of diseases such as African swine fever, and those associated with porcine circovirus 2 *infection*, clinical *surveillance* should be supplemented, as appropriate, by serological and virological *surveillance*.

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Clinical signs and pathological findings are useful for early detection; in particular, any cases where clinical signs or lesions suggestive of CSF are accompanied by high morbidity or mortality, these should be investigated without delay. In CSFV *infections* involving low virulence strains, high mortality may only be seen in young *animals* and adults may not present clinical signs.

Wild and *feral* pigs rarely present the opportunity for clinical observation, but should form part of any *surveillance* scheme and should, ideally, be monitored for virus as well as ~~antibody~~ antibodies.

3. Virological surveillance

Virological *surveillance* should be conducted:

- a) to monitor at risk populations;
- b) to investigate clinically suspected cases;
- c) to follow up positive serological results;
- d) to investigate increased mortality.

Molecular detection methods can be applied to large-scale screening for the presence of virus. If targeted at high-risk groups, they provide an opportunity for early detection that can considerably reduce the subsequent spread of disease. Epidemiological understanding of the pathways of spread of CSFV can be greatly enhanced by molecular analyses of viruses in endemic areas and those involved in *outbreaks* in ~~disease free~~ areas previously free from CSF. Therefore, CSFV isolates should be sent to an OIE Reference Laboratory for further characterisation.

4. Serological surveillance

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

- a) natural *infection* with CSFV;
- b) *vaccination* against CSF;
- c) maternal antibodies;
- d) cross-reactions with other pestiviruses;
- e) non-specific reactors.

The *infection* of pigs with other pestiviruses may complicate a *surveillance* strategy based on serology. Antibodies to bovine viral diarrhoea viruses (BVDV) and Border disease virus (BDV) can give positive results in serological tests for CSF, due to common antigens. Such samples will require differential tests to confirm their identity. One route by which ruminant pestiviruses can infect pigs is the use of vaccines contaminated with BVDV.

CSFV may lead to persistently infected, seronegative young animals, which continuously shed virus. CSFV *infection* may also lead to chronically infected pigs which may have undetectable or fluctuating antibody levels. Even though serological methods will not detect these animals, such animals are likely to be in a minority in a herd and would not confound a diagnosis based on serology as part of a *herd* investigation.

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

In countries or *zones* where *vaccination* has been recently discontinued, targeted serosurveillance of young unvaccinated animals can indicate the presence of *infection*. Maternal antibodies are usually found up to 8-10 weeks of age but may be occasionally last up to four and a half months and can interfere with the interpretation of serological results.

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Marker vaccines and accompanying DIVA tests which fulfil the requirements of the *Terrestrial Manual* may allow discrimination between vaccinal antibody and that induced by natural *infection*. The serosurveillance results using DIVA techniques may be interpreted either at animal or *herd* level.

~~Member Countries should review their *surveillance* strategies whenever an increase in the *risk* of incursion of CSFV is perceived. Such changes include but are not limited to:~~

- ~~a) an emergence or an increase in the prevalence of CSF in countries or zones from which live pigs or products are imported;~~
- ~~b) an increase in the prevalence of CSF in wild or feral pigs in the country or zone;~~
- ~~c) an increase in the prevalence of CSF in adjacent countries or zones;~~
- ~~d) an increased entry from, or exposure to, infected wild or feral pig populations of adjacent countries or zones.~~

Article 15.2.29.

Additional surveillance ~~procedures~~ for Member Countries applying for OIE recognition of classical swine fever CSF free status

The strategy and design of the *surveillance* programme will depend on the prevailing epidemiological circumstances in and around the country or *zone* and should be planned and implemented according to the conditions for status recognition described in Article 15.2.2. and 15.2.3. and methods described elsewhere in this chapter. The objective is to demonstrate the absence of *infection* with CSFV in domestic and *captive wild* pigs during the last 12 months and to assess the *infection* status in *wild* and *feral* pig populations as described in Article 15.2.31.

Article 15.2.30.

Additional surveillance ~~procedures~~ for recovery of free status

In addition to the general conditions described in this chapter, a Member Country seeking recovery of country or *zone* CSF free status, including a *containment zone*, should show evidence of an active *surveillance* programme to demonstrate absence of *infection* with CSFV.

Populations under this *surveillance* programme should include:

- 1) *establishments* in the proximity of the *outbreaks*;
- 2) *establishments* epidemiologically linked to the *outbreaks*;
- 3) animals moved from or used to repopulate affected *establishments*;
- 4) any *establishments* where contiguous culling has been carried out;
- 5) *wild* and *feral* pig populations in the area of the *outbreaks*.

The domestic and *captive wild* pig populations should undergo regular clinical, pathological, virological and serological examinations, planned and implemented according to the general conditions and methods described in these recommendations. Epidemiological evidence of the *infection* status in *wild* and *feral* pigs should be compiled. To regain CSF free status, the *surveillance* approach should provide at least the same level of confidence as within the original application for recognition of freedom.

Article 15.2.31.

Surveillance for ~~classical swine fever virus~~ CSFV in wild and feral pigs

- 1) The objective of a *surveillance* programme is either to demonstrate that CSFV *infection* is not present in *wild* and *feral* pigs or, if known to be present, to estimate the distribution and prevalence of the *infection*. While the same principles apply, *surveillance* in *wild* and *feral* pigs presents additional challenges including:

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- a) determination of the distribution, size and movement patterns associated with the *wild* and *feral* pig population;
- b) relevance and practicality of assessing the possible presence of CSFV *infection* within the population;
- c) determination of the practicability of establishing a *zone* taking into account the degree of interaction with domestic and *captive wild* pigs within the proposed *zone*.

The geographic distribution and estimated size of *wild* and *feral* pig populations need to be assessed as a prerequisite for designing a monitoring system. Sources of information to aid in the design of a monitoring system may include governmental and non-governmental *wildlife* organisations such as hunter associations.

- 2) For implementation of the ~~monitoring surveillance programme, it will be necessary to define the limits of the area over which *wild* and *feral* pigs range should be defined, in order to delineate the *epidemiological units* within the monitoring programme. It is often difficult to define *epidemiological units* for *Subpopulations of wild* and *feral* pigs may be separated from each other by natural or. The most practical approach is based on natural and artificial barriers.~~
- 3) The ~~monitoring surveillance programme should involve serological and virological testing, including *animals pigs hunted or* found dead, road kills, *animals pigs* showing abnormal behaviour or exhibiting gross lesions during dressing.~~
- 4) There may be situations where a more targeted *surveillance* programme can provide additional assurance. The criteria to define high risk areas for targeted *surveillance* include:
 - a) areas with past history of CSF;
 - b) subregions with large populations of *wild* and *feral* pigs;
 - c) border regions with CSF affected countries or *zones*;
 - d) interface between *wild* and *feral* pig populations, and domestic and *captive wild* pig populations;
 - e) areas with farms with free-ranging and outdoor pigs;
 - f) areas with a high level of hunting activity, where animal dispersion and feeding as well as inappropriate disposal of waste can occur;
 - gf) other risk areas determined by the *Veterinary Authority* such as ports, airports, garbage dumps and picnic and camping areas.

CHAPTER 3.4.

VETERINARY LEGISLATION

Article 3.4.1.

Introduction and objective

Good governance is a recognised global public good and is of critical importance to Member Countries. Legislation is a key element in achieving good governance.

Veterinary legislation should, at a minimum, provide a basis for *Competent Authorities* to meet their obligations as defined in the *Terrestrial Code* and the relevant recommendations of the Codex Alimentarius Commission. It should also comply with the relevant requirements of international instruments dedicated to the mitigation of biological threats. In addition, there is an obligation for World Trade Organization (WTO) Members under the Agreement on the Application of Sanitary and Phytosanitary Measures (SPS Agreement) to notify the WTO of changes in *sanitary measures*, including changes in legislation that affect trade, and provide relevant information.

For the purposes of the *Terrestrial Code*, *veterinary legislation* comprises all legal instruments necessary for the governance of the veterinary domain.

The objective of this chapter is to provide advice and assistance to Member Countries when formulating or modernising *veterinary legislation* so as to comply with OIE standards and other relevant standards and instruments, thus ensuring good governance of the entire veterinary domain.

Article 3.4.2.

Definitions

For the purposes of this chapter the following definitions apply:

Hierarchy of legislation: means the ranking of the legal instruments as prescribed under the fundamental law (e.g. the constitution) of a country. Respect for the hierarchy means that each legal instrument must comply with higher order legal instruments.

Legal instrument: means the legally binding rule that is issued by a body with the required legal authority to issue the instrument.

Primary legislation: means the legal instruments issued by the legislative body of a Member Country.

Secondary legislation: means the legal instruments issued by the executive body of a Member Country under the authority of primary legislation.

Stakeholder: means a person, group, or organisation that can affect or be affected by the impacts of *veterinary legislation*.

Veterinary domain: means all the activities that are directly or indirectly related to *animals*, their products and by-products, which help to protect, maintain and improve the animal health, and animal welfare and veterinary public health of humans, including by means of the protection of animal health and animal welfare, and food safety consistent with a One Health approach.

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Article 3.4.3.

General principles1. Respect for the hierarchy of legislation

Veterinary legislation should scrupulously respect the hierarchy between primary legislation and secondary legislation.

2. Legal basis

Competent Authorities should have available the primary legislation and secondary legislation necessary to carry out their activities at all administrative and geographic levels within the whole territory.

When primary legislation requires that secondary legislation be made to implement the legislative scheme, or to provide details to the legislative scheme, the relevant secondary legislation should be developed and enacted as soon as possible.

Veterinary legislation should be consistent with national, regional and international law, as appropriate, including civil, penal and administrative laws.

3. Transparency

Veterinary legislation should be inventoried and be readily accessible and intelligible for use, updating and modification, as appropriate.

Competent Authorities should ensure communication of *veterinary legislation* and related documentation to stakeholders.

4. Consultation

The drafting of new and revised legislation relevant to the veterinary domain should be a consultative process involving *Competent Authorities* and legal experts to ensure that the resulting legislation has been evaluated through an impact analysis and is scientifically, technically and legally sound.

To facilitate implementation of the *veterinary legislation*, *Competent Authorities* should establish relationships with stakeholders, including taking steps to ensure that they participate in the development of significant legislation and required follow-up.

5. Quality of legislation and legal certainty

Veterinary legislation should be clear, coherent, and stable and transparent and protect citizens against unintended adverse side effects of legal instruments. ~~‡~~The legislation should be regularly updated to be technically relevant, acceptable to society, able to be effectively implemented and sustainable in technical, financial and administrative terms. A high quality of legislation is essential for achieving legal certainty.

Article 3.4.4.

The drafting of veterinary legislation

Veterinary legislation should:

- 1) be drafted in a manner that establishes clear authorities, rights, responsibilities and obligations (i.e. 'normative');
- 2) ~~be unambiguous, with clear and consistent syntax and vocabulary;~~
- 3) ~~be precise, accurate and consistent in the repeated use of the terminology;~~ be accurate, clear, precise and unambiguous, and use consistent terminology;

- 3) include only definitions that are sufficient, necessary and relevant to the country;
- 4) contain no definitions or provisions that create ~~any duplication or contradiction or ambiguity;~~
- 5) include a clear statement of scope and objectives;
- 6) provide for the application of penalties and sanctions, either criminal or administrative, as appropriate to the situation; and
- 7) make provision for the financing needed for the execution of all activities of *Competent Authorities*; or these activities the financing should be ensured should be supported by appropriate financing in accordance with the national funding system.

Article 3.4.5.

Competent Authorities

Competent Authorities should be legally mandated, capacitated and organised to ensure that all necessary actions are taken quickly timely and coherently to effectively address animal health, animal welfare and veterinary public health and animal welfare matters of concern emergencies effectively.

Veterinary legislation should provide for a chain of command that is as effective as possible (i.e. short, with all responsibilities clearly defined). For this purpose, the responsibilities and powers of *Competent Authorities*, from the central level to those responsible for the implementation of legislation in the field, should be clearly defined. Where more than one *Competent Authority* is involved such as in relation to environmental, food safety or other public health matters, including biological threats and natural disasters, a reliable system of coordination and cooperation should be in place.

Competent Authorities should appoint technically qualified officials to take any actions needed for implementation or verification of compliance with the *veterinary legislation*, respecting the principles of independence and impartiality prescribed in Article 3.1.2.

1. Necessary powers of the Competent Authority

The *veterinary legislation* should also ensure that:

- a) ~~officials have the legal authority to intervene in accordance with the legislation and the penal procedures in force; the *Competent Authority* has all the necessary legal authorities to achieve the purposes of the legislation, including the powers to enforce the legislation;~~
- b) while executing their legal mandate, officials are protected against legal action and physical harm for actions carried out in good faith;
- c) the powers and functions of officials are explicitly and thoroughly listed to protect the rights of stakeholders and the general public against any abuse of authority. This includes respecting confidentiality, as appropriate; and
- d) at least the following powers are available through the primary legislation:
 - i) access to premises and vehicles for carrying out inspections;
 - ii) access to documents;
 - iii) ~~taking samples;~~ application of specific sanitary measures such as:
 - ≡ taking samples;
 - ~~≡~~ retention (setting aside) of *animals* and goods, pending a decision on final disposition;

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- ~~v)~~ = seizure of *animals*, products and food of animal origin;
- ~~vi)~~ = suspension of one or more activities of an inspected establishment;
- ~~vii)~~ = temporary, partial or complete closure of inspected establishments; ~~and~~
- ~~viii)~~ = suspension or withdrawal of authorisations or approvals; and
- = restrictions on movement of *commodities, vehicles/vessels* and, if required, *people*.

