

MEETING OF THE OIE TERRESTRIAL ANIMAL HEALTH STANDARDS COMMISSION**Paris, 10–19 September 2019****List of participants****MEMBERS OF THE CODE COMMISSION**

Dr Etienne Bonbon*President*Senior Veterinary Advisor
EMC-AH / Animal Health Service
Food and Agriculture Organization of the
United NationsViale delle Terme di Caracalla
00153 Rome

ITALY

Tel.: +39 06 570 52447

E-mail: etienne.bonbon@fao.orgE-mail: e.bonbon@oie.int**Prof. Salah Hammami**Epidemiologist & Virologist
Services of Microbiology-
Immunology & General Pathology
National School of Veterinary
Medicine

Sidi Thabet-2020

TUNISIA

Tel.: + 216 71 552 200

E-mail: hammami.salah@iresa.agrinet.tnE-mail: saleehammami@yahoo.fr**Dr Lucio Ignacio Carbajo Goñi***Attaché*Ministry of Agriculture, Food and Environment
Spanish Embassy in Brazil
SPAINE-mail: lcarbajo@mapama.esE-mail: lcg958@gmail.com**Dr Masatsugu Okita***2nd Vice-President*Director
International Animal Health Affairs Office
Animal Health Division
Ministry of Agriculture, Forestry and Fisheries
1-2-1 Kasumigaseki
Chiyoda-ku

Tokyo 100-8950

JAPAN

E-mail: masatsugu_okita130@maff.go.jp**Dr Gaston Maria Funes***1st Vice-President*Counsellor for Agricultural Affairs
Embassy of Argentina to the EU
Avenue Louise 225, (4th floor)

1050 Brussels

BELGIUM

E-mail: gmfunes@maqyp.gob.ar**Dr Bernardo Todeschini**Federal Superintendent of Agriculture
for Rio Grande do SulMinistry of Agriculture, Livestock
and Food Supply

BRAZIL

E-mail: bernardo.todeschini@agricultura.gov.br**OIE HEADQUARTERS**

Dr Gillian Mylrea

Head

Standards Department

E-mail: g.mylrea@oie.int**Dr Charmaine Chng**

Chargée de mission

Standards Department

E-mail: c.chng@oie.int**Dr Francisco D'Alessio**

Deputy head

Standards Department

E-mail: f.dalessio@oie.int**Dr Kiyokazu Murai**

Chargé de mission

Standards Department

E-mail: k.murai@oie.int**Dr Leopoldo Stuardo**

Chargé de mission

Standards Department

E-mail: l.stuardo@oie.int

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Adopted agenda

- 1. Welcome from the Deputy Director General**
- 2. Meeting with the Director General**
- 3. Adoption of agenda**
- 4. Cooperation with other Specialist Commissions**
 - 4.1 Scientific Commission for Animal Diseases
 - 4.2 Biological Standards Commission
- 5. Code Commission's work programme**
- 6. Texts proposed for adoption in May 2020**
 - 6.1 User's Guide
 - 6.2 Glossary Part A ('epidemiological unit')
 - 6.3 Notification of diseases, infections and infestations, and provision of epidemiological information (Chapter 1.1)
 - 6.4 Procedures for self-declaration and for official recognition by the OIE (Chapter 1.6)
 - 6.5 Veterinary legislation (Chapter 3.4)
 - 6.6 Draft new chapter on official control programmes for listed and emerging diseases (Chapter 4.Y)
 - 6.7 Draft new chapter on animal welfare and laying hen production systems (Chapter 7.Z)
 - 6.8 Infection with avian influenza viruses (Chapter 10.4)
 - 6.9 Infection with peste des petits ruminants virus (Articles 14.7.3, 14.7.7, 14.7.24 and 14.7.34)
 - 6.10 Infection with classical swine fever virus (Chapter 15.2)
- 7. Texts for comments**
 - 7.1 Glossary Part B ('captive wild [animal]', 'feral [animal]', 'wild [animal]', 'slaughter', 'euthanasia', 'stunning', 'death', 'pain', 'distress' and 'suffering')
 - 7.2 Diseases, infections and infestations listed by the OIE (Articles 1.3.1 and 1.3.9)
 - 7.3 Quality of Veterinary Services, Evaluation of Veterinary Services and draft new chapter on Veterinary Services (Chapters 3.1, 3.2, 3.X)
 - 7.4 Slaughter of animals (Chapter 7.5)

Annex 2 (contd)

7.5 Draft new chapter on infection with animal trypanosomes of African origin (Chapter 8.Y)

7.6 Infection with *Mycobacterium tuberculosis* complex (Chapter 8.11)

7.7 Infection with Rift Valley fever virus (Chapter 8.15)

7.8 Bovine spongiform encephalopathy (Chapter 11.4)

7.9 Infection with equine influenza (Article 12.6.6)

8. Other topics for information

8.1 Glossary definitions for ‘Competent Authority’, ‘Veterinary Authority’ and ‘Veterinary Services’

8.2 General hygiene in semen collection and processing centres and collection and processing of bovine, small ruminant and porcine semen (Chapters 4.6 and 4.7)

8.3 Revision of collection and processing of oocytes and *in vitro* produced embryos from livestock and horses (Chapter 4.9) to include bovine viral diarrhea

8.4 Infection with rinderpest virus (Chapter 8.16)

8.5 Contagious equine metritis and equine piroplasmiasis (Chapters 12.2 and 12.7)

8.6 Harmonisation of *Terrestrial Code* chapters for diseases with OIE official status recognition

8.7 The Scientific Commission’s recommendation on the evaluation of pathogenic agents against the listing criteria

9. Date of next meeting

USER'S GUIDE

[...]

B. *Terrestrial Code* content

[...]

- 3) The standards in the chapters of Section 1 are designed for the implementation of measures for the diagnosis, surveillance and notification of ~~pathogenic agents~~ diseases, infections and infestations. The standards include procedures for notification to the OIE, tests for international trade, and procedures for the assessment of the health status of a country, zone or compartment.

[...]

C. Specific issues

[...]

5. Trade requirements

Animal health measures related to international trade should be based on OIE standards. A Member Country may authorise the importation of animals or animal products into its territory under conditions different from those recommended by the *Terrestrial Code*. To scientifically justify more stringent measures, the importing country should conduct a risk analysis in accordance with OIE standards, as described in Chapter 2.1. Members of the WTO should refer to the Agreement on the Application of Sanitary and Phytosanitary Measures (SPS Agreement).

Chapters 5.1. to 5.3. describe the obligations and ethical responsibilities of importing and exporting countries in international trade. Veterinary Authorities and all veterinarians directly involved in international trade should be familiar with these chapters. Chapter 5.3. also describes the OIE informal procedure for dispute mediation.

The OIE aims to include an article listing the commodities that are considered safe for trade without the need for risk mitigation measures specifically directed against a particular listed disease, infection or infestation, regardless of the status of the country or zone of origin for the agent in question, at the beginning of each listed disease-specific chapter in Sections 8 to 15. This is work in progress and some chapters do not yet contain articles listing safe commodities. When a list of safe commodities is present in a chapter, importing countries should not apply trade restrictions to such commodities with respect to the agent in question. Chapter 2.2. describes the criteria used to assess the safety of commodities.

[...]

GLOSSARY

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 *an epidemiological unit* is a *herd* or a *flock*. However, an *epidemiological unit* it may also refer to be groups such as a group of *animals* in a pen or a group of *animals* belonging to residents of a village, or a group of *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 1.4.

ANIMAL HEALTH SURVEILLANCE

[...]

Article 1.4.3.

Surveillance systems

In designing, implementing and assessing a *surveillance* system, the following components should be addressed in addition to the quality of *Veterinary Services*.

1. Design of surveillance system

a) Populations

Surveillance should take into account all animal species susceptible to the *infection* or *infestation* in a country, *zone* or *compartment*. The *surveillance* activity may cover all individuals in the *population* or only some of them. When *surveillance* is conducted only on a *subpopulation*, inferences to the target *population* should be justified based on the epidemiology of the disease and the degree to which the *subpopulation* is representative of the target *population* stated.

Definitions of appropriate *populations* should be based on the specific recommendations of the relevant chapters of the *Terrestrial Code*.

b) Timing and temporal validity of surveillance data

The timing, duration and frequency of *surveillance* should be determined taking into consideration factors such as:

- objectives of the *surveillance*;
- biology and epidemiology (e.g. pathogenesis, *vectors*, transmission pathways, seasonality);
- *risk* of introduction and spread;
- husbandry practices and production systems;
- disease prevention and control measures (e.g. *vaccination*, restocking after *disinfection*);
- accessibility of target *population*;
- geographical factors;
- environmental factors, including climate conditions.

c) Case definition

Where one exists, the *case* definition in the relevant chapter of the *Terrestrial Code* should be used. If the *Terrestrial Code* does not give a *case* definition, a *case* should be defined using clear criteria for each *infection* or *infestation* under *surveillance*. For *wildlife infection* or *infestation surveillance*, it is essential to correctly identify and report host animal taxonomy, including genus and species.

Annex 6 (contd)

d) Epidemiological unit

The relevant epidemiological unit for the *surveillance* system should be defined to ensure that it is appropriate to meet the objectives of *surveillance*.

A group of *animals* may be considered an *epidemiological unit* because they share a common environment or because of common management. Usually, an *epidemiological unit* is a *herd* or a *flock*. However, it may also be a group of *animals* in a pen or a group of *animals* belonging to residents of a village, or a group of *animals* sharing a communal animal handling facility or, in some circumstances, a single *animal*. The epidemiological relationship may differ from disease to disease, or even strain to strain of the pathogenic agent.

e) Clustering

Infection or *infestation* in a country, *zone* or *compartment* usually clusters rather than being uniformly or randomly distributed through a *population*. Clustering may occur at a number of different levels (e.g. a cluster of infected *animals* within a *herd* or *flock*, a cluster of pens in a building, or a cluster of farms in a *compartment*). Clustering should be taken into account in the design of *surveillance* activities and considered in the statistical analysis of *surveillance* data.

f) Diagnostic tests

Surveillance involves the use of tests for detection of *infection* or *infestation* according to appropriate case definitions. Tests used in *surveillance* may range from clinical observations and the analysis of production records to rapid field and detailed laboratory assays.

The performance of a test at the *population* level (including field observations) may be described in terms of its sensitivity, specificity and predictive values. These values together with prevalence will have an impact on the conclusions drawn from *surveillance* and should be taken into account in the design of *surveillance* systems and analysis of *surveillance* data.

Laboratory tests should be chosen in accordance with the relevant chapters of the *Terrestrial Manual*.

g) Analytical methodologies

Surveillance data should be analysed using appropriate methodologies and at the appropriate organisational level to facilitate effective decision-making, whether it be for planning disease control interventions or demonstrating health status.

Methodologies for the analysis of *surveillance* data should be flexible to deal with the complexity of real life situations. No single method is applicable in all cases. Different methodologies may be used to accommodate different host species, pathogenic agents, production systems and *surveillance* systems, and types and amounts of data and information available.