These essential powers must be identified as they can result in actions that may conflict with individual rights ascribed in fundamental laws.

2. Delegation of powers by the Competent Authority

The *veterinary legislation* should provide the possibility for *Competent Authorities* to delegate specific tasks related to official activities. The specific tasks delegated, the competencies required, the bodies to which the tasks are delegated, and the conditions of supervision by the *Competent Authority* and the conditions of withdrawals of delegations should be defined.

For this purpose, ~~the *veterinary legislation*~~ should:

- ~~a)~~ define the field of activities and the specific tasks covered by the delegation;
- ~~b)~~ provide for the control, supervision and, when appropriate, financing of the delegation;
- ~~c)~~ define the procedures for making delegation;
- ~~d)~~ define the competencies to be held by persons receiving delegation; and
- ~~e)~~ define the conditions of withdrawals of delegations.

Article 3.4.6.

Veterinarians and veterinary paraprofessionals1. Veterinary medicine/science

~~In order to ensure quality in the conduct of veterinary medicine/science, the *veterinary legislation*~~ should:

- ~~a)~~ define the prerogatives of *veterinarians* and of the various categories of *veterinary paraprofessionals* that are recognised by the Member Country;
- ~~b)~~ define the minimum initial and continuous educational requirements and competencies for *veterinarians* and *veterinary paraprofessionals*;
- ~~c)~~ prescribe the conditions for recognition of the qualifications for *veterinarians* and *veterinary paraprofessionals*;
- ~~d)~~ define the conditions to perform the activities of veterinary medicine/science; and
- ~~e)~~ identify the exceptional situations, such as epizootics, under which persons other than *veterinarians* can undertake activities that are normally carried out by *veterinarians*.

2. The control of veterinarians and veterinary paraprofessionals

~~*Veterinary legislation*~~ should provide a basis for regulation of *veterinarians* and *veterinary paraprofessionals* in the public interest. To that end, the legislation should:

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- a) ~~describe the general system of control in terms of the political, administrative and geographic configuration of the country;~~
- b) ~~describe the various categories of *veterinary paraprofessionals* recognised by the Member Country in accordance with its needs, notably in animal health and food safety, and for each category, prescribe its training, qualifications, tasks and extent of supervision;~~
- c) ~~prescribe the powers to deal with conduct and competence issues, including licensing requirements, that apply to *veterinarians* and *veterinary paraprofessionals*;~~
- d) ~~provide for the possibility of delegation of powers to a professional organisation such as a *veterinary statutory body*; and~~
- e) ~~where powers have been so delegated, describe the prerogatives, the functioning and responsibilities of the mandated professional organisation.~~

1. The regulation of veterinarians and veterinary paraprofessionals

Veterinary legislation should provide a basis for the regulation of *veterinarians* and *veterinary paraprofessionals* in the interests of the public. To this end, the legislation should:

- a) provide for the creation of a *veterinary statutory body*;
- b) describe the prerogatives, the functioning and responsibilities of the *veterinary statutory body*;
- c) describe the general structure and system of regulation of *veterinarians* and *veterinary paraprofessionals* by the *veterinary statutory body*; and
- d) give authority to the *veterinary statutory body* to make secondary legislation or otherwise deal with the following matters:
 - i) describe the various categories of *veterinarians* and *veterinary paraprofessionals* recognised in the country in accordance with its needs, notably in animal health and food safety;
 - ii) define the prerogatives of the various categories of *veterinarians* and *veterinary paraprofessionals* that are recognised in the country;
 - iii) define the minimum initial and continuous educational requirements and competencies for the various categories of *veterinarians* and *veterinary paraprofessionals*;
 - iv) prescribe the conditions for recognition of the qualifications for *veterinarians* and *veterinary paraprofessionals*;
 - v) define the conditions to perform the activities of veterinary medicine/science, including the extent of supervision for each category of *veterinary paraprofessionals*;
 - vi) prescribe the powers to deal with conduct and competence issues, including licensing requirements, that apply to *veterinarians* and *veterinary paraprofessionals*;
 - vii) identify the exceptional situations, such as epizootics, under which persons other than *veterinarians* can undertake activities that are normally carried out by *veterinarians*.

2. If the *veterinary legislation* does not create a *veterinary statutory body* for the regulation of *veterinarians* and *veterinary paraprofessionals*, the legislation should at least address all the elements listed in paragraphs 1. d) (i) to (vii) to ensure quality in the conduct of veterinary medicine/science.

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Article 3.4.7.

Laboratories in the veterinary domain1. Facilities

Veterinary legislation should define the role, responsibilities, obligations and quality requirements for:

- a) reference *laboratories*, which are responsible for controlling the veterinary diagnostic and analytical network, including the maintenance of reference methods;
- b) *laboratories* designated by the *Competent Authority* for carrying out the analysis of official samples; and
- c) *laboratories* recognised by the *Competent Authority* to conduct analyses in-house testing required under the legislation e.g. for the purposes of safety and quality control, e.g. bacteriological testing for pathogenic agents in milk at a dairy processing plant.

Veterinary legislation should define the conditions for the classification, approval, operations and supervision of each of these types of laboratories, including conditions for laboratory biosafety and biosecurity.

2. Reagents, diagnostic kits and biological agents and products

Veterinary legislation should provide a basis for actions to address the elements listed below:

- a) procedures for authorising the use and transfer of reagents, diagnostic kits and biological agents and products that are used to perform official analyses and other purposes approved by the Competent Authority;
- b) quality assurance by manufacturers and providers of reagents used in official analyses and other purposes approved by the Competent Authority; and
- c) surveillance of marketing of reagents, diagnostic kits and biological agents and products where these can affect the quality of analyses required by the *veterinary legislation*.

3. Laboratory containment and control of biological agents and products

Veterinary legislation should make provisions for the effective containment and control of biological agents and products into, within and out of the laboratory as described in Chapter 5.8. of the Terrestrial Code and Chapter 1.1.4. of the Terrestrial Manual.

Article 3.4.8.

Health provisions relating to animal production1. Identification and traceability

Veterinary legislation should provide a basis for actions to address all the elements in point 6) of Article 4.2.3.

2. Animal markets and other gatherings

Veterinary legislation should address, for animal markets and other commercially or epidemiologically significant animal gatherings, the following elements:

- a) registration of animal markets and other animal gatherings;
- b) health measures to prevent *disease* transmission, including procedures for ~~cleaning and disinfection~~, and *animal welfare* measures; and
- c) provision for veterinary ~~checks~~ inspections.

3. Animal reproduction

Veterinary legislation should provide a basis for actions to address the health regulation of animal reproduction ~~as appropriate~~ in relation to the risk of disease transmission. Health regulations may be implemented at the level of *animals*, genetic material, establishments or operators.

4. Animal feed

Veterinary legislation should provide a basis for actions to address the elements listed below:

- a) standards for the production, composition and quality control of animal feed in relation to the risk of disease transmission;
- b) registration and, if necessary, approval of establishments and the provision of health requirements for relevant operations; and
- c) recall from the market of any product likely to present a hazard to human health or animal health.

5. Animal by-products

Veterinary legislation should provide a basis for actions to address the elements listed below:

- a) definition of the animal by-products subject to the legislation;
- b) rules for collection, transport, processing, use and disposal of animal by-products;
- c) registration and, if necessary, approval of establishments and the provision of health requirements for relevant operations; and
- d) rules to be followed by animal owners.

6. Disinfection

Veterinary legislation should provide a basis for actions to address the regulation and use of products and methods of *disinfection* relating to the prevention and control of animal *diseases*.

Article 3.4.9.

Animal diseases

Veterinary legislation should provide a basis for the *Competent Authority* to manage diseases of importance to the country ~~and to list those diseases, guided by the recommendations in Chapters 1.1 and 1.2, as well as emerging diseases, using a risk-based approach.~~ The legislation should also provide for the listing of diseases of importance to the country.

1. Surveillance

Veterinary legislation should provide a basis for the collection, transmission and utilisation of epidemiological data relevant to *diseases* listed by the *Competent Authority*.

2. Disease prevention and control

- a) *Veterinary legislation* should include general animal health measures applicable to all *diseases* and, if necessary, additional or specific measures such as *surveillance*, establishment of a regulatory programme or emergency response for particular *diseases* listed in the country.

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- b) The legislation should also provide a basis for contingency plans to include the following for use in disease responses:
- i) administrative and logistic organisation;
 - ii) exceptional powers of the *Competent Authority*; and
 - iii) ~~special and temporary~~ measures to address all identified *risks* to human or animal health including accidental or deliberate introduction of biological agents or products.
- c) *Veterinary legislation* should provide for the financing of animal disease control measures, such as operational expenses and, as appropriate, owners' compensation in the event of *killing* or *slaughtering* of *animals* and seizure or destruction of carcasses, *meat*, animal feed or other things or the financing of these measures should be ensured in accordance with the national funding system.

3. Emerging diseases

Veterinary legislation should provide for measures to investigate and respond to *emerging diseases* including those due to natural, accidental or deliberate introduction of biological agents, using a risk-based approach.

Article 3.4.10.

Animal welfare1. General provisions

Veterinary legislation should provide a basis for actions to address the *animal welfare* related requirements in Section 7.

To this end, the legislation should contain, as a minimum, a legal definition of cruelty as an offence, and provisions for direct intervention of the *Competent Authority* in the case of neglect by animal keepers.

2. Stray dogs and other free-roaming animals

Veterinary legislation should provide a basis for actions to address the requirements in Chapter 7.7. and, as appropriate, prohibition of the abandonment of *animals*, and management of abandoned *animals*, including transfer of ownership, veterinary interventions and *euthanasia*.

Article 3.4.11.

~~Veterinary medicines and biologicals~~ medicinal products

Veterinary legislation should provide a basis for assuring the quality of ~~*veterinary medicines and biologicals*~~ *medicinal products* and minimising the *risk* to human, animal and environmental health associated with their use, including the development of antimicrobial resistance.

1. General measures

Veterinary legislation should provide a basis for actions to address the elements listed below:

- a) definition of ~~*veterinary medicines and biologicals*~~ *medicinal products*, including any specific exclusions; and
- b) regulation of the importation, manufacture, distribution and usage of, and commerce in, ~~*veterinary medicines and biologicals*~~ *medicinal products*, including laboratory biosafety and biosecurity measures.

2. Raw materials for use in veterinary medicines and biologicals

Veterinary legislation should provide a basis for actions to address the elements listed below:

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- a) quality standards for raw materials used in the manufacture or composition of *veterinary medicines and biologicals* medicinal products and arrangements for checking quality;
 - b) ~~establishment of the withdrawal periods and maximum residue limits for veterinary medicines and biologicals, as appropriate; and~~
 - e) ~~requirements for restrictions on~~ substances in *veterinary medicines and biologicals* medicinal products that may, through their effects, interfere with the interpretation of veterinary diagnostic test results or the conduct of other veterinary checks.
3. Authorisation of veterinary medicinal products ~~medicines and biologicals~~
- a) *Veterinary legislation* should ensure that only authorised *veterinary medicines and biologicals* medicinal products may be placed on the market.
 - b) Special provisions should be made for:
 - i) medicated feed;
 - ii) products prepared by authorised *veterinarians* or authorised pharmacists; ~~and~~
 - iii) emergencies and temporary situations; and
 - iv) establishment of withdrawal periods for relevant *veterinary medicinal products* and maximum residue limits for the active substance contained in each such product.
 - c) *Veterinary legislation* should address the technical, administrative and financial conditions associated with the granting, renewal, refusal and withdrawal of authorisations.
 - d) In defining the procedures for seeking and granting authorisations, the legislation should:
 - i) describe the ~~role~~ responsibilities of the relevant *Competent Authorities*; and
 - ii) establish rules providing for the transparency in decision making.
 - e) *Veterinary legislation* may provide for the possibility of recognition of the equivalence of authorisations made by other countries.
4. Quality of veterinary medicines and biologicals

~~*Veterinary legislation* should address the following elements:~~

- a) ~~the conduct of clinical and non-clinical trials to verify all claims made by the manufacturer;~~
- b) ~~conditions for the conduct of trials;~~
- e) ~~qualifications of experts involved in trials; and~~
- d) ~~surveillance for adverse effects arising from the use of veterinary medicines and biologicals.~~

54. Establishments producing, storing and wholesaling veterinary medicines and biologicals medicinal products

Veterinary legislation should provide a basis for actions to address the following elements:

- a) registration or authorisation of all operators manufacturing importing, storing, processing, wholesaling or otherwise distributing *veterinary medicines and biologicals* medicinal products or raw materials for use in making *veterinary medicines and biologicals* medicinal products;
- b) definition of the responsibilities of operators;

Annex 18 (contd)

- c) good manufacturing practices appropriate;
- d) reporting on adverse effects to the *Competent Authority*; and
- e) mechanisms for traceability and recall.