The methodology used should be based on the best data sources available. It should also be in accordance with this chapter, fully documented and, whenever possible, supported by reference to scientific literature and other sources, including expert opinion. Sophisticated mathematical or statistical analyses may be carried out only when justified by the objectives of the *surveillance* and the availability and quality of field data.

Consistency in the application of different methodologies should be encouraged. Transparency is essential in order to ensure objectivity and rationality, consistency in decision-making and ease of understanding. The uncertainties, assumptions made, and the effect of these on the final conclusions should be documented.

h) Scope of the surveillance system

When designing the *surveillance* system consideration should be given to the purposes of *surveillance* and how the information it generates will be used, the limitations of the information it will generate, including representativeness of the study *population* and potential sources of bias as well as the availability of financial, technical and human resources.

i) Follow up actions

The design of the *surveillance* system should include consideration of what actions will be taken on the basis of the information generated.

[...]

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, disease, infection or infestation~~ *listed disease or emerging disease* 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~~ *initial notification* ~~within 24 hours~~ 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 7 (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 2) 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 7 (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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CHAPTER 1.6.

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

Article ~~1.6.2~~ ^{1bis} ~~1.6.1~~

Application for Official recognition of animal health status and endorsement of an official control programme by the OIE

A Member Countries may request:

- 1) official recognition of *animal health status* by the OIE of as to:
 - a) freedom of a country or zone from African horse sickness (AHS);
 - 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 where vaccination is either practised or not practised;
 - 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;
 - d) an official control programme for dog-mediated rabies.
- 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.

Annex 8 (contd)

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

~~In these cases, The Member Countries Country~~ should present documentation setting out the compliance of their Veterinary Services with the applicant country or zone with the provisions of Chapters 1.1., 1.4., 3.1., and 3.2. and 4.34. of the Terrestrial Code, when relevant, and with the provisions of the relevant disease-specific chapters in the Terrestrial Code and the Terrestrial Manual.

When requesting official recognition of disease animal health status or endorsement by the OIE of an official control programme, the Member Country should follow the Standard Operating Procedures (available on the OIE website) and 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 animal health status, the endorsement of official control programmes, and their maintenance is described in relevant Resolutions 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)[‡] adopted by the World Assembly of OIE Delegates.

The country or the zone, or the country having its official control programme endorsed will be included in the relevant lists of official animal health status or endorsed official control programmes 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.

When a Member Country requests official recognition of animal health status for a zone, the geographical boundaries of the proposed zone should be clearly defined describing the geographical boundaries of the zone. When applying for a free zone being adjacent to another zone of the same status, it should be stated if the new zone is being merged or kept separate. If the proposed zone remains separate, details should be provided on the control of the movement of susceptible animals and their products relevant commodities between the zones in accordance with Chapter 4.34.

The overall objective of the OIE endorsed official control programmes is for Member Countries to progressively improve their animal health situation and eventually attain official recognition of animal health status or in the case of dog-mediated rabies to make a self-declaration as a free country or zone. The official control programme should be applicable to the entire country even if certain measures are directed towards defined zones.

Article 1.6.2. 1.6.3.

Maintenance of official recognition of animal health status and endorsement of an official control programme by the OIE

Retention on the lists of countries and zones having an official animal health status or of countries having an endorsed official control programme 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 notified to the OIE in accordance with the requirements in Chapter 1.1.

Non-compliance with the requirements for the maintenance of an animal health status results in the suspension of that status. A Member Country/ies may apply for the recovery of a previously recognised status, following the provisions of the relevant disease-specific chapter, within 24 months after suspension. When the status has not been recovered within 24 months of its suspension, it is withdrawn and the Member Country/ies should reapply following the procedure for the application for official recognition of animal health status.

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

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

- = non-compliance with the timelines or performance indicators of the programme; or
- = significant problems with the quality of the *Veterinary Services* as described in Section 3 of the *Terrestrial Code*; or
- = an increase in the *incidence* or *distribution* of the disease that cannot be addressed by the programme.

Article 1.6.1; 1.6.3.

General principles Publication by the OIE of a self-declaration of an animal health status disease freedom by a Member Country

A Member Country 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, *infection or infestation*. 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)² for submission of a self-declaration of *disease freedom an animal health status* and provide documented information on its compliance with the relevant chapters of the *Terrestrial Code*, including:

- = evidence that the *infection or infestation disease* is a *notifiable disease* in the entire country;
- = history of absence or eradication of the *infection or infestation disease* in the country, zone or compartment;
- = *surveillance* and including an *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.

Except when otherwise provided for in the *listed disease-specific chapter*, aAn outbreak in a Member Country, a zone or a compartment having a self-declared free status results in the loss of the self-declared free status. A Member Countryies wishing to reclaim a lost free status should submit a new self-declaration following the procedure described in this article.

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) *listed diseases listed under in point 1) of Article 1.6.21bis. 1.6.1.*

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 and the recommendations 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 related 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 especially 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 for use when formulating or modernising *veterinary legislation* so as to comply with OIE standards and other relevant international 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.

Annex 9 (contd)

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, to ensure that the primary legislation provides the legal basis for the application and enforcement of the 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 and other relevant stakeholders to ensure that the resulting legislation has been evaluated through an impact analysis, as appropriate, and is scientifically, technically and legally sound. The resulting draft legislation should be evaluated through an impact analysis as appropriate.

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

5. Quality of legislation and legal certainty

Veterinary legislation should be clear, and coherent, and stable and transparent should provide legal certainty and protect citizens and the environment against unintended adverse side effects of legal instruments. The legislation should be stable but regularly evaluated and updated as appropriate to be ensure that it is technically relevant, acceptable to society, able to be effectively implemented effectively 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;~~
- 32) ~~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 unnecessary duplication 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) when relevant, make provision for the collection, use and disclosure of information gathered under the veterinary legislation;
- 78) ~~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; and~~
- 89) indicate when the legislation comes into effect and its impact on similar pre-existing legislation, in particular regulations secondary legislation.

Article 3.4.5.

Competent Authorities

Competent Authorities should be legally mandated, ~~empowered~~ have the necessary technical, administrative and infrastructure capacity and be organised to ensure that all necessary actions are taken quickly in a timely, and coherently to and effectively manner to 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. as short as possible, and~~ 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 for example 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, including clarifying the role of each Competent Authority.

Competent Authorities should appoint technically qualified officials to take any actions needed for implementation, review of and 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 and in accordance with professional standards;
- 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 and transparency, as appropriate; and
- d) at least the following powers are available through the primary legislation:
 - i) access to premises and ~~vehicles~~ vessels for carrying out inspections;
 - ii) access to documents;

Annex 9 (contd)

iii) taking samples; application of specific sanitary measures such as:

= taking samples;

~~iv)~~ = retention (setting aside) of ~~animals and goods~~ commodities, pending a decision on final disposition;

~~v)~~ = seizure and destruction of ~~animals, products and feed of animal origin~~ commodities and fomites;

~~vi)~~ = suspension of one or more activities of an inspected establishment facility;

~~vii)~~ = temporary, partial or complete closure of inspected establishments facilities; and

~~viii)~~ = suspension or withdrawal of authorisations or approvals; and

= restrictions on the movement of commodities, vehicles/vessels and, if required, other fomites and people;

= establishment of compensation mechanisms;

= listing disease for mandatory reporting; and

= ordering of disinfection, disinfection or pest control;

iv) establishment of compensation mechanisms.

These essential powers ~~must~~ should be clearly identified as because 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 powers and tasks related to official activities. The specific powers and tasks delegated, the competencies required, the bodies or officers to which the powers and 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 paraprofessionals

4. 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;

Annex 9 (contd)

- ~~e) 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:~~

- ~~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 provide basic principles for or regulate the following matters:
 - i) describe the various categories professional categories specialisations of veterinarians (e.g. specialisations) and categories of veterinary paraprofessionals recognised in the country in accordance with its needs, notably in animal health, animal welfare and food safety;
 - ii) define the prerogatives of the various categories professional categories specialisations of veterinarians (e.g. specialisations) and categories of veterinary paraprofessionals that are recognised in the country;
 - iii) define the minimum initial and continuous educational requirements and competencies for the various categories professional categories specialisations of veterinarians (e.g. specialisations) and categories of veterinary paraprofessionals;
 - iv) prescribe the conditions for recognition of the qualifications for veterinarians and veterinary paraprofessionals;

Annex 9 (contd)

- v) define the conditions to for performing the activities of veterinary medicine/science, including the extent of supervision for each category of *veterinary paraprofessionals*;
- vi) prescribe the powers to deal with issues of conduct and competence issues, including licensing requirements and mechanisms to appeal, that apply to *veterinarians* and *veterinary paraprofessionals*;
- vii) identify the exceptional situations, such as epizootics, define the conditions (except those that are under the responsibilities responsibility of the *Competent Authority*) 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.

Article 3.4.7.

Laboratories in the veterinary domain

1. 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 that ~~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 laboratory*, 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 following 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 for other purposes approved by the *Competent Authority*; and
- c) surveillance oversight 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, including their disposal when applicable, 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.~~ 4.3.3.

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 following elements listed below:

- a) definition of the animal feed subject to the legislation;
- b) standards for the production, composition and quality control of animal feed in relation to the biological, chemical and physical risks of disease transmission;
- ~~b)~~ registration and, if necessary, approval of establishments facilities and the provision of health requirements for relevant operations; ~~and~~
- ~~c)~~ distribution and use of animal feed in relation to the biological, chemical and physical risks; and
- e) 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 following elements listed below:

- a) definition of the animal by-products subject to the legislation;
- b) rules for sourcing, collection, transport, processing, use and disposal of animal by-products;
- c) registration and, if necessary, approval of establishments facilities 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*.

Annex 9 (contd)

Article 3.4.9.

Animal diseases

Veterinary legislation should provide a basis for ~~the~~ *Competent Authorities* to manage diseases of importance to the country, ~~present or not, 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 and mandatory reporting of diseases of importance to the country. It should also provide powers for the *Veterinary Authority* to access information needed to comply with its notification obligations to the OIE.

1. Surveillance

Veterinary legislation should provide a basis for the collection, transmission, dissemination 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 by the *Competent Authority*.
- b) The legislation should also provide a basis for contingency emergency response plans for use in responding to disease, to include the following for use in disease responses:
 - i) the administrative administration and logistics organization necessary to activate, implement and coordinate activities;
 - 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 alternatively, 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 or products, 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 cruelty or neglect by animal keepers.

2. Stray dogs and other free-roaming domestic 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 following elements listed below:

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

2. Raw materials for use in veterinary medicines and biologicals medicinal products

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

- 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
- eb) 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) veterinary medicinal products incorporated into medicated feed;
 - ii) products prepared by authorised *veterinarians* or authorised pharmacists; and
 - iii) emergencies and temporary situations; and
 - iv) establishment of maximum residue limits for active substances and withdrawal periods for relevant veterinary medicinal products containing these substances and maximum residue limits for the active substance contained in each such product; and
 - v) restrictions of use of veterinary medicinal products for food-producing animals.

Annex 9 (contd)

- c) *Veterinary legislation* should address the technical, administrative and financial conditions associated with the granting, **suspension**, renewal, refusal and withdrawal of authorisations.
- d) In defining the procedures for seeking and granting, **or refusing**, 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;~~
- ~~c) qualifications of experts involved in trials; and~~
- ~~d) surveillance for adverse effects arising from the use of veterinary medicines and biologicals.~~

54. Establishments Facilities 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, **exporting**, 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;
- c) good manufacturing practices **as** 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 biologicals medicinal products

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

- a) control over the distribution of ~~*veterinary medicines and biologicals*~~ medicinal products and arrangements for traceability, recall and conditions of use;
- b) establishment of rules for the prescription and provision of ~~*veterinary medicines and biologicals*~~ medicinal products to end users, **including appropriate labelling**;
- c) restriction to *veterinarians or other* authorised professionals and, as appropriate, authorised ~~*veterinary paraprofessionals*~~, of commerce in ~~*veterinary medicines and biologicals*~~ 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;

- ~~de)~~ the supervision by an authorised professional of organisations approved for the holding and use of ~~veterinary medicines and biologicals~~ medicinal products;
- ~~ef)~~ the regulation of advertising claims and other marketing and promotional activities, including a system of surveillance for falsification; and
- ~~fg)~~ a system of surveillance of the quality of veterinary medicinal products marketed in the country and the 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 in accordance with Chapter 6.3.;
- ~~ab)~~ controls over all stages of the production, processing and distribution of food of animal origin;
- ~~bc)~~ recording all significant animal and public health events that occur during primary production including slaughter;
- ~~cd)~~ giving operators of food production premises facilities the primary responsibility for compliance with food safety requirements, including traceability established by the *Competent Authority*;
- ~~de)~~ inspection for compliance with food standards, where this is relevant to health or safety;
- ~~ef)~~ inspection and audit of premises facilities;
- ~~fg)~~ prohibition of the marketing of products not fit for human consumption; and
- ~~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;
- ~~ca)~~ health standards including measures to control diseases, and monitoring and enforcement of maximum residue levels (MRL); and
- ~~cb)~~ the application use of health identification marks that are visible to the intermediary or and final user visible marks that indicate the product has been inspected complies with the health standards.

The *Competent Authority* should have the necessary powers and means to rapidly to 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.

Annex 9 (contd)3. Operators responsible for premises facilities 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 facilities 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 Section 2 Risk Analysis and Section 5 Trade measures, import/export procedures and veterinary certification.

CHAPTER 4.Y.

OFFICIAL CONTROL PROGRAMMES MANAGEMENT OF OUTBREAKS OF FOR 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, the Veterinary Services Authority 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. the first occurrence to of 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 for the prepare preparation, develop development and implement implementation of 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 providing ready-made fit-for-all solutions, but rather at outlining principles to follow when combating transmissible animal diseases, including zoonoses 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 the diseases to establish against which official control programmes against and at which regulatory level are implemented, according to an evaluation of the actual or likely impact of the disease. Disease Official 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.

When a listed disease or emerging disease occurs in a Member Country, the Veterinary Authority should implement control measures proportionate to the likely impact of the disease in order to minimise its spread and consequences and, if possible, eradicate it. These measures can vary from a rapid response (e.g. to the first occurrence of a disease) to long-term control (e.g. of an endemic disease).

Control plans They Official control programmes should be justified by rationales developed through based on the basis of risk analyses 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 situations, 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 should include:

- 1) a plan of the programme to control or eradicate the relevant disease infection or infestation in the country or zone;
- 2) regular and prompt animal disease reporting appropriate veterinary legislation;
- 3) emergency preparedness plans and emergency response plans;
- 4) surveillance of the relevant disease infection or infestation in accordance with Chapter 1.4.;
- 45) regular and prompt animal disease reporting;

Annex 10 (contd)

- 6) rapid detection and management of, and response to, cases of the relevant disease infection or infestation, to reduce the incidence and the prevalence to by eliminating minimising transmission;
- 57) measures implemented to prevent introduction or spread of the relevant disease infection or infestation, including biosecurity and sanitary measures including such as movement control;
- 68) a vaccination programme, as if relevant appropriate;
- 79) preparedness and contingency plans measures to protect public health, as if appropriate;
- 810) communication and collaboration with other among all relevant Competent Authorities.

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

Official control programmes and the application of their components should be regularly evaluated. 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 future 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 effectively, 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 those with a right of entry to establishments or other related enterprises such as live animal markets, slaughterhouses/abattoirs and processing plants for animal products processing plants, for regulated purposes of surveillance and disease control actions, with the possibility of obliging owners or operators to assist;
 - sources of financing finance for dedicated staff and additional supporting staff when needed;
 - sources of financing finance for epidemiological enquiries, laboratory diagnostic diagnosis, disinfectants, insecticides, vaccines and other critical supplies;
 - sources of financing finance for communication and awareness campaigns;
 - sources of financing finance and a compensation policy for livestock commodities and property that may be lost or 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.

Annex 10 (contd)

- 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 forward and backward tracing of animals and animal products commodities and fomites;
 - 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 zones 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 commodities 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 collection, treatment or safe disposal or processing of contaminated or potentially contaminated animal products of animal origin and other materials;
 - procedures for collection, treatment or safe disposal of contaminated or potentially contaminated fomites such as fodder and effluents such as fodder, bedding, and litter, manure and waste water;
 - procedures for cleaning, disinfection and disinsection of establishments and related premises, vehicles/vessels or equipment;
 - procedures ~~for~~ of compensation for the owners of animals or animal products commodities, 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; ~~;~~
 - procedures for post-control surveillance and possible gaining or recovery of status, as relevant.

Article 4.Y.3.

Emergency Preparedness

Rapid and effective response to animal health emergencies, such as in case of occurrence of an emerging disease or a listed disease that was not present in the country or zone, or of a sudden increase of in the incidence of a listed disease that is already present, Rapid and effective response to a new occurrence or emergence of contagious infectious diseases is dependent on the level of preparedness.

Annex 10 (contd)

The *Veterinary Authority* should define emergencies and integrate emergency preparedness planning, and practice equipping, training and exercising exercises within the official control programmes against for 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.

Emergency 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 emergency 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 define 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 or changes in possible pathways) and be updated accordingly, taking into account the latest scientific findings.

2. Planning

Four kinds of plans, Emergency planning consists of describing the following in advance of an emergency:

- what governmental or national and local authorities, and all relevant stakeholders should do; comprise any comprehensive preparedness and response system
- how they should be trained, equipped and exercised to be ready to do it;
- how their actions should be activated and coordinated.

This implies the development of:

- a) a preparedness plan, which outlines what should be done before an outbreak of a notifiable listed disease or an emerging disease or a notifiable disease occurs an emergency;
- b) a response or contingency plan, which details what should be done in the event of an occurrence of a notifiable listed disease or an emerging disease or notifiable disease an emergency, beginning from the triggering 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 listed disease or the emerging disease emergency.

3. Simulation exercises

A simulation exercise is a controlled activity where a situation, that could exist in reality, is imitated for training or assessment of capabilities and plans. 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 within a country or among the Veterinary Services of neighbouring several countries and with 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 ~~specific~~ epidemiological and environmental situation. Early warning systems are an integral component of emergency preparedness management. 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 of a *listed disease* or an *emerging disease* based on supportive, but not definitive, findings should lead to at least the implementation of local pre-emptive 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;
 - 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;

Annex 10 (contd)

- 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 listed disease or an emerging disease or a notifiable disease that is subject to an official control programme, is confirmed effective risk management should be applied. ~~This~~ depends on the application implementation of a combination of measures ~~that are~~ operating at the same time or consecutively. These measures should aimed at:

- 1) epidemiological investigation to tracing back and forward and backward animals in contact and potentially infected or contaminated products commodities or fomites through epidemiological investigation:
- 42) eliminating the source of the pathogenic agent, through by:
 - the *killing* or *slaughter* of *animals* infected or suspected of being infected, as appropriate, and safe disposal of dead *animals* and other potentially contaminated products commodities and fomites, such as beddings and single use clothing and equipment;
 - the cleaning, *disinfection* and, if relevant, *disinsection* of premises and other fomites such as vehicles, clothing and equipment;
- 23) stopping preventing the spread of disease, infection, or infestation through:
 - movement restrictions on *animals* commodities and fomites, ~~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 objective and expected outcome of the official control programme (i.e. eradication, containment or partial prevalence 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 will be effective as a the 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 outcome of the official control programme.

In any case, the management plan response measures should consider the costs of the response measures, including the compensation of owners for losses incurred by the measures as described in regulations, policies or guidance, should be considered 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 response measures 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 potentially contaminated commodities

Living infected *animals* can be the greatest most significant source of pathogenic agents. These *animals* may directly transmit the pathogenic agent to other *animals*. They may also cause lead to indirect infection transmission of pathogenic agents through live living organisms (vectors, people) or through the contamination of fomites, including breeding and handling equipment, bedding, feed, vehicles/vessels, and people's clothing and footwear, or the contamination of the environment. Although in some cases carcasses may remain contaminated infective 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 potentially contaminated 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 so 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 other commodities, 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 other related potentially contaminated products commodities 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 rapidly 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.

Annex 10 (contd)

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 they are 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 avoiding any possible direct or indirect contacts with other *animals*. These ~~S~~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. 4.314. Where premises cannot be practically disinfected, alternate means of elimination of the causal pathogenic agent, such as extended following periods or composting, may be considered.

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~~ more suitable 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 the test and cull strategy will depend on the sensitivity and specificity of the tests. Veterinary Services may adjust test and cull strategies in response to the changes of in the prevalence.

Apart from the selection of *animals* to be culled, the same principles apply as for a *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 commodities and fomites 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 commodities, and to different types of fomites (e.g. people, clothing, vehicles/vessels and equipment). They may vary from pre-movement certification to total standstill, and be limited to one ~~or more~~ establishment only or multiple establishments, or cover specific zones, or the entire country. The restrictions can include the complete isolation of individual *animals* or groups of *animals*, and specific rules may be applied to movements, such as protection from *vectors*.

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 that they are no longer needed.

When implementing movement control operations, *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.

Zoning

The Veterinary Authority should use the tool of zoning in official control programmes, in accordance with Chapter 4.34.

The use of zoning for disease control and eradication is inherently linked with measures of killing or slaughter, movement control, vaccination, and surveillance, biosecurity and communication, 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 in response to outbreaks of listed diseases or emerging diseases are usually infected zones, containment zones and protection zones. However, other types of zones, such as zones where specific surveillance, vaccination or other activities are conducted, can also be used.

Article 4.Y.89.

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 should be taken to avoid the contamination of people's clothes, clothing 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, other commodities. 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.910.

Vaccination and treatment and treatment

Vaccination as part of an official control programme in response to a contagious disease outbreak should be conducted in accordance with Chapter 4.1718.

Vaccination programmes, especially in response to an outbreak, require previous planning to identify potential sources of vaccine, including vaccine or antigen banks, and to plan, determine 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 of differentiate differentiating the immune response produced by the vaccine from that produced induced by infection with the pathogenic agent, or to differentiate differentiating live vaccine strains from field strains.