65. Retailing, use and traceability of veterinary medicines and biological medicinal products

Veterinary legislation should provide a basis for actions to address the following elements:

- a) control over the distribution of *veterinary medicines and biological medicinal products* and arrangements for traceability, recall and conditions of use;
- b) establishment of rules for the prescription and provision of *veterinary medicines and biological medicinal products* to end users;
- c) restriction to *veterinarians or other* authorised professionals and, as appropriate, authorised *veterinary paraprofessionals*, of commerce in *veterinary medicines and biological medicinal products* that are subject to prescription;
- d) obligation of *veterinarians, other authorised professionals or authorised veterinary paraprofessionals* to inform end users of the withdrawal periods of relevant *veterinary medicinal products* and the obligation of end users to observe those withdrawal periods when using those products;
- ~~e)~~ the supervision by an authorised professional of organisations approved for holding and use of *veterinary medicines and biological medicinal products*;
- ~~f)~~ the regulation of advertising claims and other marketing and promotional activities; and
- ~~g)~~ reporting on adverse effects to the *Competent Authority*.

Article 3.4.12.

Human food production chain

Veterinary legislation should provide a basis for actions to safeguard the human food production chain through controls at all critical steps, consistent with national food safety standards and taking into account the risk of accidental and deliberate contamination. The role of the *Veterinary Services* in food safety is described in Chapter 6.2.

1. General provisions

Veterinary legislation should provide a basis for actions to address the following elements:

- a) the conduct of veterinary ante- and post-mortem inspections at *slaughterhouses/abattoirs*;
- ~~a)~~ controls over all stages of the production, processing and distribution of food of animal origin;
- ~~b)~~ recording all significant animal and public health events that occur during primary production including *slaughter*;
- ~~c)~~ giving operators of food production premises the primary responsibility for compliance with food safety requirements, including traceability established by the *Competent Authority*;
- ~~d)~~ inspection for compliance with food standards, where this is relevant to health or safety;
- ~~e)~~ inspection and audit of premises;
- ~~f)~~ prohibition of the marketing of products not fit for human consumption; and

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~~gh)~~ provisions for recall from the marketplace of all products likely to be hazardous for human or animal health.

2. Products of animal origin intended for human consumption

Veterinary legislation should provide a basis for actions to address the following elements:

- ~~a)~~ arrangements for inspection and audit;
- ~~b)~~ the conduct of inspection and audit;
- ~~ea)~~ health standards including measures to control diseases, and monitoring and enforcement of maximum residue levels (MRL); and
- ~~eb)~~ the application of health identification marks that are visible to the intermediary ~~or~~ and final user.

The *Competent Authority* should have the necessary powers and means to rapidly withdraw any products deemed to be hazardous from the food chain or to prescribe uses or treatments that ensure the safety of such products for human or animal health.

3. Operators responsible for premises and establishments pertaining to the food chain

Veterinary legislation should provide a basis for actions to address the following elements as appropriate:

- a) registration of premises and establishments by the *Competent Authority*;
- b) the use of *risk*-based management procedures; and
- c) prior authorisation of operations that are likely to constitute a significant *risk* to human or animal health.

Article 3.4.13.

Import and export procedures and veterinary certification

Veterinary legislation should provide a basis for actions to address the elements ~~relating to import and export procedures and veterinary certification~~ referred to in Sections 2 Risk Analysis and 5 Trade measures, import/export procedures and veterinary certification.

CHAPTER 10.4.

INFECTION WITH HIGH PATHOGENICITY AVIAN INFLUENZA VIRUSES

Article 10.4.1.

General provisions

- 1) The objective of this chapter is to mitigate animal and public health risks posed by avian influenza viruses, and prevent their international spread. The chapter focuses on high pathogenicity avian influenza viruses, which cause the listed disease of concern. However, since they have the ability to mutate into high pathogenicity viruses, low pathogenicity avian influenza viruses of H5 and H7 subtypes should be included in any surveillance and control programmes for high pathogenicity viruses. This chapter deals not only with the occurrence of clinical signs caused by avian influenza, but also with the presence of infection with avian influenza viruses in the absence of clinical signs.

For the purposes of the *Terrestrial Code*, avian influenza is defined as an *infection of poultry* caused by any influenza A virus of the H5 or H7 subtypes or by any influenza A virus with an intravenous pathogenicity index (IVPI) greater than 1.2 (or as an alternative at least 75% mortality) as described below. These viruses are divided into high pathogenicity avian influenza viruses and low pathogenicity avian influenza viruses:

- a) high pathogenicity avian influenza viruses have an IVPI in six-week-old chickens greater than 1.2 or, as an alternative, cause at least 75% mortality in four to eight-week-old chickens infected intravenously. H5 and H7 viruses which do not have an IVPI of greater than 1.2 or cause less than 75% mortality in an intravenous lethality test should be sequenced to determine whether multiple basic amino acids are present at the cleavage site of the haemagglutinin molecule (HA0); if the amino acid motif is similar to that observed for other high pathogenicity avian influenza isolates, the isolate being tested should be considered as high pathogenicity avian influenza virus;
- b) low pathogenicity avian influenza viruses are all influenza A viruses of H5 and H7 subtypes that are not high pathogenicity avian influenza viruses.
- 2) For the purposes of the *Terrestrial Code*:
- a) High pathogenicity avian influenza means an infection of poultry by any influenza A virus with an intravenous pathogenicity index (IVPI):
- ≡ in six-week-old chickens greater than 1.2 or, as an alternative, causes at least 75% mortality in four to eight-week-old chickens infected intravenously. Viruses of H5 and H7 subtypes that do not have an IVPI of greater than 1.2 or cause less than 75% mortality in an intravenous lethality test should be sequenced to determine whether multiple basic amino acids are present at the cleavage site of the haemagglutinin molecule (HA0); if the amino acid motif is similar to that observed for other high pathogenicity avian influenza isolates, the isolate being tested should be considered as a high pathogenicity avian influenza virus.
- b) The following defines the occurrence of infection with a high pathogenicity avian influenza virus: the virus has been isolated and identified as such or specific viral ribonucleic acid has been detected in one or more samples from poultry or a product derived from poultry.
- 3) Poultry is defined as 'all domesticated birds, including backyard poultry, used for the production of meat or eggs for consumption, for the production of other commercial products, for restocking supplies of game, or for breeding these categories of birds, as well as fighting cocks used for any purpose'.

Annex 19 (contd)

~~Birds that are kept in captivity for any reason other than those reasons referred to in the preceding paragraph, including those that are kept for shows, races, exhibitions, competitions or for breeding or selling these categories of birds as well as pet birds, are not considered to be *poultry*.~~

- c) *Poultry* means all domesticated birds used for the production of *meat* or eggs for consumption, for the production of other commercial products, or for breeding these categories of birds, as well as fighting cocks used for any purpose. All birds used for restocking supplies of game are considered *poultry*. If birds are kept in a single household and their products are only used in the same household, these birds are not considered *poultry*.

Birds that are kept in captivity for any reason other than those referred to in the preceding paragraph, including those that are kept for shows, races, exhibitions, competitions or for breeding or selling these categories of birds as well as pet birds, are not considered *poultry*.

- d) the *incubation period* at the *flock* level for high pathogenicity avian influenza shall be 14 days.

- 3) In accordance with Chapter 1.1., a sudden and unexpected change in the distribution, host range, or increase in incidence or virulence of, or morbidity or mortality caused by avian influenza viruses is notifiable to the OIE, as well as zoonotic avian influenza viruses. Occurrences of influenza A viruses of high pathogenicity in birds other than *poultry*, including *wild* birds, are notifiable. Six-monthly reports on the presence of avian influenza viruses in a country or *zone* should include low pathogenicity viruses of H5 and H7 subtypes.

A notification of infection with influenza A viruses of high pathogenicity in birds other than *poultry*, including *wild* birds, or of low pathogenicity avian influenza viruses in *poultry* does not affect the status of the country or *zone*. A Member Country should not impose bans on the trade in *poultry* and *poultry commodities* in response to such notification, or to other information on the presence of any influenza A virus in birds other than *poultry*, including *wild* birds.

~~For the purposes of the *Terrestrial Code*, the *incubation period* for avian influenza shall be 21 days.~~

- ~~5) This chapter deals not only with the occurrence of clinical signs caused by avian influenza, but also with the presence of *infection* with avian influenza viruses in the absence of clinical signs.~~
- ~~6) Antibodies against H5 or H7 subtype, which have been detected in *poultry* and are not a consequence of vaccination, should be immediately investigated. In the case of isolated serological positive results, *infection* with avian influenza viruses may be ruled out on the basis of a thorough epidemiological and laboratory investigation that does not demonstrate further evidence of such an *infection*.~~
- ~~7) For the purposes of the *Terrestrial Code*, 'avian influenza free establishment' means an establishment in which the *poultry* have shown no evidence of infection with avian influenza viruses, based on surveillance in accordance with Articles 10.4.27. to 10.4.33.~~
- ~~8) *Infection* with influenza A viruses of high pathogenicity in birds other than *poultry*, including *wild* birds, should be notified according to Article 1.1.3. However, a Member Country should not impose bans on the trade in *poultry* and *poultry commodities* in response to such a notification, or other information on the presence of any influenza A virus in birds other than *poultry*, including *wild* birds.~~
- 4) The use of vaccination against high pathogenicity avian influenza in *poultry* may be recommended under specified conditions, while not affecting the status of a free country or *zone* if the vaccine complies with the standards in the *Terrestrial Manual*. Vaccination is an effective complementary control tool that can be used when a *stamping-out* policy alone is not sufficient. The decision whether to vaccinate or not is to be made by the *Veterinary Authorities* based on the avian influenza situation as well as the ability of the *Veterinary Services* to execute the proper vaccination strategy, as described in Chapter 4.17. Any vaccine used should comply with the standards described in the *Terrestrial Manual*.

59) Standards for diagnostic tests and vaccines, including pathogenicity testing, are described in the *Terrestrial Manual*. Any vaccine used should comply with the standards described in the *Terrestrial Manual*.

Article 10.4.1bis.

Safe commodities

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

- 1) heat-treated poultry meat in a hermetically sealed container with a F-value of 3.00 or above;
- 2) extruded dry pet food and poultry-based coated ingredients after extrusion;
- 3) rendered meat and bone meal, blood meal, feather meal, and poultry oil;
- 4) feathers and down from poultry and other birds processed by washing and steam-drying.

Other commodities of poultry and other birds can be traded safely if in accordance with the relevant articles of this chapter.

Article 10.4.2.

Determination of the avian influenza status of a country, zone or compartment

The avian influenza status of a country, a zone or a compartment can be determined on the basis of the following criteria:

- 1) ~~avian influenza is notifiable in the whole country, an ongoing avian influenza awareness programme is in place, and all notified suspect occurrences of avian influenza are subjected to field and, where applicable, laboratory investigations;~~
- 2) ~~appropriate surveillance is in place to demonstrate the presence of infection in the absence of clinical signs in poultry, and the risk posed by birds other than poultry; this may be achieved through an avian influenza surveillance programme in accordance with Articles 10.4.27. to 10.4.33.;~~
- 3) ~~consideration of all epidemiological factors for avian influenza occurrence and their historical perspective.~~

Article 10.4.3.

Country, zone or compartment free from avian influenza

~~A country, zone or compartment may be considered free from avian influenza when it has been shown that infection with avian influenza viruses in poultry has not been present in the country, zone or compartment for the past 12 months, based on surveillance in accordance with Articles 10.4.27. to 10.4.33.~~

~~If infection has occurred in poultry in a previously free country, zone or compartment, avian influenza free status can be regained:~~

- 1) ~~In the case of infections with high pathogenicity avian influenza viruses, three months after a stamping-out policy (including disinfection of all affected establishments) is applied, providing that surveillance in accordance with Articles 10.4.27. to 10.4.33. has been carried out during that three-month period.~~
- 2) ~~In the case of infections with low pathogenicity avian influenza viruses, poultry may be kept for slaughter for human consumption subject to conditions specified in Article 10.4.19. or a stamping-out policy may be applied; in either case, three months after the disinfection of all affected establishments, providing that surveillance in accordance with Articles 10.4.27. to 10.4.33. has been carried out during that three-month period.~~

Annex 19 (contd)

Article 10.4.34.

Country, or zone or compartment free from ~~infection with high pathogenicity avian influenza viruses in poultry~~

A country, or zone or compartment may be considered free from ~~infection with high pathogenicity avian influenza viruses in poultry~~ when:

- = infection with high pathogenicity avian influenza viruses in poultry is a notifiable disease in the entire country;
- = an ongoing avian influenza surveillance is implemented to monitor the general situation of H5 and H7 low pathogenicity avian influenza viruses in poultry and an awareness programme is in place related to biosecurity and management of H5 and H7 low pathogenicity avian influenza viruses;
- =) based on surveillance in accordance with Chapter 1.4. and Articles 10.4.27. to 10.4.33., it has been shown demonstrated that infection with high pathogenicity avian influenza viruses in ~~poultry~~ as defined in Article 10.4.1. has not been present occurred in the country, or zone or compartment for the past 12 months; Although its status with respect to low pathogenicity avian influenza viruses may be unknown; or
- = bird commodities are imported in accordance with Articles 10.4.5. to 10.4.23.

The surveillance should ~~may need~~ to be adapted to parts of the country or existing zones or compartment depending on historical or geographical factors, industry structure, population data, ~~or~~ proximity to recent outbreaks or the use of vaccination.