Although vaccination may hide ongoing infection or agent transmission of pathogenic agents, it can be used to decrease the shedding of the pathogenic agent, hence reduce reducing 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 strategies 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 official control programme plan should include consider a cost-benefit analysis with regard to trade and public health and an exit strategy, i.e. when and how to stop the vaccination or whether vaccination should become systematic routine.

Annex 10 (contd)

Treatment can also be used as part of an official control programme. It would require planning to identify potential sources of veterinary medicinal products, and to plan determine the possible strategies for application and an exit strategy.

Article 4.Y.10.

Zoning

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

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 animal owners or keepers, *veterinarians*, veterinary paraprofessionals, local authorities, the media, consumers and the 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 to 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 to inform further disease control plans. This requires staff who have been trained in the way to conduct it appropriate methods and in the use of the standardised data collection forms.

Furthermore, feedback from persons involved in the organisation and implementation of official control programmes should be gathered.

The information information gathered and experience gained should be used to monitor, evaluate and review disease the official control programmes plans.

DRAFT CHAPTER 7.Z.

**ANIMAL WELFARE AND LAYING HEN
PRODUCTION SYSTEMS**

Article 7.Z.1.

Definitions

For the purposes of this chapter:

Laying hens means sexually mature female birds of the species *Gallus gallus domesticus* kept for the commercial production of eggs for human consumption. Breeding hens are not included.

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

Layer 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 provides recommendations for the animal welfare aspects of commercial laying hen production systems. It covers the production period from the arrival of *day-old birds* onto the pullet-rearing farm through to the removal of end-of-lay hens from the laying production facilities. Laying hens kept in village or backyard flocks and used to produce eggs for personal consumption are not included.

Commercial laying hen production systems involve the confinement of layer pullets and laying hens, the application of *biosecurity* and trade in eggs or pullets.

These recommendations address the welfare aspects of layer pullets or laying hens kept in cage or non-cage systems, whether indoors or outdoors.

Commercial layer pullet or laying hen production systems include:

1. Completely housed systems

Layer pullets or laying hens are completely confined in a poultry house, with or without mechanical environmental control.

2. Partially housed systems

Layer pullets or laying hens are kept in a poultry house with access to a designated outdoor area.

3. Completely outdoor systems

Layer pullets or laying hens are not confined inside a poultry house during the day but are confined in 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.

Annex 11 (contd)

Article 7.Z.3.

Outcome-based criteria (or measurables) for the welfare of layer pullets and laying hens

The welfare of layer pullets and laying hens should be assessed using outcome-based criteria or measurables, preferably animal-based measurables, as described in Article 7.1.4. Outcome-based criteria or measurables are particularly useful for evaluating compliance and improving animal welfare. Animal-based outcomes are usually the most sensitive measurables (e.g. mortality rate). However, resource and management-based outcomes can also have important applications (e.g. interpretation of mortality rate data may be informed by decisions made to euthanise). There is no one single measurable that addresses all aspects of animal welfare. The use of measurables and the appropriate thresholds should be adapted to the different situations in which layer pullets and laying hens are kept, also taking into account the genetics used, resources provided, and the design and management of the system. Animal-based criteria or measurables can be considered as tools to monitor and refine these factors.

Criteria (or measurables) that can be used at farm level include conditions such as skeletal and foot problems, disease and *infection* or *infestation* that can be assessed during routine or targeted *monitoring*, or at depopulation. It is recommended that target values or thresholds for animal welfare measurables be determined by taking into account current scientific knowledge and appropriate national, sectorial or regional recommendations for layer pullets or laying hens. Determining the age and stage of production at which problems are detected may help to determine the cause.

The following animal-based and outcome-based measurables, in alphabetical order, may be useful indicators of layer pullet or laying hen welfare:

1. Beak condition

Evaluation of beak condition provides useful information about the extent to which layer pullets and laying hens are able to engage in normal behaviour, such as foraging, feeding, drinking and preening [Dennis and Cheng, 2012; Vezzoli *et al.*, 2015]. Tools for assessing beak condition have been developed and implemented in animal welfare assessment programmes [e.g. Kajlich *et al.*, 2016].

2. Behaviour

The presence or absence of certain behaviours may indicate either good *animal welfare* or an *animal welfare* problem, such as fear, pain or sickness. Some behaviours may not be uniquely indicative of one type of problem; they may be exhibited for a variety of reasons. *Gallus gallus domesticus* has evolved behaviours that they are 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 and 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 a complex behaviour providing body maintenance benefits. During dust bathing, layer pullets and laying hens remove loose substrate material, such as litter, through their feathers. This behaviour helps remove stale lipids [van Liere and Bokma, 1987]; which contributes to the maintenance of plumage condition; This helps to regulate body temperature and protect against skin injury. Reduced dust bathing behaviour in the *flock* may indicate problems with substrate or range quality, such as the substrate or ground being wet or not friable [Olson and Keeling, 2005; Van Liere and Bokma, 1987]. The demonstration of complete sequences of dust bathing may be associated with positive affect [Widowski and Duncan, 2000].

b) Fear behaviour

Fearful layer pullets and laying hens show high reactivity to various stimuli [Jones, 1987; Zeltner and Hirt, 2008] and this may result in traumatic injuries or suffocation if the layer pullets or laying hens pile on top of one another. Fearful layer pullets and laying hens may be less productive [Barnett *et al.*, 1992] and more prone to injurious feather pecking behaviour [de Haas *et al.*, 2014]. Methods have been developed for evaluating fearfulness [Forkman *et al.*, 2007], for example by observing layer pullet and laying hen behaviour when people, including *animal handlers*, walk through the pullet and hen area of the poultry house [Jones, 1996; Waiblinger *et al.* 2006].

c) Feeding and drinking behaviour

Changes in feeding or drinking behaviour can 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]. Feed and water intake often reduce when pullets or hens are ill. Feed or water intake may also change as a result of heat [Lara L. J. & Rostagno M. H., 2013; Lin H. *et al.*, 2006] or cold [Alves *et al.*, 2012] stress.

d) Foraging behaviour

Foraging is a motivated behaviour [de Jong *et al.*, 2007, Nicol *et al.*, 2011]. Foraging is the act of searching for food, typically by pecking or scratching the substrate. Reduced foraging activity may suggest problems with substrate quality or the presence of conditions that decrease foraging ability [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].

e) Injurious feather pecking and cannibalism

Injurious feather pecking can result in significant feather loss and lead to cannibalism. Cannibalism is the tearing of the flesh of another layer pullet or laying hen, and can result in severe injury or death. These behaviours can have multifactorial causes and be difficult to control [Nicol, 2018; Hartcher, 2016; Estevez, 2015; Nicol *et al.*, 2013; Rodenburg, 2013; Lambton, 2013; Newberry, 2004].

f) Locomotory and comfort behaviours

Layer pullets and laying hens may display a variety of locomotory and comfort behaviours, including walking, running, leaping, turning, stretching legs and wings, wing flapping, feather ruffling, tail wagging and preening [Bracke and Hopster, 2006; Harthcher and Jones, 2017; Dawkins and Hardie, 1989; Shipov *et al.*, 2010; Norgaard, 1990]. Some of these behaviours have been shown to be important for skeletal, body and plumage development and maintenance. For example, walking and wing movements contribute to improved leg and wing bone strength [Knowles and Broom, 1990], and preening helps remove stale lipids from the skin [Vezzoli *et al.*, 2015] and keeps the feathers flexible and intact [Shawkey *et al.*, 2003].

g) Nesting

Nesting is a motivated behaviour that includes nest site selection, nest formation and egg laying [Cooper and Albentosa, 2003; Weeks and Nicol, 2006; Cronin *et al.*, 2012; Yue and Duncan, 2003]. Uneven nest box utilisation, delayed oviposition, increased pacing and egg laying outside the nest may be indicative of problems with environmental or social behavioural factors [Cronin *et al.*, 2012; Cooper and Appleby, 1996; Gunnarsson *et al.*, 1999; Yue and Duncan, 2003; Widowski *et al.*, 2013].

h) Perching

Perching is a motivated behaviour. Layer pullets and laying hens may seek elevation during the day; however, 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 or pullet rearing experience [Janczak and Riber, 2015; Gunnarsson *et al.*, 1999].

i) Resting and sleeping

Sleep is an adaptive state that allows animals to recover from daily stress, conserve energy and consolidate memory [Siegel, 2009]. Layer pullets and laying hens display synchronised resting and sleeping behaviours, which can be disrupted by light intensity, photoperiod, environmental or social factors [Malleau *et al.*, 2007; Alvino *et al.*, 2009].

Annex 11 (contd)

j) Social behaviour

Pullets and hens are social and engage in synchronised behaviour [Olsson *et al.*, 2002; Olsson and Keeling, 2005]. 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 damage caused by aggression and competition for resources [Estevez *et al.*, 2002; Blatchford *et al.*, 2016].

k) Spatial distribution

Uneven spatial distribution of layer pullets and laying hens may indicate fear reactions, thermal discomfort or, uneven availability or use of resources such as light, feed or water, shelter, nesting areas or comfortable resting locations [Rodríguez-Aurrekoetxea and Estevez, 2016; Bright and Johnson, 2011].

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 distress vocalisations.

m) Vocalisation

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

3. Body condition

Poor body condition is reflective of *animal welfare* problems for individual layer pullet and laying hens. At *flock* level, uneven body condition may be an indicator of poor *animal welfare*. 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 the fact that feather cover can mask actual body condition.

4. 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 be associated with very low light intensity (<5 lux) [Jenkins *et al.*, 1979; Lewis and Gous, 2009; Prescott *et al.*, 2003].

5. Foot problems

Hyperkeratosis, bumblefoot, contact dermatitis, excessive claw growth, broken claws and toe injuries are painful conditions associated with, amongst other things, inappropriate flooring, poorly designed perches, poorly maintained substrate [EFSA, 2005; Lay *et al.*, 2011; Abrahamsson and Tauson, 1995; Tauson and Abrahamson, 1996; Abrahamsson and Tauson, 1997] and inadequate maintenance of aspects of the production system.

If severe, the foot and hock problems may contribute to locomotion problems and lead to secondary *infections*. Scoring systems for foot problems have been developed [Blatchford *et al.*, 2016].

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

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

7. Injury rate and severity

Injuries are associated with pain and risk of infection. They can be a consequence of the actions of other pullets and hens (e.g. scratches, feather loss or wounding), management (e.g. nutritional deficits leading to skeletal problems), environmental conditions (e.g. fractures and keel bone deformation), genetics used or human intervention (e.g. during handling and catching). It is important to assess both the rate and severity of injuries.

8. 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 may reflect an *animal welfare* problem. Recording and evaluating causes of morbidity and mortality can be useful aids in diagnosing and remediating *animal welfare* problems.

9. Performance indicators

Daily, weekly and cumulative performance should be within expected ranges. Any unforeseen reduction in these rates may reflect an *animal welfare* problem. Types of measure that can be used include:

- a) pullet growth rate, which measures average daily mass gain per pullet and *flock* uniformity;
- b) pullet feed conversion, which 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, which measures quantity of *feed* consumed by a *flock* relative to the unit of egg production;
- d) egg production, which measures the number and size of eggs per hen housed;
- e) egg quality and downgrades, which can be measured by, for example, grade percentage, shell strength, Haugh units, abnormalities and mis-laid or floor eggs;

10. Plumage condition

Evaluation of plumage condition provides useful information about aspects of *animal welfare* in terms of feather pecking and cannibalism, ability to thermoregulate, illness, and protection from injury [Rodriguez-Aurrekoetxea and Estevez, 2016; Drake *et al.*, 2010]. Dirty plumage may be associated with illness, environmental conditions or the layer pullet and laying hen housing system. Plumage cover and cleanliness scoring systems have been developed for these purposes [Blokhuys, 2007; Blatchford *et al.*, 2016].

11. Water and feed consumption

Monitoring and evaluating daily water and *feed* consumption is a useful tool which may indicate thermal stress, disease, *infection* or *infestation* and other welfare conditions, taking into consideration ambient temperature, relative humidity and other related factors. Changes in intake, crowding at feeders and drinkers and wet substrate may be associated with problems with the quality or supply of water, or *feed*.

Article 7.Z.4.

Recommendations for layer pullets and laying hens

Ensuring good welfare of layer pullets and laying hens is contingent upon several management factors, such as system design, environmental management practices, and animal management practices including responsible husbandry and provision of appropriate care, and the genetics used. Serious problems can arise in any system if one or more of these elements are lacking. Although pullets and hens can adapt to a range of thermal environments, particularly if appropriate breeds and housing are used for the anticipated conditions, sudden fluctuations in temperature can cause heat or cold stress.

Articles 7.Z.5. to 7.Z.29. provide recommendations for layer pullets and laying hens.

Each recommendation includes a list of relevant outcome-based criteria or measurables derived from Article 7.Z.3. and when appropriate other criteria or measurables. The suitability of some of these criteria or measurables should be determined in accordance with the system in which the pullets and hens are housed.

Annex 11 (contd)

Article 7.Z.5.

Location, design, construction and equipment of establishments

The location of layer pullet and laying hen *establishments* should 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 and exposure of layer pullets and laying hens to chemical and physical contaminants, noise and adverse climatic conditions.

Good welfare outcomes for layer pullets and laying hens can be achieved in a range of housing systems. Houses, outdoor areas and accessible equipment should be designed after considering the opportunities for layer pullets and laying hens to perform motivated behaviours as well as health, environmental factors, and animal management capability. They should also be maintained to avoid injury or discomfort. Pullet and hen houses should be constructed with materials, electrical and fuel installations that minimise the risk of fire and other hazards, and are easy to clean and maintain. Producers should have a maintenance programme in place, including record-keeping for all equipment and contingency plans to address failures that could jeopardise layer pullets and laying hens welfare.

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

Article 7.Z.6.

Matching the layer pullets and laying hens with the housing and production system

Animal welfare and health considerations should balance any decisions on performance when choosing the genetics to be used for a particular location, housing and production system. The pullet rearing system should pre-adapt the bird for the intended production system [Aerni *et al.*, 2005].

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

Article 7.Z.7.

Space allowance

Layer pullets and laying hens should be housed with a space allowance that allows them to have adequate access to resources and to adopt normal postures. Providing sufficient space for the expression of locomotory and comfort behaviours that contribute to good musculoskeletal health and plumage condition is desirable. Problems with space allowance may increase stress and the occurrence of injuries.

The following factors, in alphabetical order, should be considered when determining space allowance:

- age and mass of layer pullets and laying hens,
- ambient conditions,
- *biosecurity* strategy,
- equipment selection,
- feed and watering systems,

Annex 11 (contd)

- flooring substrate,
- genetics,
- housing design,
- management capabilities,
- production system,
- usable space,
- ventilation.

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

Article 7.Z.8.

Nutrition

Layer pullets and laying hens should always be fed a diet appropriate to their age, production stage and genetics. The form of the feed should be acceptable to the layer pullets and laying hens and contain adequate nutrients to meet requirements for good *animal welfare* and health. Feed and water should be free from contaminants, debris and microorganisms or other potential *hazards*.

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

Layer pullets and laying hens should be provided with adequate access to feed on a daily basis. Water should be continuously available except under veterinary advice. Special provisions should be made to enable newly hatched pullets to access appropriate feed and water.

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

Article 7.Z.9.

Flooring

The slope, design and construction of the floors should provide adequate support for the locomotion of layer pullets and laying hens, prevent injuries and entrapments, ensure good health and allow the performance of normal behaviour. Changes of flooring types from pullet to hen housing should be avoided. Manure contamination from other layer pullets and laying hens within the house should be minimised through appropriate floor design and other elements of system design. The flooring should be easy to clean and disinfect.

When litter is provided, it should be managed to remain dry and friable, and adequately treated or replaced when required to prevent disease and minimise any detrimental effects on *animal welfare*.

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

Annex 11 (contd)

Article 7.Z.10.

Dust bathing areas

Access to friable, dry substrate to encourage dust bathing is desirable. When provided, dust bathing areas should be 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 [Weeks and Nicol, 2006].

Outcome-based measurables include: dust bathing, incidence of diseases, *infections* and *infestations*, injury rate and severity, plumage condition and spatial distribution.

Article 7.Z.11.

Foraging areas

Access to substrate that encourages foraging behaviour activity is desirable. When provided, foraging areas should be designed and positioned to encourage synchronised behaviour, prevent undue competition and not cause damage or injuries. Foraging areas should be easy to inspect and maintain.

Outcome-based measurables include: foraging behaviour, incidence of diseases, *infections* and *infestations*, injurious feather pecking and cannibalism, injury rate and severity and spatial distribution.

Article 7.Z.12.

Nesting areas

Access to nesting areas is desirable. When provided nesting areas should be built of suitable materials, and 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.

Outcome-based measurables include: incidence of diseases, *infections* and *infestations*, injurious feather pecking and cannibalism, injury rate and severity, nesting, performance (mis-laid or floor eggs), and spatial distribution.

Article 7.Z.13.

Perches

Access to perches is desirable. When provided perches should be built of suitable materials, designed, elevated and positioned to encourage perching by all layer pullets and laying hens, prevent undue competition, minimise keel bone deformation, foot problems or other injuries, and to ensure stability during perching. In the absence of designated perches, other structures such as platforms, grids or slats that are perceived by the pullets and hens as elevated and that do not cause damage or injuries, may be a suitable alternative. When provided, perches or their alternatives should be made available from an early age, be easy to clean and maintain, and be positioned to minimise faecal fouling [Hester, 2014; EFSA, 2015].

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

Article 7.Z.14.

Outdoor areas

Layer pullets and laying hens may be given access to outdoor areas when they have sufficient feather cover and can range safely. Where pullets and hens are partially housed, there should be sufficient appropriately designed 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 layer pullets and laying hens becoming infected by pathogenic agents or infested by parasites or being injured. This may include limiting the stocking density or using several pieces of land consecutively in rotation.

Annex 11 (contd)

Outdoor areas should be located on well-drained ground and managed to minimise stagnant water and mud. The outdoor area should be able to contain the layer pullets and laying hens and prevent them from escaping. Outdoor areas should be designed, built and maintained to allow layer pullets and laying hens to feel safe outdoors and to encourage them to utilise the range optimally, while mitigating predation, disease risks, and adverse climatic conditions [Gilani *et al.*, 2014; Hegelund *et al.*, 2005; Nagle and Glatz, 2012]. Pullets and hens should be habituated early to the outdoor area [Rodríguez–Aurrekoetxea and Estevez, 2016]. Outdoor areas should be free from harmful plants and contaminants.

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

Article 7.Z.15.

Thermal environment

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

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

The thermal environment should be monitored regularly so that failure of the system can be detected and corrected before they cause *animal welfare* problem.

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

Article 7.Z.16.

Air quality

Ventilation, housing, space allowance and manure management can affect air quality. Actions are required to maintain air quality at levels required for good *animal welfare*, including the removal or mitigation of noxious gases such as carbon dioxide and ammonia, dust and excess moisture in the environment.

Ammonia concentrations should not routinely exceed 25 ppm at layer pullet and laying hen level [David *et al.*, 2015; Miles *et al.*, 2006; Olanrewai, 2007].

Dust levels should be kept to a minimum [David *et al.*, 2015].

Outcome-based measurables include: ammonia level, carbon dioxide level, dust level, eye conditions, incidence of diseases, *infections*, metabolic disorders and *infestations*, morbidity and mortality rates, plumage condition, performance indicators, temperature and humidity and thermoregulatory behaviours.

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 normal development, allow layer pullets and laying hens to find feed and water, to stimulate activity, to stimulate onset of lay, minimise the likelihood of feather pecking and cannibalism, and to allow adequate inspection [Prescott *et al.*, 2003; Prescott and Wathes, 1999; Green *et al.*, 2000].

Annex 11 (contd)

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

Changes in lighting should occur gradually or in a step-wise fashion, as needed, except during induced moulting when rapid adjustments to lighting should be considered [Tanaka and Hurnik, 1990; Kristenson, 2008].

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

Article 7.Z.18.

Noise

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

Location of *establishments* should, where possible, consider existing local sources of noise. Strategies should be implemented to acclimatise the layer pullets and laying hens to the conditions [Candland *et al.*, 1963; Morris, 2009].

Outcome-based measurables include: fear behaviours, injury rate and severity, mortality rate, performance indicators, resting and sleeping, and 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 systems.

Management methods that may reduce the risk of occurrence include:

- adapting the diet and form of feed during rearing and lay [Lambton *et al.*, 2010],
- choosing genetics with a low propensity for injurious feather pecking [Craig and Muir, 1996; Kjaer and Hocking, 2004],
- increasing age at onset of lay [Pöttsch, 2001],
- increasing space allowance during rearing [Jung and Knierim, 2018],
- managing light during rearing and lay [Nicol *et al.*, 2013; van Niekerk *et al.*, 2013],
- minimising fear-related stimuli [Uitdehaag K. A. *et al.*, 2009],
- providing elevated perches during rearing and lay [Green *et al.*, 2000],
- providing foraging or other manipulable materials during rearing and lay [Huber-Eicher and Wechsler, 1998; de Jong *et al.*, 2010; Daigle *et al.*, 2014; Dixon *et al.*, 2010; Nicol, 2018],
- reducing group size during rearing and lay [Bilcik and Keeling, 1999].

Management methods should be implemented, where applicable, and in the event of injury affected layer pullets and laying hens should be promptly removed and treated or euthanased.

If these management methods are unsuccessful, partial beak removal [Gentle *et al.*, 1997], may be considered as a final course of action.

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

Article 7.Z.20.

Moulting

Induced moulting can lead to *animal welfare* problems if not well managed [Nicol *et al.*, 2017; Sariozkan *et al.*, 2016; Holt, 2003, Ricke, 2003, Webster, 2003]. When induced moulting is practised, methods that do not involve withdrawal of feed and are consistent with Article 7.Z.8. should be used. Laying hens should have access to light and to water at all times [Anderson, 2015]. Only laying hens in good body condition and health should be moulted. During the moulting period, loss of body mass should not compromise the laying hen welfare, including welfare during the subsequent laying period. Total mortality and culling rates during the moult period should not exceed normal variations in *flock* mortality and culling rate.