If ~~infection~~ has occurred in poultry in a previously free country, zone or compartment, the free status can be regained three months after a ~~stamping-out policy~~ (including ~~disinfection~~ of all affected ~~establishments~~) is applied, providing that surveillance in accordance with Articles 10.4.27. to 10.4.33. has been carried out during that three-month period.

Article 10.4.3bis.**Compartment free from high pathogenicity avian influenza**

The establishment of a compartment free from high pathogenicity avian influenza should follow the relevant requirements of this chapter and the principles in Chapters 4.3. and 4.4.

Article 10.4.3ter.**Establishment of a containment zone within a country or zone free from high pathogenicity avian influenza**

In the event of outbreaks of high pathogenicity avian influenza within a previously free country or zone, a containment zone, which includes all epidemiologically linked outbreaks, may be established for the purposes of minimising the impact on the rest of the country or zone.

In addition to the requirements for the establishment of a containment zone outlined in Article 4.3.7., the surveillance programme should take into account the density of poultry production, types of poultry, local management practices (including inter-premise movement pattern of poultry, people and equipment), relevant biosecurity and presence and potential role of birds other than poultry, including wild birds and the proximity of poultry establishments to perennial and seasonal water bodies.

The free status of the areas outside the containment zone is suspended while the containment zone is being established. It may be reinstated irrespective of the provisions of Article 10.4.3quater., once the containment zone is clearly established. It should be demonstrated that commodities for international trade either have originated outside the containment zone or comply with the relevant articles of this chapter.

Article 10.4.3quater.**Recovery of free status**

If infection has occurred in poultry in a previously free country or zone, the free status can be regained after a minimum period of 28 days after a stamping-out policy has been completed, provided that surveillance in accordance with Articles 10.4.27. to 10.4.33., in particular point 3) of Article 10.4.30., has been carried out during that period and has demonstrated the absence of infection.

If a stamping-out policy is not implemented, Article 10.4.3. applies.

Article 10.4.5.

Recommendations for importation from a country, zone or compartment free from high pathogenicity avian influenza

For live poultry (other than day-old poultry)

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

- 1) the *poultry* showed no clinical signs of avian influenza on the day of shipment;
- 2) a) the poultry were kept in originated from an avian influenza free a country, zone or compartment free from high pathogenicity avian influenza since they were hatched or for at least the past 21 days;
b) the poultry originated from a flock free from infection with any H5 or H7 influenza A viruses;
- 3) the *poultry* are transported in new or appropriately sanitized *containers*.

If the *poultry* have been vaccinated against avian influenza, the nature of the vaccine used and the date of vaccination should be ~~attached to~~ mentioned in the *international veterinary certificate*.

Article 10.4.6.

Recommendations for the importation of live birds other than poultry

Regardless of the ~~avian influenza~~ status of the country of origin, *Veterinary Authorities* should require the presentation of an *international veterinary certificate* attesting that:

- 1) on the day of shipment, the birds showed no clinical signs of *infection* with a virus which would be considered avian influenza in *poultry*;
- 2) the birds were kept in isolation approved by the *Veterinary Services* since they were hatched or for at least 24 ~~28~~ days prior to shipment and showed no clinical signs of *infection* with a virus which would be considered avian influenza in *poultry* during the isolation period;
- 3) a statistically valid sample of the birds, selected in accordance with the provisions of Article 10.4.29., was subjected to a diagnostic test for influenza A viruses within 14 days prior to shipment, with negative results for H5 and H7 to demonstrate freedom from infection with a virus which would be considered avian influenza in poultry;
- 4) the birds are transported in new or appropriately sanitized *containers*.

If the birds have been vaccinated against avian influenza, the nature of the vaccine used and the date of vaccination should be ~~attached to~~ mentioned in the *international veterinary certificate*.

Annex 19 (contd)

Article 10.4.7.

Recommendations for importation from a country, zone or compartment free from avian influenzaFor day-old live poultry

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

- 1) ~~the *poultry* were kept in an avian influenza free country, zone or compartment since they were hatched;~~
- 2) ~~the *poultry* were derived from parent *flocks* which had been kept in an avian influenza free country, zone or compartment for at least 21 days prior to and at the time of the collection of the eggs;~~
- 3) ~~the *poultry* are transported in new or appropriately sanitized *containers*.~~

~~If the *poultry* or the parent *flocks* have been vaccinated against avian influenza, the nature of the vaccine used and the date of *vaccination* should be attached to the *certificate*.~~

Article 10.4.8.

Recommendations for importation from a country, zone or compartment free from infection with high pathogenicity avian influenza viruses in poultryFor day-old live poultry

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

- 1) ~~the *poultry* were kept in a country, zone or compartment free from *infection with* high pathogenicity avian influenza since they were hatched;~~
- 2) ~~a) the *poultry* were derived from parent *flocks* free from *infection with any H5 or H7 influenza A viruses* which had been kept in an avian influenza free establishment for at least 21 days prior to and at the time of the collection of the eggs from which the day-old *poultry* hatched; or~~
 - ~~b) the day-old live *poultry* that hatched from eggs that have had their surfaces sanitized in accordance with point 4 d) of Article 6.5.5.;~~
- 2) ~~the *poultry* are transported in new or appropriately sanitized *containers*.~~

~~If the *poultry* or the parent *flocks* have been vaccinated against avian influenza, the nature of the vaccine used and the date of *vaccination* should be attached to mentioned in the *international veterinary certificate*.~~

Article 10.4.9.

Recommendations for the importation of day-old live birds other than poultry

~~Regardless of the *avian influenza* status of the country of origin, *Veterinary Authorities* should require the presentation of an *international veterinary certificate* attesting that:~~

- 1) ~~on the day of shipment, the birds showed no clinical signs of *infection* with a virus which would be considered avian influenza in *poultry*;~~
- 2) ~~the birds were hatched and kept in isolation approved by the *Veterinary Services*;~~
- 3) ~~the parent *flock* birds were subjected to a diagnostic test for *influenza A viruses* at the time of the collection of the eggs, with negative results for H5 and H7 to demonstrate freedom from *infection* with a virus which would be considered avian influenza in *poultry*;~~
- 4) ~~the birds are transported in new or appropriately sanitized *containers*.~~

Annex 19 (contd)

If the birds or parent *flocks* have been vaccinated against avian influenza, the nature of the vaccine used and the date of *vaccination* should be ~~attached to~~ mentioned in the *international veterinary certificate*.

Article 10.4.10.

Recommendations for importation from a country, zone or compartment free from avian influenzaFor hatching eggs of poultry

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

- 1) ~~the eggs came from an avian influenza free country, zone or compartment;~~
- 2) ~~the eggs were derived from parent flocks which had been kept in an avian influenza free country, zone or compartment for at least 21 days prior to and at the time of the collection of the eggs;~~
- 3) ~~the eggs are transported in new or appropriately sanitized packaging materials.~~

If the parent *flocks* have been vaccinated against avian influenza, the nature of the vaccine used and the date of *vaccination* should be ~~attached to~~ mentioned in the *international veterinary certificate*.

Article 10.4.11.

Recommendations for importation from a country, zone or compartment free from infection with high pathogenicity avian influenza viruses in poultryFor hatching eggs of poultry

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

- 1) the eggs came from a country, *zone* or *compartment* free from ~~infection with~~ high pathogenicity avian influenza viruses ~~in poultry~~;
- 2) a) the eggs were derived from parent *flocks* free from infection with any H5 or H7 influenza A viruses which had been kept in an avian influenza free establishment for at least 21 days prior to and at the time of the collection of the eggs; or
 - b3) the eggs have had their surfaces sanitized (in accordance with ~~Chapter 6.5. point 4 d) of Article 6.5.5.;~~
- 34) the eggs are transported in new or appropriately sanitized packaging materials.

If the parent *flocks* have been vaccinated against avian influenza, the nature of the vaccine used and the date of *vaccination* should be ~~attached to~~ mentioned in the *international veterinary certificate*.

Article 10.4.12.

Recommendations for the importation of hatching eggs from birds other than poultry

Regardless of the ~~avian influenza~~ status of the country of origin, *Veterinary Authorities* should require the presentation of an *international veterinary certificate* attesting that:

- 1) a statistically valid sample of birds from the parent *flock* ~~birds were~~ was subjected to a diagnostic test for influenza A viruses seven 14 days prior to and at the time of the collection of the eggs, with negative results for H5 and H7 to demonstrate freedom from infection with a virus which would be considered avian influenza in poultry;
- 2) the eggs have had their surfaces sanitized (in accordance with point 4 d) of Article 6.5.5. Chapter 6.5.;

Annex 19 (contd)

- 3) the eggs are transported in new or appropriately sanitized packaging materials.

If the parent *flocks* have been vaccinated against avian influenza, the nature of the vaccine used and the date of vaccination should be ~~attached to~~ mentioned in the international veterinary certificate.

~~Article 10.4.13.~~

~~Recommendations for importation from a country, zone or compartment free from avian influenza~~~~For eggs for human consumption~~

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

- ~~1) the eggs were produced and packed in an avian influenza free country, zone or compartment;~~
~~2) the eggs are transported in new or appropriately sanitized packaging materials.~~

Article 10.4.14.

Recommendations for importation from a country, zone or compartment free from infection with high pathogenicity avian influenza viruses in poultryFor eggs for human consumption

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

- 1) the eggs were produced and packed in a country, zone or compartment free from ~~infection with~~ high pathogenicity avian influenza viruses in poultry;
 2) ~~the eggs have had their surfaces sanitized (in accordance with Chapter 6.5.);~~
 2) the eggs are transported in new or appropriately sanitized packaging materials.

Article 10.4.15.

Recommendations for importation of egg products of poultry

Regardless of the ~~avian influenza~~ status of the country of origin, *Veterinary Authorities* should require the presentation of an *international veterinary certificate* attesting that:

- 1) the *commodity* is derived from eggs which meet the requirements of ~~Articles 10.4.13. or~~ 10.4.14. or
 2) the *commodity* has been processed to ensure the ~~destruction~~ inactivation of high pathogenicity avian influenza virus in accordance with Article 10.4.25.;

AND

- 3) the necessary precautions were taken to avoid contact of the *commodity* with any source of high pathogenicity avian influenza virus.

~~Article 10.4.16.~~

~~Recommendations for importation from a country, zone or compartment free from avian influenza~~~~For poultry semen~~

~~Veterinary Authorities should require the presentation of an international veterinary certificate attesting that the donor poultry:~~

Annex 19 (contd)

- 1) ~~showed no clinical sign of avian influenza on the day of semen collection;~~
- 2) ~~were kept in an avian influenza free country, zone or compartment for at least 21 days prior to and at the time of semen collection.~~

Article 10.4.17.

Recommendations for the importation from a country, zone or compartment free from ~~infection with high pathogenicity avian influenza viruses in poultry~~

For poultry semen

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

- 1) showed no clinical signs of ~~infection with high pathogenicity~~ avian influenza viruses in ~~poultry~~ on the day of semen collection;
- 2) were kept in a country, *zone* or *compartment* free from ~~infection with high pathogenicity avian influenza viruses in poultry~~ for at least 21 days prior to and at the time of semen collection.

Article 10.4.18.

Recommendations for the importation of semen of birds other than poultry

Regardless of the ~~avian influenza~~ status of the country of origin, *Veterinary Authorities* should require the presentation of an *international veterinary certificate* attesting that the donor birds:

- 1) were kept in isolation approved by the *Veterinary Services* for at least 24 28 days prior to semen collection;
- 2) showed no clinical signs of *infection* with a virus which would be considered avian influenza in *poultry* during the isolation period;
- 3) were tested within 14 days prior to semen collection and shown to be free from *infection* with a virus which would be considered avian influenza in *poultry*.

Article 10.4.19.

Recommendations for importation from a country, zone or compartment ~~free from avian influenza or free from infection with high pathogenicity avian influenza viruses in poultry~~

For fresh meat of poultry

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

- 1) which ~~have been kept in~~ originated from a country, *zone* or *compartment* free from ~~infection with high pathogenicity avian influenza viruses in poultry since they were hatched or for at least the past 21 days;~~
- 2) which have been slaughtered in an approved *abattoir* in a country, *zone* or *compartment* free from ~~infection with high pathogenicity avian influenza viruses in poultry~~ and have been subjected to ante- and post-mortem inspections in accordance with Chapter 6.3. ~~and have been found free of any signs suggestive of avian influenza with favorable results.~~

Annex 19 (contd)

Article 10.4.20.

Recommendations for the importation of meat products of poultry

Regardless of the ~~avian influenza~~ status of the country of origin, *Veterinary Authorities* should require the presentation of an *international veterinary certificate* attesting that:

- 1) the *commodity* is derived from *fresh meat* which meets the requirements of Article 10.4.19.; or
- 2) the *commodity* has been processed to ensure the ~~destruction~~ inactivation of high pathogenicity avian influenza virus in accordance with Article 10.4.26.;

AND

- 3) the necessary precautions were taken to avoid contact of the *commodity* with any source of high pathogenicity avian influenza virus.

Article 10.4.21.**Recommendations for the importation of poultry products not listed in Article 10.4.1bis and intended for use in animal feeding, or for agricultural or industrial use**

Regardless of the status of the country of origin, *Veterinary Authorities* should require the presentation of an *international veterinary certificate* attesting that:

- 1) these *commodities* were processed in a country, *zone* or *compartment* free from high pathogenicity avian influenza and from *poultry* which originated in a country, *zone* or *compartment* free from high pathogenicity avian influenza; or
- 2) these *commodities* have been processed to ensure the inactivation of high pathogenicity avian influenza virus using:
 - a) moist heat treatment for 30 minutes at 56 °C; or
 - b) heat treatment where the internal temperature throughout the product reaches at least 74 °C; or
 - c) any equivalent treatment that has been demonstrated to inactivate avian influenza virus;

AND

- 3) the necessary precautions were taken to avoid contact of the *commodity* with any source of high pathogenicity avian influenza virus.

Article 10.4.21.**Recommendations for the importation of products of poultry origin, other than feather meal and poultry meal, intended for use in animal feeding, or for agricultural or industrial use**

~~Regardless of the avian influenza status of the country of origin, *Veterinary Authorities* should require the presentation of an *international veterinary certificate* attesting that:~~

- 1) ~~these *commodities* were processed in an avian influenza free country, *zone* or *compartment* from *poultry* which were kept in an avian influenza free country, *zone* or *compartment* from the time they were hatched until the time of *slaughter* or for at least the 21 days preceding *slaughter*; or~~
- 2) ~~these *commodities* have been processed to ensure the destruction of avian influenza virus using;~~
 - a) ~~moist heat treatment for 30 minutes at 56°C; or~~
 - b) ~~any equivalent treatment which has been demonstrated to inactivate avian influenza virus;~~

Annex 19 (contd)

AND

- 3) ~~the necessary precautions were taken to avoid contact of the commodity with any source of avian influenza virus.~~

Article 10.4.22.

Recommendations for the importation of feathers and down of poultry not listed in Article 10.4.1bis.

~~Regardless of the avian influenza status of the country of origin, Veterinary Authorities should require the presentation of an *international veterinary certificate* attesting that:~~

- 1) these *commodities* originated from *poultry* as described in Article 10.4.19. and were processed in ~~an avian influenza free~~ a country, zone or compartment free from high pathogenicity avian influenza; or
- 2) these *commodities* have been processed to ensure the inactivation of high pathogenicity avian influenza virus using one of the following:
 - a) ~~washed and steam dried at 100°C for 30 minutes;~~
 - b) fumigation with formalin (10% formaldehyde) for 8 hours;
 - b_e) irradiation with a dose of 20 kGy;
 - c_d) any equivalent treatment which has been demonstrated to inactivate avian influenza virus;

AND

- 3) the necessary precautions were taken to avoid contact of the *commodity* with any source of high pathogenicity avian influenza virus.

Article 10.4.23.

Recommendations for the importation of feathers and down of birds other than poultry

~~Regardless of the avian influenza status of the country of origin, Veterinary Authorities should require the presentation of an *international veterinary certificate* attesting that:~~

- 1) these *commodities* have been processed to ensure the ~~destruction~~ inactivation of any virus which would be considered high pathogenicity avian influenza in *poultry* using one of the following:
 - a) ~~washed and steam dried at 100°C for 30 minutes;~~
 - b) fumigation with formalin (10% formaldehyde) for 8 hours;
 - b_e) irradiation with a dose of 20 kGy;
 - c_d) any equivalent treatment which has been demonstrated to inactivate avian influenza virus;
- 2) the necessary precautions were taken to avoid contact of the *commodity* with any source of viruses which would be considered high pathogenicity avian influenza in *poultry*.

Article 10.4.24.

~~Recommendations for the importation of feather meal and poultry meal~~

~~Regardless of the avian influenza status of the country of origin, Veterinary Authorities should require the presentation of an *international veterinary certificate* attesting that:~~

Annex 19 (contd)

- 1) ~~these commodities were processed in an avian influenza free country, zone or compartment from poultry which were kept in an avian influenza free country, zone or compartment from the time they were hatched until the time of slaughter or for at least the 21 days preceding slaughter, or~~
- 2) ~~these commodities have been processed either:~~
- a) ~~with moist heat at a minimum temperature of 118°C for minimum of 40 minutes; or~~
 - b) ~~with a continuous hydrolysing process under at least 3.79 bar of pressure with steam at a minimum temperature of 122°C for a minimum of 15 minutes; or~~
 - e) ~~with an alternative rendering process that ensures that the internal temperature throughout the product reaches at least 74°C;~~

AND

- 3) ~~the necessary precautions were taken to avoid contact of the commodity with any source of avian influenza viruses.~~

Article 10.4.25.

Procedures for the inactivation of high pathogenicity avian influenza viruses in eggs and egg products

The following times for industry standard temperatures are suitable for the inactivation of high pathogenicity avian influenza viruses present in eggs and egg products:

	Core temperature (°C)	Time
Whole egg	60	188 seconds
Whole egg blends	60	188 seconds
Whole egg blends	61.1	94 seconds
Liquid egg white	55.6	870 seconds
Liquid egg white	56.7	232 seconds
Plain or pure egg yolk	60	288 seconds
10% salted yolk	62.2	138 seconds
Dried egg white	67	20 hours
Dried egg white	54.4	50.4 hours
Dried egg white	51.7	73.2 hours

The listed temperatures are indicative of a range that achieves a 7-log kill of avian influenza virus. These are listed as examples in a variety of egg products, but when scientifically documented, variances from these times and temperatures and for additional egg products may also be suitable when they achieve equivalent inactivation of the virus.

Article 10.4.26.

Procedures for the inactivation of high pathogenicity avian influenza viruses in meat

The following times for industry standard temperatures are suitable for the inactivation of high pathogenicity avian influenza viruses.

	Core temperature (°C)	Time
Poultry meat	60.0	507 seconds
	65.0	42 seconds
	70.0	3.5 seconds
	73.9	0.51 second

The listed temperatures are indicative of a range that achieves a 7-log kill. Where scientifically documented, variances from these times and temperatures may also be suitable when they achieve the inactivation of the virus.

Article 10.4.26bis.

Procedures for the inactivation of high pathogenicity avian influenza viruses in scientific specimens and skins and trophies

For the inactivation of high pathogenicity avian influenza virus in scientific specimens and skins and trophies, one of the following procedures should be used:

- 1) boiling in water for an appropriate time so as to ensure that any matter other than bone, claws or beaks is removed; or
- 2) soaking, with agitation, in a 4% (w/v) solution of washing soda (sodium carbonate-Na₂CO₃) maintained at pH 11.5 or above for at least 48 hours; or
- 3) soaking, with agitation, in a formic acid solution (100 kg salt [NaCl] and 12 kg formic acid per 1,000 litres water) maintained below pH 3.0 for at least 48 hours; wetting and dressing agents may be added; or
- 4) in the case of raw hides, treating for at least 28 days with salt (NaCl) containing 2% washing soda (sodium carbonate-Na₂CO₃); or
- 5) treatment with 1% formalin for a minimum of six days; or
- 6) any equivalent treatment which has been demonstrated to inactivate the virus.

Article 10.4.27.

Introduction to surveillance of high pathogenicity avian influenza

Articles 10.4.27. to 10.4.33. define the principles and provide a guide on the *surveillance* for avian influenza complementary to Chapter 1.4., applicable to Member Countries seeking to determine their high pathogenicity avian influenza status. Surveillance is also necessary to support vaccination programmes, to monitor general situation of H5 and H7 low pathogenicity avian influenza viruses in poultry and for monitoring avian influenza in wild birds. This may be for the entire country, *zone or compartment*. Guidance for Member Countries seeking free status following an outbreak and for the maintenance of avian influenza status is also provided.

~~The presence of influenza A viruses in wild birds creates a particular problem. In essence, no Member Country can declare itself free from influenza A in wild birds. However, the definition of avian influenza in this chapter refers to the infection in poultry only, and Articles 10.4.27. to 10.4.33. were developed under this definition.~~

~~The impact and epidemiology of avian influenza differ widely in different regions of the world and therefore it is impossible to provide specific detailed recommendations for all situations. Surveillance strategies employed for demonstrating freedom from avian influenza at an acceptable level of confidence should be adapted to the local situation. Variables such as the frequency of contacts of poultry with wild birds, different biosecurity levels and production systems and the commingling of different susceptible species including domestic waterfowl require specific surveillance strategies to address each specific situation. It is incumbent upon the Member Country to provide scientific data that explains the epidemiology of avian influenza in the region concerned and also demonstrates how all the risk factors are managed. There is therefore considerable latitude available to Member Countries to provide a well-reasoned argument to prove that absence of infection with avian influenza viruses is assured at an acceptable level of confidence. Surveillance of H5 and H7 low pathogenicity avian influenza viruses in poultry is relevant as they might mutate into high pathogenicity viruses. There is currently no scientific evidence~~

Annex 19 (contd)

to predict if and when mutation might occur. Outbreaks of low pathogenicity viruses can be managed at establishment level, however spread to other poultry establishments increases the risk of virus mutation, in particular if it is not detected and managed. Therefore, a surveillance system should be in place to detect clusters of infected poultry establishments where H5 and H7 low pathogenicity viruses spread between poultry establishments.

Surveillance for avian influenza should be in the form of a continuing programme designed to establish that the country, zone or compartment, for which application is made, is free from infection with avian influenza viruses.

In cases where potential public health implications are suspected, reporting to the appropriate public health authorities is essential.

Article 10.4.28.

General conditions and methods for surveillance – Surveillance for early warning of high pathogenicity avian influenza

- 1) Surveillance for avian influenza should be in the form of a continuing programme designed to detect the presence of infection with high pathogenicity avian influenza viruses in the country or zone in a timely manner. A surveillance system in accordance with Chapter 1.4. should be under the responsibility of the Veterinary Authority. In particular:
 - a) a formal and ongoing system for detecting and investigating outbreaks of disease or infection with avian influenza viruses should be in place;
 - b) a procedure should be in place for the rapid collection and transport of samples from suspect cases of avian influenza to a laboratory for avian influenza diagnosis;
 - e) a system for recording, managing and analysing diagnostic and surveillance data should be in place.

- 2) The high pathogenicity avian influenza surveillance programme should:
 - a) include an early warning system in accordance with Article 1.4.5. throughout the production, marketing and processing chain for reporting suspicious suspected cases. Farmers and workers, who have day-to-day contact with poultry, as well as diagnosticians, should report promptly any suspicion of high pathogenicity avian influenza to the Veterinary Authority. They should be supported directly or indirectly (e.g. through private veterinarians or veterinary para-professionals) by government information programmes and the Veterinary Authority. All suspected cases of high pathogenicity avian influenza should be investigated immediately. As suspicion cannot always be resolved by epidemiological and clinical investigation alone, samples should be taken and submitted to a laboratory for appropriate tests. This requires that sampling kits and other equipment are available for those responsible for surveillance. Personnel responsible for surveillance should be able to call for assistance from a team with expertise in avian influenza diagnosis and control. In cases where potential public health implications are suspected, notification to the appropriate public health authorities is essential;
 - b) implement, when as relevant, regular and frequent clinical inspection, and or serological and virological testing of high-risk groups of animals, such as those adjacent to an high pathogenicity avian influenza infected country or zone, places where birds and poultry of different origins are mixed, such as live bird markets, poultry in close proximity to waterfowl or other potential sources of influenza A viruses. This activity is particularly applicable to domestic waterfowl where detection of high pathogenicity avian influenza via clinical suspicion can be of low sensitivity;
 - c) ensure that antibodies against influenza A viruses, which have been detected in poultry and are not a consequence of vaccination, be immediately investigated. In the case of isolated serological positive results, infection with high pathogenicity avian influenza viruses may be ruled out on the basis of a thorough epidemiological and laboratory investigation that does not demonstrate further evidence of such an infection.

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 influenza A viruses. The rate at which such suspicious cases are likely to occur will differ between epidemiological situations and cannot therefore be predicted reliably. Documentation for freedom from *infection* with avian influenza viruses should, in consequence, provide details of the occurrence of suspicious cases and how they were investigated and dealt with. This should include the results of *laboratory* testing and the control measures to which the *animals* concerned were subjected during the investigation (quarantine, movement stand-still orders, etc.).

Article 10.4.29.

Surveillance strategies

4. Introduction

The target population for *surveillance* aimed at identification of *disease* and *infection* should cover all the susceptible *poultry* species within the country, *zone* or *compartment*. Active and passive *surveillance* for avian influenza should be ongoing with the frequency of active *surveillance* being appropriate to the epidemiological situation in the country. *Surveillance* should be composed of random and targeted approaches using molecular, virological, serological and clinical methods.

The strategy employed may be based on randomised sampling requiring *surveillance* consistent with demonstrating the absence of *infection* with avian influenza viruses at an acceptable level of confidence. Random *surveillance* is conducted using serological tests. Positive serological results should be followed up with molecular or virological methods.

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

A Member Country should justify the *surveillance* strategy chosen as adequate to detect the presence of *infection* with avian influenza viruses in accordance with Chapter 1.4. and the prevailing epidemiological situation, including cases of high pathogenicity influenza A detected in any birds. It may, for example, be appropriate to target clinical *surveillance* at particular species likely to exhibit clear clinical signs (e.g. chickens). Similarly, virological and serological testing could be targeted to species that may not show clinical signs (e.g. ducks).