Outcome-based measurables include: body condition, feeding and drinking, foraging behaviour [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 and social behaviour.

Article 7.Z.21.

Painful procedures

Painful procedures should not be practised unless necessary and should be performed in such a way as to minimise any pain, distress and suffering. If used, partial beak removal should be carried out at the earliest age possible and care should be taken to remove the minimum amount of beak necessary using a method that minimises pain and controls bleeding. If management methods to control injurious feather pecking and cannibalism are not successful, therapeutic partial beak removal 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]. Partial beak removal at a mature age can cause chronic pain. Dubbing, toe trimming and other mutilations should not be performed in layer pullets and laying hens.

Potential options for improving *animal welfare* in relation to these procedures include: ceasing the procedure, reducing or eliminating the need for the painful procedures through management strategies, using genetics that do not require the painful procedures, or replacing the current procedures with less painful or invasive alternatives.

Outcome-based measurables include: beak condition, body condition, feeding and drinking behaviour, foraging behaviour, injurious feather pecking and cannibalism, locomotory and comfort behaviours, mortality rate, morbidity rate, performance, plumage condition and 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 knowledge of normal layer pullet and laying hen behaviour, and be able to detect signs of ill-health or distress, such as a change in feed or water intake, reduced production, changes in behaviour and abnormalities in plumage condition faeces or other physical features.

If *animal handlers* are unable to identify the cause of disease, ill-health or distress, or are unable to correct these, or if they suspect the presence of a *notifiable disease*, they should seek advice from a *veterinarian* or other qualified advisers. Veterinary treatments should be prescribed by a *veterinarian*.

There should be an effective programme for the prevention of diseases that is consistent with the programmes established by *Veterinary Services* as appropriate, and which includes record-keeping.

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

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

Annex 11 (contd)

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

Article 7.Z.23.

Biosecurity plans

Biosecurity plans should be designed, implemented, and reviewed regularly, commensurate with the best possible layer pullet and laying hen health status. The *biosecurity plan* should be sufficiently robust to be effective in addressing the current disease *risks* that are specific to each epidemiological group of layer pullets and laying hens and in accordance with relevant recommendations in the *Terrestrial Code*.

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

- aerosols,
- direct transmission from other *poultry*, *domestic animals* and *wildlife* and humans,
- feed,
- fomites, such as equipment, facilities and vehicles,
- *vectors* (e.g. arthropods and rodents),
- water supply.

Partially restocking (back filling), in a response to catastrophe or incomplete flock placement, should only be practised with due consideration to biosecurity and in a manner that prevents co-mingling of flocks.

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

Article 7.Z.24.

Euthanasia of individual layer pullets or laying hens

Individual layer pullets or laying hens may be euthanised. Techniques used should be performed, in accordance with Chapter 7.6.

Reasons for euthanasia may include:

- disaster management,
- diagnostic purposes,
- rapid deterioration of a medical condition for which treatment has been unsuccessful,
- bone fractures or other injuries,
- emaciation,
- severe pain that cannot be alleviated.

The decision to euthanise an animal and the procedure itself should be undertaken by a competent person. The *establishment* should have documented procedures and appropriate equipment.

Outcome-based measurables include: injury rate and severity.

Article 7.Z.25.

Depopulation of pullet and hen facilities

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

The period of feed withdrawal prior to depopulation of layer pullets and laying hens should be minimised.

Water should be available up to the time of depopulation.

Annex 11 (contd)

Layer pullets and laying hens that are not fit for *loading* or transport should be euthanised. Hens with poor plumage condition are at risk of thermal stress and injury during transport [Broom, 1990; Fleming *et al.*, 2006; Gregory and Wilkins 1989; Newberry *et al.*, 1999; Webster, 2004; Whitehead and Fleming, 2000]. On-farm *killing* should be performed in accordance with Chapter 7.6.

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

Layer pullets and laying hens should be handled and placed into the transport *container* in accordance with Chapter 7.3.

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

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

The stocking density in transport *containers* should be in accordance with Chapters 7.2., 7.3. and 7.4.

Outcome-based measurables include: fear behaviour, injury rate and severity, mortality rate, spatial distribution, and vocalisation.

Article 7.Z.26.

Contingency plans

Layer pullet and laying hen producers should have 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, include the provision, maintenance and testing of backup generators and fail-safe alarm devices to detect malfunctions, 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 an alternative feed supply and a plan for managing ventilation emergencies.

The 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 and be in accordance with the methods recommended in Chapter 7.6.

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

Article 7.Z.27.

Competencies of personnel

Animal handlers should have the ability, knowledge and competencies necessary to maintain the welfare and health of the layer pullets and laying hens.

All people responsible for layer pullets and laying hens should have received appropriate training and be able to demonstrate that they are competent to carry out their responsibilities, which should include the assessment of pullet and hen behaviour, handling techniques, *euthanasia* and *killing* procedures, implementation of *biosecurity*, and the detection of general signs of diseases and indicators of poor *animal welfare* and procedures for their alleviation.

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

Article 7.Z.28.

Inspection and handling

Layer pullets and laying hens, and the facilities and equipment within their poultry house should be inspected at least daily. Inspection should have the following objectives

Annex 11 (contd)

- to collect and remove dead layer pullets and laying hens, and dispose of them in accordance with Chapter 4.13.;
- to identify sick or injured layer pullets and laying hens, and treat or euthanised them in accordance with Article 7.Z.24.;
- to detect and correct any *animal welfare* or health problems in the *flock*; and
- to detect and correct malfunctioning equipment and other problems with the facility.

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

When layer pullets and laying hens are handled, particularly when placed into or removed from the poultry house, they should not be injured, and should be held in a manner that minimises fear and stress [Gregory & Wilkins, 1989; Gross & Siegel, 2007; Kannan & Mench, 1996]. The distance over which layer pullets and laying hens are carried should be minimised. Laying hens are prone to bone fractures when not handled properly.

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

Article 7.Z.29.

Protection from predators

Layer pullets and laying 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.

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

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DRAFT 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 not included.~~ ~~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 ~~provides recommendations for the~~ ~~addresses the animal~~ welfare aspects of commercial laying hen production systems. ~~This chapter~~ It covers the production period from the arrival of *day-old birds* on to the pullet-rearing farm through to the removal of end-of-lay hens from the laying production facilities. ~~Laying hens kept in village or backyard flocks and used to produce eggs for personal consumption are not included.~~ ~~excluded.~~

Commercial laying hen production systems involve the confinement of layer pullets and laying hens/birds, the application of *biosecurity* and trade in the eggs or pullets.

These recommendations ~~cover~~ address the welfare aspects of layer pullets or laying hens kept in cage or non-cage systems, whether indoors or outdoors.

Commercial layer pullet or laying hen production systems include:

1. Indoor-Completely housed systems

Layer ~~P~~pullets or laying hens are completely confined in a poultry house, with or without mechanical environmental control ~~and with no designated outdoor area.~~

2. Outdoor-Partially housed systems

Layer ~~P~~pullets or laying hens are kept in premises a poultry house with ~~or without mechanical~~ environmental control ~~but have access to that include~~ a designated outdoor area.

3. Completely outdoor systems

Layer ~~P~~pullets or laying hens are not confined inside a poultry house during the day but are confined in 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.

Annex 12 (contd)

Article 7.Z.3.

Outcome-based criteria (or measurables) for the welfare of layer pullets and/or laying hens

The welfare of layer pullets and/or laying hens should be assessed using outcome-based criteria or measurables, specifically preferably animal-based measurables, as described in Article 7.1.4. 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. Outcome-based criteria or measurables are particularly useful for evaluating compliance and improving animal welfare. Animal-based outcomes are usually the most sensitive measurables (e.g. mortality rate). However, resource and management-based outcomes can also have important applications (e.g. interpretation of mortality rate data may be informed by decisions made to euthanise). There is no one single measurable that addresses all aspects of animal welfare. The use of these measurables indicators and the appropriate thresholds should be adapted to the different situations wherein which layer pullets and laying hens are kept/managed, also taking into account the genetics used, strain of bird concerned. Consideration should also be given to the resources provided as well as, and the design and management of the system. Animal-based criteria or measurables can be considered as tools to monitor and refine these factors.

Criteria (or measurables) that can be measured used at in the farm level 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-skeletal and foot problems, disease and infection or infestation that can be assessed during routine or targeted sampling monitoring, or at depopulation. It is recommended that target values or thresholds for animal welfare measurables be determined by taking into account with reference to current scientific knowledge and appropriate national, sectorial or regional standards recommendations for layer pullets or laying hens. Determining the age and stage of production at which problems are detected may help to determine the cause.

The following animal-based and outcome-based criteria and measurables, in alphabetical order, are may can be useful indicators of layer pullet or laying hen welfare:

1. Beak condition

Evaluation of beak condition provides useful information about the extent to which layer pullets and laying hens are able to engage in normal behaviour, such as foraging, feeding, drinking and preening [Dennis and Cheng, 2012; Vezzoli *et al.*, 2015]. Tools for assessing beak condition have been developed and implemented in animal welfare assessment programmes [e.g. Kajlich *et al.*, 2016].

2. Behaviour

The presence or absence of certain chicken behaviours may 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 *Gallus gallus domesticus* has 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 and 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 a complex behaviour providing body maintenance behaviour benefits. During dust bathing, layer pullets and laying hens/birds remove work loose substrate 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 the maintenance of maintaining plumage condition; This which in turn helps to regulate maintain body temperature and protect against skin injury. Reduced dust bathing behaviour in the flock may indicate problems with litter substrate or range quality, such as the litter substrate or ground being wet or not friable [Olson and Keeling, 2005; Van Liere and Bokma, 1987]. The demonstration presence of complete sequences of dust bathing may indicate good welfare be associated with positive affect [Widowski and Duncan, 2000].

b) Fear behaviour

Fearful layer pullets and laying hens show high reactivity to various stimuli [Jones, 1987; Zeltner and Hirt, 2008]. Fearfulness can lead and this may result in traumatic injuries, and or suffocation if when the layer pullets and or laying hens pile on top of, and sometimes suffocate, one another. Fearful layer pullets and laying hens may be less productive [Barnett *et al.*, 1992] and more prone to injurious feather pecking behaviour [Hass de Haas *et al.*, 2014]. Methods have been developed for evaluating fearfulness [Forkman *et al.*, 2007], for example by observing layer pullet and laying hen behaviour when people, including when while animal handlers, walk through the poultry house or pullets and hens area of the poultry house [Jones, 1996; Waiblinger *et al.* 2006; 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 water drinking intake are often depressed reduce when pullets or hens are ill, and Feed or water intake may also be reduced change as a result of during periods of heat [Lara L. J. & Rostagno M. H., 2013; Lin H. *et al.*, 2006.] stress and increased or during cold [Alves *et al.*, 2012] [Garner *et al.*, 2012; Thogerson *et al.*, 2009a; Thogerson *et al.*, 2009b] stress.

d) Foraging activity behaviour

Foraging is a motivated behaviour [de Jong *et al.*, 2007, Nicol *et al.*, 2011]. Foraging is the act of searching for food, typically by walking and pecking or scratching the litter substrate. Reduced foraging activity may could suggest problems with litter substrate quality or the presence of conditions that decrease pullets and hens movement foraging activityability [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 may result in significant feather loss and may lead to cannibalism. Cannibalism is the tearing of the flesh of another layer pullet or laying hen bird, and can result in severe injury or death. These behaviours can have multifactorial causes and be difficult to control [Nicol, 2018; 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, allow 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, 1989; Shipov *et al.*, 2010; Norgaard, 1990].