If a Member Country wishes to declare freedom from *infection* with avian influenza viruses in a specific *zone* or *compartment*, the design of the survey and the basis for the sampling process would need to be aimed at the population within the *zone* or *compartment*.

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

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

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

Annex 19 (contd)

The principles involved in *surveillance for disease and infection* are technically well defined. The design of *surveillance* programmes to prove the absence of *infection* with, or circulation of, avian influenza viruses should be carefully followed to avoid producing results that are either insufficiently reliable, or excessively costly and logistically complicated. The design of any *surveillance* programme, therefore, requires inputs from professionals competent and experienced in this field.

2- Clinical surveillance

Clinical *surveillance* aims at the detection of clinical signs of avian influenza at the *flock* level. Whereas significant emphasis is placed on the diagnostic value of mass serological screening, *surveillance* based on clinical inspection should not be underrated. Monitoring of production parameters, such as increased mortality, reduced feed and water consumption, presence of clinical signs of a respiratory disease or a drop in egg production, is important for the early detection of *infection* with avian influenza viruses. In some cases, the only indication of *infection* with low pathogenicity avian influenza virus may be a drop in feed consumption or egg production.

Clinical *surveillance* and laboratory testing should always be applied in series to clarify the status of avian influenza suspects detected by either of these complementary diagnostic approaches. Laboratory testing may confirm clinical suspicion, while clinical *surveillance* may contribute to confirmation of positive serology. Any sampling unit within which suspicious *animals* are detected should have restrictions imposed upon it until avian influenza *infection* is ruled out.

Identification of suspect *flocks* is vital to the identification of sources of avian influenza viruses and to enable the molecular, antigenic and other biological characteristics of the virus to be determined. It is essential that avian influenza virus isolates are sent regularly to the regional Reference Laboratory for genetic and antigenic characterisation.

3- Virological surveillance

Virological *surveillance* should be conducted:

- a) to monitor at risk populations;
- b) to confirm clinically suspect cases;
- c) to follow up positive serological results;
- d) to test 'normal' daily mortality, to ensure early detection of *infection* in the face of vaccination or in establishments epidemiologically linked to an outbreak.

4- Serological surveillance

Serological *surveillance* aims at the detection of antibodies against avian influenza virus. Positive avian influenza viruses antibody test results can have four possible causes:

- a) natural *infection* with avian influenza viruses;
- b) vaccination against avian influenza;
- c) maternal antibodies derived from a vaccinated or infected parent *flock* are usually found in the yolk and can persist in progeny for up to four weeks;
- d) lack of specificity of the test.

It may be possible to use serum collected for other survey purposes for avian influenza *surveillance*. However, the principles of survey design described in these recommendations and the requirement for a statistically valid survey for the presence of avian influenza viruses should not be compromised.

The discovery of clusters of seropositive *flocks* may reflect any of a series of events, including but not limited to the demographics of the population sampled, vaccinal exposure or *infection*. As clustering may signal *infection*, the investigation of all instances should be incorporated in the survey design. Clustering of positive *flocks* is always epidemiologically significant and therefore should be investigated.

~~If vaccination cannot be excluded as the cause of positive serological reactions, diagnostic methods to differentiate antibodies due to infection or vaccination should be employed.~~

~~The results of random or targeted serological surveys are important in providing reliable evidence that no infection with avian influenza viruses is present in a country, zone or compartment. It is therefore essential that the survey be thoroughly documented.~~

5- Virological and serological surveillance in vaccinated populations

~~The surveillance strategy is dependent on the type of vaccine used. The protection against influenza A virus is haemagglutinin subtype specific. Therefore, two broad vaccination strategies exist: 1) inactivated whole viruses, and 2) haemagglutinin expression-based vaccines.~~

~~In the case of vaccinated populations, the surveillance strategy should be based on virological or serological methods and clinical surveillance. It may be appropriate to use sentinel birds for this purpose. These birds should be unvaccinated, virus antibody free birds and clearly and permanently identified. Sentinel birds should be used only if no appropriate laboratory procedures are available. The interpretation of serological results in the presence of vaccination is described in Article 10.4.33.~~

Article 10.4.30.

Surveillance for demonstrating Documentation of freedom from avian influenza or freedom from infection with high pathogenicity avian influenza viruses in poultry

1. Additional surveillance requirements for Member Countries declaring freedom of the country, zone or compartment from avian influenza or from infection with high pathogenicity avian influenza viruses in poultry

~~In addition to the general conditions described in above mentioned articles, a Member Country declaring freedom of the entire country, or a zone or a compartment from avian influenza or from infection with high pathogenicity avian influenza viruses in poultry should provide evidence for the existence of an effective surveillance programme.~~

~~The strategy and design of the surveillance programme depend on the prevailing epidemiological circumstances and should be planned and implemented according to general conditions and methods described in this chapter and in Article 1.4.6, to demonstrate absence of infection with avian influenza viruses or with high pathogenicity avian influenza viruses, during the preceding 12 months in susceptible poultry populations (vaccinated and non-vaccinated). This requires the availability of demographic data on the poultry population and the support of a laboratory able to undertake identification of infection with avian influenza viruses through virus detection and antibody tests. This surveillance may be targeted to poultry population at specific risks linked to the types of production, possible direct or indirect contact with wild birds, multi-age flocks, local trade patterns including live bird markets, use of possibly contaminated surface water, and the presence of more than one species on the holding establishment and poor biosecurity measures in place. It should include the monitoring of high pathogenicity avian influenza virus in wild birds and of H5 and H7 low pathogenicity avian influenza virus in poultry, in order to adapt the biosecurity and possible control measures.~~

~~Documentation for freedom from infection with high pathogenicity avian influenza should provide details of the poultry population, the occurrence of suspected cases and how they were investigated and dealt with. This should include the results of laboratory testing and the biosecurity and control measures to which the animals concerned were subjected during the investigation.~~

2. Additional requirements for countries, zones or compartments that practice vaccination

~~Vaccination to prevent the transmission of high pathogenicity avian influenza virus may be part of a disease control programme. The level of flock immunity required to prevent transmission depends on the flock size, composition (e.g. species) and density of the susceptible poultry population. It is therefore impossible to be prescriptive. Based on the epidemiology of avian influenza in the country, zone or compartment, it may be that a decision is reached to vaccinate only certain species or other poultry subpopulations.~~

Annex 19 (contd)

In all vaccinated *flocks* there is a need to perform virological and serological tests to ensure the absence of virus circulation. The use of sentinel *poultry* may provide further confidence of the absence of virus circulation. The tests have to be repeated at least every six months or at shorter intervals according to the *risk* in the country, *zone* or *compartment*.

Evidence to show the effectiveness of the *vaccination* programme should also be provided.

Member Countries seeking the demonstration of freedom from high pathogenicity avian influenza in vaccinated population should refer to Chapter 2.3.4, paragraph C 4 of the *Terrestrial Manual*.

3. Additional requirements for recovery of free status

In addition to the conditions described in the point above, a Member Country declaring that it has regained country, zone or compartment freedom after an outbreak of high pathogenicity avian influenza in poultry should show evidence of an active surveillance programme depending on the epidemiological circumstances of the outbreak to demonstrate the absence of the infection. This will require surveillance incorporating virus detection and antibody tests. The use of sentinel birds may facilitate the interpretation of surveillance results. The Member Country should report the results of an active surveillance programme in which the susceptible poultry population undergoes regular clinical examination and active surveillance planned and implemented according to the general conditions and methods described in these recommendations. The surveillance samples should be representative of poultry populations at risk.

Populations under this surveillance programme should include:

- 1) establishments in the proximity of the outbreaks;
- 2) establishments epidemiologically linked to the outbreaks;
- 3) animals moved from or used to re-populate affected establishments;
- 4) any establishments where contiguous culling has been carried out;

Article 10.4.30bis.

Surveillance of wild bird populations

The presence of high pathogenicity avian influenza viruses in wild birds creates a particular problem. In essence, no Member Country can declare itself free from influenza A viruses in wild birds. However, the definition of high pathogenicity avian influenza in this chapter refers to the infection in poultry only, and Articles 10.4.27. to 10.4.33. were developed under this definition.

Passive surveillance (i.e. sampling of birds found dead) is an appropriate method of surveillance in wild birds as infection with high pathogenicity avian influenza is usually associated with mortality. Mortality events, or clusters of birds found dead should be reported to the local Veterinary Authorities and investigated.

Active surveillance in wild birds usually has lower sensitivity for detection of high pathogenicity avian influenza, but may be necessary for detection of some strains of high pathogenicity avian influenza virus that produce infection without mortality in wild birds.

Surveillance in wild birds should be targeted towards species, locations and times of year in which infection is more likely.

Surveillance in wild birds should be enhanced by awareness raising and active searching and monitoring for dead or moribund wild birds when high pathogenicity avian influenza has been detected in the region. The movements of migratory water birds, in particular ducks, geese and swans, should be taken into account as a potential pathway for introduction of virus to uninfected areas.

Article 10.4.30ter.**Monitoring of H5 and H7 low pathogenicity avian influenza in poultry populations**

Monitoring the presence of H5 and H7 low pathogenicity avian influenza viruses can be achieved through the combination of clinical investigations where infection is suspected through changes in production indicators such as reductions in egg production or feed and water intake and active serological and virological surveillance.

Serological monitoring should aim at detecting clusters of infected flocks to identify spread between establishments. Epidemiological follow-up (tracing forward and back) of serologically positive flocks should be carried out to determine if there is clustering of infected flocks regardless of whether the seropositive birds are still present on the establishment or whether active virus infection has been detected.

Article 10.4.31.**Additional surveillance requirements for countries, zones or compartments declaring that they have regained freedom from avian influenza or from infection with high pathogenicity avian influenza viruses in poultry following an outbreak**

~~In addition to the general conditions described in the above-mentioned articles, a Member Country declaring that it has regained country, zone or compartment freedom from avian influenza or from infection with high pathogenicity avian influenza viruses in poultry should show evidence of an active surveillance programme depending on the epidemiological circumstances of the outbreak to demonstrate the absence of the infection. This will require surveillance incorporating virus detection and antibody tests. The use of sentinel birds may facilitate the interpretation of surveillance results.~~

~~A Member Country declaring freedom of country, zone or compartment after an outbreak of avian influenza should report the results of an active surveillance programme in which the susceptible poultry population undergoes regular clinical examination and active surveillance planned and implemented according to the general conditions and methods described in these recommendations. The surveillance should at least give the confidence that can be given by a randomised representative sample of the populations at risk.~~

Article 10.4.32.**Additional surveillance requirements for the avian influenza free establishments**

The declaration of avian influenza free establishments requires the demonstration of absence of infection with avian influenza viruses. Birds in these establishments should be randomly tested using virus detection or isolation tests, and serological methods, following the general conditions of these recommendations. The frequency of testing should be based on the risk of infection and at a maximum interval of ~~24~~ 28 days.

Article 10.4.33.**The use and interpretation of serological and virus detection tests**

~~Poultry infected with avian influenza virus produce antibodies against haemagglutinin (HA), neuraminidase (NA), nonstructural proteins (NSPs), nucleoprotein/matrix (NP/M) and the polymerase complex proteins. Detection of antibodies against the polymerase complex proteins is not covered in this chapter. Tests for NP/M antibodies include direct and blocking ELISA, and agar gel immunodiffusion (AGID) tests. Tests for antibodies against NA include the neuraminidase inhibition (NI), indirect fluorescent antibody and direct and blocking ELISA tests. For the HA, antibodies are detected in haemagglutination inhibition (HI), ELISA and neutralisation (SN) tests. The HI test is reliable in avian species but not in mammals. The SN test can be used to detect subtype specific antibodies against the haemagglutinin and is the preferred test for mammals and some avian species. The AGID test is reliable for detection of NP/M antibodies in chickens and turkeys, but not in other avian species. As an alternative, blocking ELISA tests have been developed to detect NP/M antibodies in all avian species.~~

~~The HI and NI tests can be used to subtype influenza A viruses into 16 haemagglutinin and 9 neuraminidase subtypes. Such information is helpful for epidemiological investigations and in categorization of influenza A viruses.~~

Annex 19 (contd)

~~Poultry can be vaccinated with a variety of influenza A vaccines including inactivated whole virus vaccines, and haemagglutinin expression based vaccines. Antibodies against the haemagglutinin confer subtype specific protection. Various strategies can be used to differentiate vaccinated from infected birds including serosurveillance in unvaccinated sentinel birds or specific serological tests in the vaccinated birds.~~

~~Influenza A virus infection of unvaccinated birds including sentinels is detected by antibodies against the NP/M, subtype specific HA or NA proteins, or NSP. Poultry vaccinated with inactivated whole virus vaccines containing a virus of the same H sub-type but with a different neuraminidase may be tested for field exposure by applying serological tests directed to the detection of antibodies against the NA of the field virus. For example, birds vaccinated with H7N3 in the face of a H7N1 epidemic may be differentiated from infected birds (DIVA) by detection of subtype specific NA antibodies of the N1 protein of the field virus. Alternatively, in the absence of DIVA, inactivated vaccines may induce low titres of antibodies against NSP and the titre in infected birds would be markedly higher. Encouraging results have been obtained experimentally with this system, but it has not yet been validated in the field. In poultry vaccinated with haemagglutinin expression based vaccines, antibodies are detected against the specific HA, but not any of the other viral proteins. Infection is evident by antibodies against the NP/M or NSP, or the specific NA protein of the field virus.~~

~~All flocks with seropositive results should be investigated. Epidemiological and supplementary laboratory investigation results should document the status of avian influenza infection for each positive flock.~~

~~A confirmatory test should have a higher specificity than the screening test and sensitivity at least equivalent than that of the screening test.~~

~~Information should be provided on the performance characteristics and validation of tests used.~~

4- Procedure in case of positive test results if vaccination is used

~~In case of vaccinated populations, one has to exclude the likelihood that positive test results are indicative of virus circulation. To this end, the following procedure should be followed in the investigation of positive serological test results derived from surveillance conducted on vaccinated poultry. The investigation should examine all evidence that might confirm or refute the hypothesis that the positive results to the serological tests employed in the initial survey were not due to virus circulation. All the epidemiological information should be substantiated, and the results should be collated in the final report.~~

~~Knowledge of the type of vaccine used is crucial in developing a serological based strategy to differentiate infected from vaccinated animals.~~

- ~~a) Inactivated whole virus vaccines can use either homologous or heterologous neuraminidase subtypes between the vaccine and field strains. If poultry in the population have antibodies against NP/M and were vaccinated with inactivated whole virus vaccine, the following strategies should be applied:

 - ~~i) sentinel birds should remain NP/M antibody negative. If positive for NP/M antibodies, indicating influenza A virus infection, specific HI tests should be performed to identify H5 or H7 virus infection;~~
 - ~~ii) if vaccinated with inactivated whole virus vaccine containing homologous NA to field virus, the presence of antibodies against NSP could be indicative of infection. Sampling should be initiated to exclude the presence of avian influenza virus by either virus isolation or detection of virus specific genomic material or proteins;~~
 - ~~iii) if vaccinated with inactivated whole virus vaccine containing heterologous NA to field virus, presence of antibodies against the field virus NA or NSP would be indicative of infection. Sampling should be initiated to exclude the presence of avian influenza virus by either virus isolation or detection of virus specific genomic material or proteins.~~~~
- ~~b) Haemagglutinin expression based vaccines contain the HA protein or gene homologous to the HA of the field virus. Sentinel birds as described above can be used to detect avian influenza infection. In vaccinated or sentinel birds, the presence of antibodies against NP/M, NSP or field virus NA is indicative of infection. Sampling should be initiated to exclude the presence of avian influenza virus by either virus isolation or detection of virus specific genomic material or proteins.~~

2- Procedure in case of test results indicative of infection with avian influenza viruses

The detection of antibodies indicative of an infection with avian influenza virus in unvaccinated poultry should result in the initiation of epidemiological and virological investigations to determine if the infections are due to low and high pathogenicity viruses.

Virological testing should be initiated in all antibody-positive and at risk populations. The samples should be evaluated for the presence of avian influenza virus, by virus isolation and identification, or detection of influenza A specific proteins or nucleic acids (Figure 2). Virus isolation is the gold standard for detecting infection by avian influenza virus. All influenza A virus isolates should be tested to determine HA and NA subtypes, and *in vivo* tested in chickens or sequencing of HA proteolytic cleavage site of H5 and H7 subtypes for determination of classification as high or low pathogenicity avian influenza viruses or other influenza A viruses. As an alternative, nucleic acid detection tests have been developed and validated; these tests have the sensitivity of virus isolation, but with the advantage of providing results within a few hours. Samples with detection of H5 and H7 HA subtypes by nucleic acid detection methods should either be submitted for virus isolation, identification, and *in vivo* testing in chickens, or sequencing of nucleic acids for determination of proteolytic cleavage site as high or low pathogenicity avian influenza viruses. The use of antigen detection systems, because of low sensitivity, should be limited to screening clinical field cases for infection by influenza A virus looking for NP/M proteins. NP/M positive samples should be submitted for virus isolation, identification and pathogenicity determination.

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

- a) characterisation of the existing production systems;
- b) results of clinical surveillance of the suspects and their cohorts;
- c) quantification of vaccinations performed on the affected sites;
- d) sanitary protocol and history of the affected establishments;
- e) control of animal identification and movements;
- f) other parameters of regional significance in historic avian influenza virus transmission.

The entire investigative process should be documented as standard operating procedure within the epidemiological surveillance programme.

Figures 1 and 2 indicate the tests which are recommended for use in the investigation of poultry flocks.

Key abbreviations and acronyms:	
AGID	Agar gel immunodiffusion
DIVA	Differentiating infected from vaccinated animals
ELISA	Enzyme-linked immunosorbent assay
HA	Haemagglutinin
HI	Haemagglutination inhibition
NA	Neuraminidase
NP/M	Nucleoprotein and matrix protein
NSP	Nonstructural protein
S	No evidence of avian influenza virus

Fig. 1. Schematic representation of laboratory tests for determining evidence of avian influenza infection through or following serological surveys

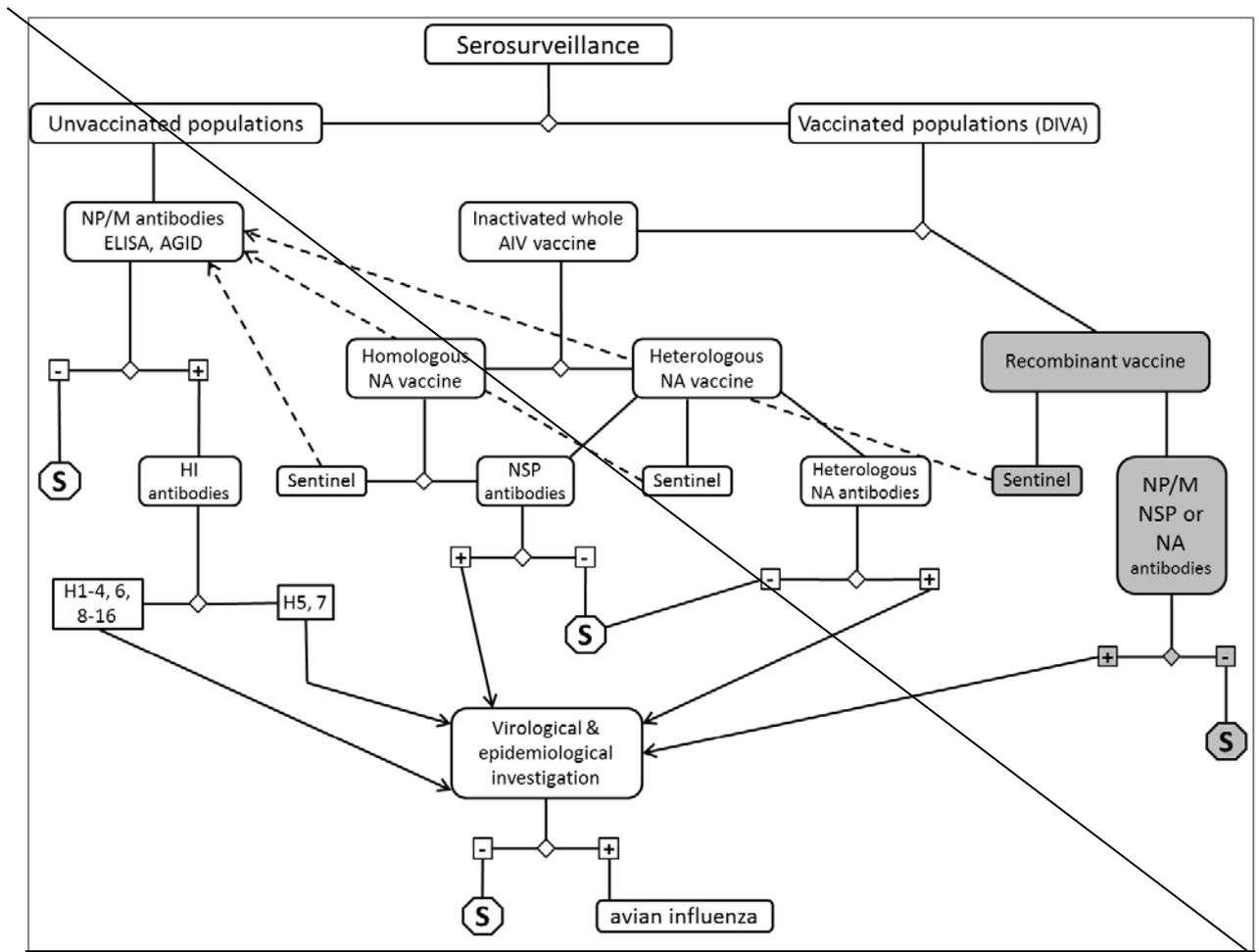
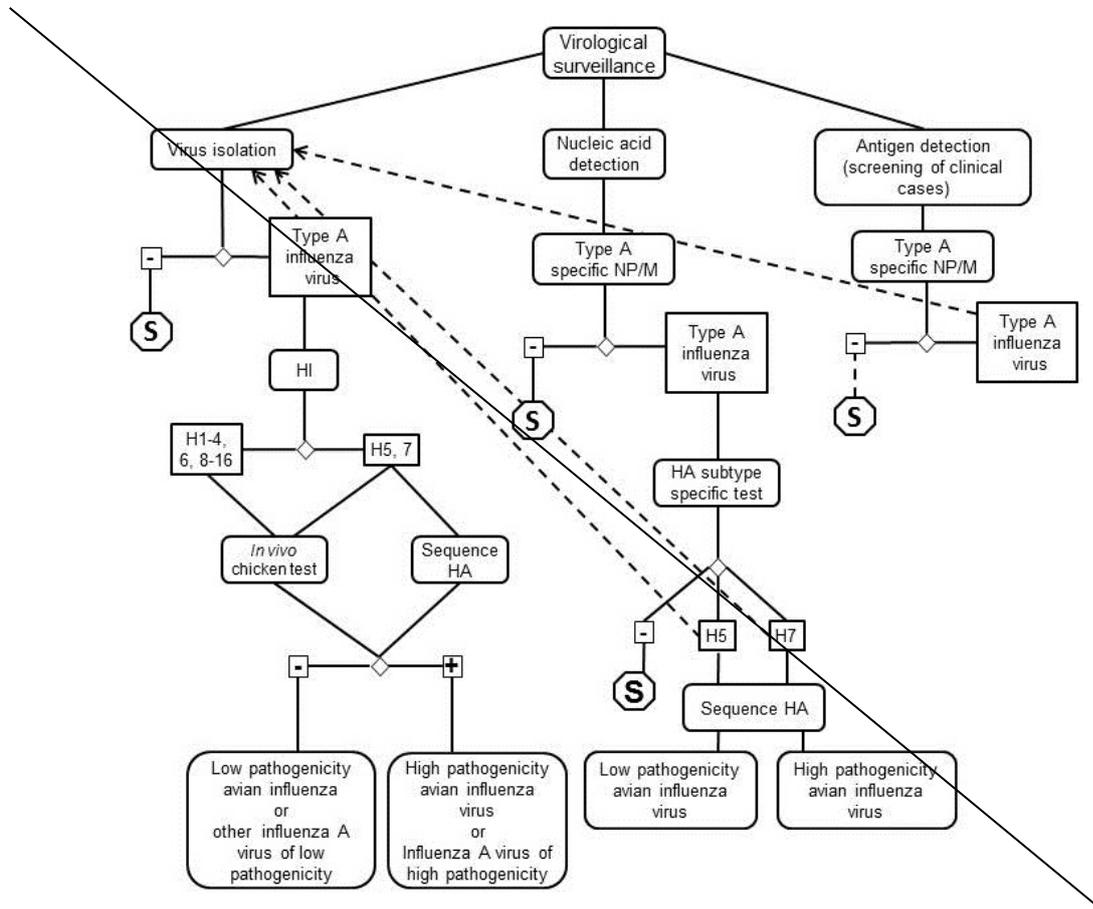


Fig. 2. Schematic representation of laboratory tests for determining evidence of avian influenza infection using virological methods



CHAPTER 1.1.

NOTIFICATION OF DISEASES, INFECTIONS AND INFESTATIONS, AND PROVISION OF EPIDEMIOLOGICAL INFORMATION

Article 1.1.1.

For the purposes of the *Terrestrial Code* and in terms of Articles 5, 9 and 10 of the OIE Organic Statutes, Member Countries shall recognise the right of the *Headquarters* to communicate directly with the *Veterinary Authority* of its territory or territories.

All *notifications* and all information sent by the OIE to the *Veterinary Authority* shall be regarded as having been sent to the country concerned and all *notifications* and all information sent to the OIE by the *Veterinary Authority* shall be regarded as having been sent by the country concerned.

Article 1.1.2.