Layer pullets and laying hens may display a variety of locomotory and comfort behaviours, including walking, running, leaping, turning, stretching legs and wings, wing flapping, feather ruffling, tail wagging, and preening [Bracke and Hopster, 2006; Hartcher and Jones, 2017; Dawkins and Hardie, 1989; Shipov *et al.*, 2010; Norgaard, 1990]. Some of these behaviours have been shown to be important for skeletal, body and plumage development and maintenance. For example, walking and wing movements contribute to improved leg and wing bone strength [Knowles and Broom, 1990], and preening helps remove stale lipids from the skin [Vezzoli *et al.*, 2015] and keeps the feathers flexible and intact [Shawkey *et al.*, 2003].

Opportunities to display these behaviours are influenced by housing system and space [Widowski *et al.*, 2016; Lay *et al.*, 2014].

Annex 12 (contd)

g) Nesting

Nesting is a natural and highly motivated behaviour that includes nest site selection, nest formation and egg laying [Cooper and Albentosa, 2003; Weeks and Nicol, 2006; Cronin *et al.*, 2012; Yue and Duncan, 2003]. Uneven nest box utilisation, delayed oviposition, increased pacing and egg laying outside the nest may be indicative of problems with environmental or social behavioural factors [Cronin *et al.*, 2012; Cooper and Appleby, 1996; Gunnarsson *et al.*, 1999; Yue and Duncan, 2003; Widowski *et al.*, 2013].

h) Perching

Perching is a natural and highly motivated behaviour. Birds Layer pPullets and laying hens may seek elevation during the day; however, 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 or and pullet rearing experience [Janczak and Riber, 2015; Gunnarsson *et al.*, 1999].

i) Resting and sleeping

Sleeping, including slow wave and fast wave states, is a natural normal behaviour in pullets and hens, including slow wave and fast wave sleep states [Blokhuis, 1983]. Sleep is an adaptive state that allows animals to recover from daily stress, conserve energy and consolidate memory [Siegel, 2009]. Layer pPullets and laying hens display highly synchronised 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 hensChickens are a highly social species and, 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 damage caused by aggression damage and competition for resources [Estevez *et al.*, 2002; Blatchford *et al.*, 2016].

jk) Spatial distribution

Uneven spatial distribution of the birds layer pullets and laying hens may indicate fear reactions, thermal discomfort or, uneven availability or use of resources such as light, food feed or water, shelter, nesting and areas or comfortable resting locations [Rodríguez-Aurrekoetxea and Estevez, 2016; Cornotto and Estevez, 2004; Bright and Johnson, 2011].

kl) 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.

lm) Vocalisation

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

23. Body condition

Poor body condition is reflective of poor animal welfare outcomes problems for individual birds, layer pullet and laying hens. 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 the fact that feather cover that can mask actual body condition.

34. 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 very low light intensity (<5 lux) [Jenkins *et al.*, 1979; Lewis and Gous, 2009; Prescott *et al.*, 2003].

45. Foot problems

Hyperkeratosis, and bumblefoot, contact dermatitis, excessive claw growth, broken claws and toe injuries are painful conditions associated with amongst other things, inappropriate flooring, poorly designed perches, or poorly maintained litter substrate [EFSA, 2005; Lay *et al.*, 2011; Abrahamsson and Tauson, 1995; Tauson and Abrahamson, 1996; Abrahamsson and Tauson, 1997] and inadequate system maintenance of aspects of the production system.

~~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 problems may contribute to locomotion problems and lead to secondary infections. Scoring systems for foot problems have been developed [Blatchford *et al.*, 2016].~~

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

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

67. 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 pullets and hens (e.g. scratches, feather loss or wounding), management (e.g. nutritional deficits leading to skeletal problems), by environmental conditions, (e.g. fractures and keel bone deformation), genetics used and or by human interventions (e.g. during handling and catching). It is important to assess both the rate and severity of injuries.

78. 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 may reflect an animal welfare problem. Recording and evaluating causes of morbidity and mortality can be useful aids in diagnosing and remediating animal welfare problems.

89. Performance indicators

Daily, weekly and cumulative performance should be within expected ranges. Any unforeseen reduction decreases in these rates could may be reflective of reflect an animal welfare status problem. Types of measures that can be used include:

- a) Ppullet growth rate, which measures average daily mass gain per average pullet and flock uniformity;
- b) Ppullet feed conversion, which 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) Hhen feed conversion, which measures the quantity mass of feed consumed by a flock relative to the unit of egg production;
- d) Eegg production, such as when which measures by e.g. the number and size of eggs per hen housed;

Annex 12 (contd)

- e) Egg quality and downgrades, such as when which can be measured by, for example, grade percentage, shell strength and, Haugh units, abnormalities and mis-laid or floor eggs.

910. Plumage condition

Evaluation of the plumage condition of pullets and hens provides useful information about aspects of *animal welfare in terms of feather pecking and cannibalism, ability to thermoregulate, illness, and protection from injury*. 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]. *Dirty plumage dirtiness* may be associated with *illness, the environmental conditions and or production the layer pullet and laying hen housing system*. Plumage *cover and cleanliness* scoring systems have been developed for these purposes [Blokhuis, 2007; Blatchford *et al.*, 2016].

4011. Water and feed consumption

Monitoring *and evaluating* 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-substrate 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 or supply of water, or feed.*

Article 7.Z.4.

Recommendations for layer pullets and laying hens

Ensuring good welfare of layer pullets and laying hens is contingent upon several management factors, including such as system design, environmental management practices, and animal management practices including responsible husbandry and provision of appropriate care, and the genetics used. Serious problems can arise in any system if one or more of these elements are lacking. Although pullets and hens can adapt to a range of thermal environments, particularly if appropriate breeds and housing are used for the anticipated conditions, sudden fluctuations in temperature can cause heat or cold stress.

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

Each recommendation in Article 7.Z.5. to 7.Z.29. includes a list of relevant animal outcome-based criteria and or measurables derived from Article 7.Z.3. and when appropriate. This does not exclude other criteria and or measurables being used where or when appropriate. The suitability of some of these criteria and or measurables will should be determined by in accordance with 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.

Article 7.Z.5.

Location, design, construction and equipment of establishments

The location of *layer* pullets and *laying* 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, *and* exposure of *layer* pullets and *laying* hens to chemical and physical contaminants, noise and adverse climatic conditions.

Annex 12 (contd)

Good welfare outcomes for layer pullets and pullet-laying hens can be achieved in a range of housing systems. Pullet and layer houses, outdoor areas and accessible equipment should be designed, after consideration of considering bird the opportunities for layer pullets and laying hens for pullets and hens to perform highly motivated behaviours (e.g. perching and nesting), and as well as health, environmental factors, and animal management capability, to promote good animal welfare and They should also be maintained to avoid injury or discomfort pain to the birds. Pullet and layer hen houses should be constructed with materials and electrical and fuel installations that minimise the risk of fire and other hazards, and are easy to clean and maintain. Producers should have a maintenance programme in place, including record-keeping for all equipment and contingency plans to address the failures of that could jeopardise bird layer pullets and hen laying hens welfare.

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

Article 7.Z.6.

Matching the layer pullets and laying hens with the housing and production system

Animal welfare and health considerations should balance any decisions on performance when choosing the genetics to be used 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].

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

Article 7.Z.7.

Stocking density Space allowance

Layer pullets and laying hens should be housed with at a space allowance stocking density that allows them to have adequate access to resources and to adopt normal postures. Providing sufficient space for the expression of locomotion and comfort behaviours that contribute to good musculoskeletal health and plumage condition is desirable. Problems with space allowance may increase stress and the occurrence of injuries.

The following factors, in alphabetical order, should be taken into account considered when determining space allowance:

- age and mass of layer pullets and laying hens,
- ambient conditions,
- housing design system,
- biosecurity strategy,
- equipment selection,
- feed and watering systems,
- litter flooring substrate,
- genetics,

Annex 12 (contd)

- housing design.
- management capabilities,
- production system,
- usable space.
- ventilation.
- genetics strain,
- age and bird mass.

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

Article 7.Z.8.

Nutrition

Layer pPullets and laying 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 of the feed should be acceptable to the layer pullets and laying hens and contain adequate nutrients to meet requirements for good animal welfare and health. Feed and water should be free from contaminants, debris and microorganisms or other potential hazards.

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 Layer pPullets and laying hens should be provided with adequate access to feed on a daily basis. Water should be continuously available except under veterinary advice. Special provisions should be made to enable newly hatched pullets chicks to access appropriate feed and water.

Outcome/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, and water and feed consumption.

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 locomotion and comfort behaviours. The slope, design and construction of the floors should provide adequate support for the locomotion of for the layer pullets and laying hens the birds adequately, prevent injuries, and entrapments, and ensure good health and allow the performance of normal behaviour that manure does not contaminate other birds pullets and hens. Changes of flooring types from pullet to layer-hen housing should be avoided. Manure contamination from other layer pullets and laying hens within the house should be minimised through appropriate floor design and other elements of system design. The flooring should be easy to clean and disinfect and should not cause harm.

Annex 12 (contd)

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. When litter is provided, Litter should be managed to remain dry and friable, replaced or and adequately treated or replaced when required to prevent diseases and minimise any detrimental effects on animal welfare, infections and infestations.

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

Article 7.Z.10.

Dust bathing areas

Access to The provision of friable, dry litter-substrate material is desirable to encourage dust bathing is desirable by pullets and hens. When provided, 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.*, 2011] [Weeks and Nicol, 2006].

Outcome Animal Outcome-based measurables include: dust bathing, incidence of diseases, infections and infestations, injury rate and severity, plumage condition and, spatial distribution.

Article 7.Z.11.

Foraging areas

The provision of Access to substrate that friable, dry litter material is desirable to encourages foraging behaviour activity is desirable. When provided, 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.

Outcome Animal Outcome-based measurables include: foraging behaviour activity, incidence of diseases, infections and infestations, injurious feather pecking and cannibalism, injury rate and severity, and spatial distribution.

Article 7.Z.12.

Nesting areas

Access to When n nesting areas is desirable. When should be provided are offered, nesting areas they and should should be built of suitable materials, and 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.

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

Article 7.Z.13.

Perches

Access to When p perches is desirable. When should be provided are offered, they and perches should should be built of suitable materials, designed, elevated and positioned to encourage perching by for all layer pullets and laying hens, prevent undue competition, to prevent minimise keel bone deformation or, foot problems or other injuries harms, and to ensure maintain stability of the birds during perching. In the absence of designated perches, other structures such as platforms, grids or 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. When provided, p Perches or their alternatives should be made available from an early age, be easy to clean and maintain disinfect and be positioned to minimise faecal fouling. [Hester, 2014; EFSA, 2015].