- 1) Member Countries shall make available to other Member Countries, through the OIE, whatever information is necessary to minimise the spread of important animal diseases, and their pathogenic agents, and to assist in achieving better worldwide control of these diseases.
- 2) To achieve this, Member Countries shall comply with the *notification* requirements specified in Articles 1.1.3. and 1.1.4.
- 3) For the purposes of this chapter, an 'event' means a single *outbreak* or a group of epidemiologically related *outbreaks* of a given ~~disease, infection or infestation~~ that is the subject of a *notification*. An event is specific to a pathogenic agent and strain, when appropriate, and includes all related *outbreaks* reported from the time of the immediate *notification* through to the final report. Reports of an event include susceptible species, number and geographical distribution of affected animals and *epidemiological units*.
- 4) To assist in the clear and concise exchange of information, reports shall conform as closely as possible to the OIE disease reporting format.
- 5) The detection of the pathogenic agent of a *listed disease* in an *animal* should be reported, even in the absence of clinical signs. Recognising that scientific knowledge concerning the relationship between diseases and their pathogenic agents is constantly developing and that the presence of a pathogenic agent does not necessarily imply the presence of a disease, Member Countries shall ensure, through their reports, that they comply with the spirit and intention of point 1) above.
- 6) In addition to notifying new findings in accordance with Articles 1.1.3. and 1.1.4., Member Countries shall also provide information on the measures taken to prevent the spread of diseases, ~~infections and infestations~~. Information shall include biosecurity and quarantine sanitary measures ~~and including~~ restrictions applied to the movement of *animals*, animal products, biological products and other miscellaneous objects which could by their nature be responsible for the transmission of diseases, ~~infections or infestations~~. In the case of diseases transmitted by *vectors*, the measures taken against such *vectors* shall also be specified.

Article 1.1.3.

Veterinary Authorities shall, under the responsibility of the Delegate, send to the *Headquarters*:

- 1) in accordance with relevant provisions in the disease-specific chapters, *notification*, through the World Animal Health Information System (WAHIS) or by fax or email within 24 hours, of any of the following events:

Annex 20 (contd)

- a) first occurrence of a *listed disease*, ~~infection or infestation~~ in a country, a *zone* or a *compartment*;
 - b) recurrence of an eradicated *listed disease*, ~~infection or infestation~~ in a country, a *zone* or a *compartment* following the final report that declared the outbreak event ended;
 - c) first occurrence of a new strain of a pathogenic agent of a *listed disease*, ~~infection or infestation~~ in a country, a *zone* or a *compartment*;
 - d) recurrence of an eradicated strain of a pathogenic agent of a listed disease in a country, a zone or a compartment following the final report that declared the event ended;
 - ~~e) a sudden and unexpected change in the distribution or increase in incidence or virulence of, or morbidity or mortality caused by, the pathogenic agent of a listed disease, infection or infestation present within a country, a zone or a compartment;~~
 - ~~f) occurrence of a listed disease, infection or infestation in an unusual host species;~~
- 2) weekly reports subsequent to a *notification* under point 1) above, to provide further information on the evolution of the event which justified the *notification*. These reports should continue until the listed disease, infection or infestation has been eradicated or the situation has become sufficiently stable so that six-monthly reporting under point 3) will satisfy the obligation of the Member Country; for each event notified, a final report should be submitted;
 - 3) six-monthly reports on the absence or presence and evolution of *listed diseases, infections or infestations* and information of epidemiological significance to other Member Countries;
 - 4) annual reports concerning any other information of significance to other Member Countries.

Article 1.1.4.

Veterinary Authorities shall, under the responsibility of the Delegate, send to the *Headquarters*:

- 1) a *notification* through WAHIS or by fax or email, when an *emerging disease* has been detected in a country, a *zone* or a *compartment*;
 - 2) periodic reports subsequent to a *notification* of an *emerging disease*:
 - a) for the time necessary to have reasonable certainty that:
 - the ~~disease, infection or infestation~~ has been eradicated; or
 - the situation has become stable;
- OR
- b) until sufficient scientific information is available to determine whether it meets the criteria for inclusion in the OIE list as described in Chapter 1.2.;
 - 3) a final report once point 2 a) or b) above is complied with.

Article 1.1.5.

- ~~1) The *Veterinary Authority* of a country in which an *infected zone* is located shall inform the *Headquarters* when this zone or the entire country becomes free from the *disease, infection or infestation*.~~
- ~~2) A country or zone may be considered to have regained freedom from a specific *disease, infection or infestation* when all relevant conditions given in the *Terrestrial Code* have been fulfilled.~~

Annex 20 (contd)

- 3) ~~The Veterinary Authority of a Member Country which establishes one or several free zones shall inform the Headquarters giving necessary details, including the criteria on which the free status is based, the requirements for maintaining the status and indicating clearly the location of the zones on a map of the territory of the Member Country.~~

Article 1.1.65.

- 1) Although Member Countries are only required to notify *listed diseases*, ~~*infections and infestations*~~ and *emerging diseases*, they are encouraged to provide the OIE with other important animal health information.
 - 2) The *Headquarters* shall communicate by email or through the interface of WAHIS to *Veterinary Authorities* all *notifications* received as provided in Articles 1.1.2. to 1.1.54. and other relevant information.
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WORK PROGRAMME FOR THE TERRESTRIAL ANIMAL HEALTH STANDARDS COMMISSION

Subject	Issue by priority order (Reason for new work)	Status and Action (Start date, # of rounds for comments)
Horizontal chapters		
Restructuring of the Code	1) Work with AAHSC towards harmonisation, as appropriate, of the horizontal parts of the <i>Codes</i> , notably Glossary, User's Guide and Section 4 on disease control and Section 6 on veterinary public health (MCs comments)	Ongoing
	2) Work with BSC for accurate disease description and diagnostic in the <i>Manual</i> and case definitions in the <i>Code</i> and names of diseases and country and zone disease status (MCs comments)	Ongoing
	3) Revision and formatting of chapters (articles numbering, tables and figures) (MCs comments and to improve consistency)	Ongoing
	4) Revision of the Users' guide (MCs comments and changes in the <i>Code</i>)	Ongoing
Glossary	1) 'early warning system' and 'sanitary measures' (experts comments)	Revised definitions sent for adoption (Sep 2016/3rd and Feb 2018/2nd)
	2) 'Competent Authority', 'Veterinary Authority' and 'Veterinary Services' (AHG comments), 'epidemiological unit' and 'captive wild [animal]' (MCs comments)	Revised definitions sent for comments (Sep 2018/1st)
Horizontal issues not yet in the Code		
Section 4. Disease control	1) New CH on official control of listed and emerging diseases (MCs comments and part of restructuring of Section 4)	Revised new CH sent for adoption (Feb 2017/4th)
	2) New introductory CH in Section 4 (Part of restructuring of Section 4)	Revised new CH sent for comments and adoption (Sep 2017/3rd)
	3) New CH on biosecurity (Discussion with ACC)	Preliminary discussion
	4) New CH on application of zoning (MCs comments)	Preliminary discussion
Section 6. Veterinary public health	1) Control of Shiga toxin-producing <i>E. coli</i> (STEC) in food-producing animals (MCs comments)	Preliminary discussion pending FAO/WHO expert consultation
Section 7. Animal welfare	1) New CH on slaughter and killing methods of farmed reptiles (MCs comments)	Revised new CH sent for comments and adoption (Sep 2017/3rd)
	2) New CH on AW and laying hen production systems (MCs comments)	Revised new CH sent for comments (Sep 2017/2nd)

Annex 21 (contd)

Subject	Issue by priority order (Reason for new work)	Status and Action (Start date, # of rounds for comments)
Horizontal chapters in need of revision		
Section 1. Animal disease diagnosis, surveillance and notification	1) CH 1.4. on animal health surveillance (MCs comments and implications for status recognition)	Revised CH sent for comments and adoption (Feb 2016/4th)
	2) CH 1.6. on status: revision and reorganisation (MCs comments and implications for status recognition)	Revised CH sent for comments (Feb 2018/2nd)
	3) CH 1.1. on notification of diseases (for clarity, HQs and MCs comments)	Revised CH sent for comments (Sep 2018/1st)
	4) CH 1.3. on listed diseases: assess CWD, WNF, PED, <i>Theileria (orientalis)</i> , for small ruminants), <i>M. tuberculosis</i> , <i>M. paratuberculosis</i> against the listing criteria (MCs comments)	Pending expert's advice
Section 3. Veterinary Services	1) CHs 3.4. on veterinary legislation (the return of experience of the PVS Pathway)	Revised CH sent for comments (Sep 2018/1st)
	2) CHs 3.1. and 3.2. on Veterinary Services (the return of experience of the PVS Pathway)	Pending proposal from AHG
Section 4. Disease control	1) CH 4.13. on disinfection (MCs comments)	Preliminary discussion
	2) CH 4.6. on collection and processing of semen (MCs comments and trade implications)	Pending expert's advice
	3) CH 4.5. on general hygiene in semen collection and processing centres	Pending expert's advice
	4) CH 4.7. on collection and processing of <i>in vivo</i> derived embryos (MCs comments)	Pending expert's advice
Section 5. Trade measures	1) CHs 5.4. to 5.7. on measures applicable at departure and on arrival (MCs comments)	Preliminary discussion and pending decision on AHG
	2) CH 5.12. on model certificates for competition horses (MCs comments)	Preliminary discussion and pending revision of CHs on horse diseases
	3) CH 5.10. to include a model certificate for petfood (NGO comments)	Preliminary discussion and pending supporting data from industry
Section 6. Veterinary public health	1) CH 6.3. on meat inspection (Planned work by TAHSC)	Preliminary discussion pending AHG
Section 7. Animal welfare	1) CH 7.5. on slaughter and CH 7.6. on killing of animals (MCs comments)	Pending work of AHG
	2) CH 7.7. on stray dog population control (global control programme)	Preliminary discussion

Subject	Issue by priority order (Reason for new work)	Status and Action (Start date, # of rounds for comments)
Diseases not yet in the Code		
Disease-specific chapters	1) New CH on non-equine surra and revision of CH on Dourine (Non-tsetse transmitted Trypanosomosis) (MCs comments)	New/revised CHs sent for comments and pending work of AHG (Sep 2017/2nd)
	2) New CH on Tsetse transmitted trypanosomosis (MCs comments)	Pending work of AHG
	3) New CH on Crimean Congo hemorrhagic fever (MCs comments, listed disease without chapter)	Preliminary discussion
Listed disease chapters/articles in need of revision		
Sections 8 to 15	1) CH 10.4. on AI (MCs comments and trade implications)	AHG report and draft revised CH sent for comments (Sep 2018/1st)
	2) CH 8.14. on rabies (MCs comments and global control programme)	Revised CH sent for comments and adoption (Feb 2018/2nd)
	3) CH 11.4. on BSE (MCs comments and trade implications)	Pending work of AHGs (Feb 2015/1st)
	4) CH 15.2. on CSF (MCs comments and implications for status recognition)	Revised CH sent for comments (Feb 2017/2nd)
	5) Revision of Articles 8.15.1., 8.15.4. and 8.15.5. (HQs and MC comments)	Pending work from HQs
	6) CH 11.12. on Theileriosis and new CH 14.X. on infection with <i>Theileria</i> in small ruminants (outdated CH)	Revised/new CHs sent for experts advice on listing pathogenic agents (Sep 2017/1st)
	7) Harmonisation of articles regarding official status recognition by the OIE (SCAD and HQs)	Pending work of HQs
	8) CH 8.8. on FMD (MCs comments and implications for status recognition)	Pending outcome of discussion on zoning (Sep 2015/2nd)
	9) Chapter 8.16. on rinderpest (HQs, proposal by JAC, global rinderpest action plan)	Pending work of HQs and JAC
	10) Revision of Article 15.3.9. on import of semen from countries not free from PRRS (MCs comments)	Pending experts advice
	11) CH 14.8. on scrapie (MCs comments)	Pending experts opinion on MCs comments
	12) CH 10.5. on avian mycoplasmosis (MCs comments and trade implications)	Pending experts opinion
	13) CH 11.7. on CBPP (implications for status recognition)	Pending HQs advice
	14) Revision of safe commodities list to add lactose (MC comments)	Pending experts' advice

Annex 21 (contd)

Subject	Issue by priority order (Reason for new work)	Status and Action (Start date, # of rounds for comments)
Follow-up revision of chapters recently adopted		
Recently adopted chapters	1) Articles 15.1.1bis., 15.1.2. and 15.1.22. on ASF (MCs comments at 85GS)	Revised CH sent for comments and adoption (Sep 2017/3rd)
	2) CH 4.3. on zoning and compartmentalisation (MCs comments at 86GS)	Pending discussion on temporary protection zone
	3) CH 6.2. on the role of Veterinary Services in food safety systems (MCs comments at 86GS)	Revised CH sent for comments and adoption
	4) Article 7.1.4. on the guiding principles for the use of measures to assess animal welfare (MCs comments at 86GS)	Revised article sent for comments and adoption
	5) CH 7.13. on animal welfare and pig production systems (MCs comments at 86GS)	Revised article sent for comments and adoption

List of abbreviations	
AAHSC	Aquatic Animal Health Standards Commission
AHG	<i>ad hoc</i> Group
AMR	Antimicrobial resistance
AI	Avian influenza
ASF	African swine fever
AW	Animal Welfare
BSC	Biological Standards Commission
BSE	Bovine Spongiform Encephalopathy
CBPP	Contagious bovine pleuropneumonia
CH	Chapters
CSF	Classical swine fever
CWD	Chronic wasting disease
FMD	Foot and mouth disease
HQs	Headquarters
JAC	FAO-OIE Rinderpest Joint Advisory Committee
LSD	Lumpy skin disease
NGO	Non-Governmental Organisation
PVS	Performance of Veterinary Service
TAHSC	Terrestrial Animal Health Standards Commission
WNF	West Nile fever