Annex 12 (contd)

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

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

Article 7.Z.14.

Outdoor areas

Layer pullets and laying hens may be given access to outdoor areas ~~as soon as~~ when they have sufficient feather cover and ~~are old enough to~~ can range safely. Where pullets and hens are partially housed, 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 layer pullets and laying hens becoming infected by pathogenic agents, or infested by parasites or being injured. This may 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 stagnant water and mud. The outdoor area should be able to contain the layer pullets and laying hens birds and prevent them from escaping. Outdoor areas should be designed, built and maintained to allow layer pullets and laying hens to feel safe outdoors and to be encouraged them to optimise optimally utilisation-utilise of the range optimally, while mitigating predation, and disease risks, and adverse climatic conditions [Gilani *et al.*, 2014; Hegelund *et al.*, 2005; Nagle and Glatz, 2012]. Pullets and Hens should be habituated early to the outdoor area [Rodríguez-Aurrekoetxea and Estevez, 2016]. Outdoor areas should provide shelter for the birds and be free from ~~poisonous~~ harmful plants and contaminants.

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

Article 7.Z.15.

Thermal environment

Thermal conditions for layer pullets and laying hens should be maintained within a range that is appropriate for their stage of life, and the genetics used; and extremes of heat, humidity and cold should be avoided. A heat index can assist in identifying the thermal comfort zones for the layer pullets and laying hens at varying temperatures, air velocities and relative humidity levels [Xin and Harmon, 1998], and can be found in management guidelines provided by laying hen genetics companies 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 against the adverse effects on the layer pullets and laying 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 regularly enough so that failure of the system can be noticed detected and corrected before they it causes an animal welfare problems.

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

Article 7.Z.16.

Air quality

Ventilation, housing, space allowance and manure management can affect air quality. Actions are required to maintain air quality at levels required for good animal welfare 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 ammonia concentrations should not routinely exceed 25 ppm at bird layer pullet and laying hen level [David *et al.*, 2015; Miles *et al.*, 2006; Olanrewaiu, 2007].

Dust levels should be kept to a minimum [David *et al.*, 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.~~

~~Outcome~~ Animal Outcome-based measurables include: ammonia level, carbon dioxide level, dust level, eye conditions, incidence of respiratory diseases, infections, metabolic disorders and infestations, morbidity and mortality rates, plumage condition, performance indicators, temperature and humidity and thermoregulatory behaviours.

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~~, allow layer pullets and laying hens to ~~for~~ finding feed and water, to stimulate activity, to stimulate onset of lay, minimise the 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 layer pullets and laying hens ~~the birds~~ to rest and sleep, to reduce stress, and ~~to~~ promote circadian rhythms [Malleau *et al.*, 2007].

~~When~~ Changes in lighting should occur gradually or are needed, they should be performed in a step-wise fashion, as needed, except during induced moulting (if practised) when rapid adjustments to lighting should be considered ~~are desired~~ [Tanaka and Humik, 1990; Kristenson, 2008].

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

Article 7.Z.18.

Noise

~~Although~~ Layer pullets and laying hens are can adaptable to different levels and types of noise; ~~However,~~ Exposure of birds layer pullets and laying 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 and~~ other indoor or outdoor equipment should be constructed, placed, operated and maintained in such a way ~~that it~~ as to causes the least possible amount of noise [Chloupek *et al.*, 2009].

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

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

Annex 12 (contd)

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 systems.

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],
- adapting the diet and form of feed during rearing and lay [Lambton *et al.*, 2010],
- choosing genetics strain with a low propensity to for injurious feather pecking [Craig and Muir, 1996; Kjaer and Hocking, 2004],
- influencing increasing age of at onset of lay [Green *et al.*, 2010; Pöttsch, 2001],
- reducing stocking density [Zimmerman *et al.*, 2006]; increasing space allowance during rearing [Jung and Knierim, 2018],
- managing light in during rearing and lay [Nicol *et al.*, 2013; van Niekerk *et al.*, 2013],
- minimising fear-related stimuli [Uitdehaag K. A. *et al.*, 2009],
- treating beaks in chicks [Gentle and Hughes, 1997], especially by using new non-invasive beak treatments that are being developed,
- providing elevated perches during in rearing and lay [Green *et al.*, 2000],
- adapting diet and form of feed in rearing and lay [Lambton *et al.*, 2010],
- providing foraging or other manipulable materials in during rearing and lay [Huber-Eicher and Wechsler, 1998; de Jong *et al.*, 2010; Daigle *et al.*, 2014; Dixon *et al.*, 2010; Nicol, 2018],
- reducing group size in during rearing and lay [Bilcik and Keeling, 1999].
- introducing males [Bestman and Wagenaar, 2003].

These management methods should be to control the occurrence include the above list implemented, where applicable, and in the event of injury prompt removal of affected layer pullets and laying hens birds should be promptly removed and treated to a hospital area or euthanasia.

If these management strategies methods are unsuccessful fail, therapeutic partial beak removal treatment [Gentle *et al.*, 1997], trimming is the last resort, may be considered as a final course of action.

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

Article 7.Z.20.

Moult

Induced moulting can lead to *animal welfare* problems if not well managed [Nicol *et al.*, 2017; Sariozkan *et al.*, 2016; Holt, 2003, Ricke, 2003, Webster, 2003]. When induced moulting is practised, techniques methods that do not involve withdrawal of feed should be used and are consistent with Article 7.Z.8, should be used. Laying hens should have access to lights and access to water at all times [Anderson, 2015]. Only laying hens in good body condition and health should be moulted. During the moulting period, body mass loss of body mass should not compromise the laying hen welfare, including welfare during the subsequent laying period. Total mortality and culling rates during the moult period should not exceed normal variations in *flock* mortality and culling rate.

Outcome Animal Outcome-based measurables include: body condition, feeding and drinking, foraging behaviour 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, and social behaviour.

Article 7.Z.21.

Painful procedures interventions

Painful procedures interventions, such as beak treatment/trimming, should not be practised unless absolutely necessary and should be pain mitigation interventions should be used performed in such a way as to minimise any pain, distress and suffering. 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 used, partial preventive beak removal treatment trimming 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 that 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 methods to control injurious feather pecking and cannibalism are not successful fail, therapeutic partial beak treatment removal 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]. Partial beak removal at a mature age can cause chronic pain. Other mutilations (e.g. dubbing and toe trimming) should not be performed in pullets and hens. Dubbing, toe trimming and other mutilations should not be performed in layer pullets and laying hens.

Potential options for improving animal welfare in relation to these procedures include: ceasing the procedure, reducing or eliminating the need for the painful procedures through management strategies, using genetics that do not require the painful procedures, or replacing the current procedures with less painful or invasive alternatives.

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.

Outcome/Animal Outcome-based measurables include: beak condition, body condition, feeding and drinking behaviour, and foraging behaviour activity, feeding, injurious feather pecking and cannibalism, locomotory and comfort behaviours, mortality rate, morbidity rate, performance, plumage condition, and 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 layer pullet and laying hen behaviour, the and be able to detect signs of ill-health or distress, such as a change in feed and or water intake, reduced production, changes in behaviour, and abnormalities in plumage condition appearance of feathers, faeces, or other physical features.

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

There should be an effective programme for the prevention of diseases that is consistent with the programmes established by Veterinary Services as appropriate, and which includes record-keeping.

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

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

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

Annex 12 (contd)

Article 7.Z.23.

Biosecurity plans

Biosecurity plans should be designed, and implemented, and reviewed regularly, commensurate with the best possible layer pullet and laying hen birds health status and . The *biosecurity plan* should be sufficiently robust to be effective in addressing the current disease risks (endemic and exotic) that is/are specific to each epidemiological group of layer pullets and laying hens and in accordance with relevant recommendations in the *Terrestrial Code*.

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

Partially restocking (back filling), in a response to catastrophe or incomplete flock placement, should only be practised with due consideration to biosecurity and in a manner that prevents co-mingling of flocks.

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

Article 7.Z.24.

Humane killing Euthanasia of individual birds or flocks layer pullets or laying hens

Individual sick or injured layer pullets or laying hens requiring euthanasia may be should be humanely killed as soon as possible. When an individual or groups of pullets or hens birds are killed for euthanasia or humanely killed for 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.

Reasons for euthanasia may include:

- disaster management,
- diagnostic purposes,
- rapid deterioration of a medical condition for which treatment has been unsuccessful,
- bone fractures or other injuries,
- emaciation,
- severe pain that cannot be alleviated.

The decision to euthanise an animal and the procedure itself should be undertaken by a competent person. The establishment should have documented procedures and appropriate equipment.

Outcome-based measurables include: injury rate and severity.

Article 7.Z.25.

Depopulation of pullet and layer hen facilities

This article refers to the removal of flocks of layer 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~~ The period of feed withdrawal prior to the expected depopulation time of layer pullets and laying hens should be minimised.

Water should be available up to the time of depopulation.

~~Birds Layer pullets and laying hens that are not fit for loading or transport because they are sick or injured should be euthanised humanely killed. Hens with poor plumage condition are at risk of thermal stress and injury during transport [Broom, 1990; Fleming et al., 2006; Gregory and Wilkins 1989; Newberry et al., 1999; Webster, 2004; Whitehead and Fleming, 2000]. On-farm killing should be performed in accordance with Chapter 7.6.~~

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

~~Birds Layer pullets and laying hens should be handled and placed into the transport container in accordance to with Chapter 7.3, Article 7.Z.14.~~

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

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

~~The~~ Stocking density in transport containers should be in accordance ~~comply~~ with Chapters 7.2., 7.3. and 7.4.

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

Article 7.Z.26.

Emergency Contingency plans

~~Layer pullet and laying 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 backup generators and 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 an 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 and be in accordance ~~ing to with the methods~~ recommended in Chapter 7.6.

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

Article 7.Z.27.

Competencies of Personnel competency

~~Animal handlers responsible for the pullets and hens should have the ability, knowledge and competencies necessary to maintain the welfare and health of the layer pullets and laying hens.~~

Annex 12 (contd)

All people responsible for layer pullets and laying hens should have received appropriate training, and or be able to demonstrate that they are competent to carry out their responsibilities, which should include and should have sufficient knowledge of the assessment of pullet and hen behaviour, handling techniques, euthanasia and killing emergency killing procedures, implementation of biosecurity, and the detection of general signs of diseases, and indicators of poor animal welfare and procedures for their alleviation.

Outcome/Animal Outcome-based measurables include: body condition, culling and morbidity rate, fear behaviour, incidence of diseases, locomotion and comfort behaviours, performance, morbidity rate, mortality rate, culling and morbidity rates spatial distribution, and vocalisation.

Article 7.Z.28.

Inspection and handling

Layer pullets and laying hens, and the facilities and equipment within their poultry house 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 kill them in accordance with Article 7.Z.24.;~~
- ~~to pick up collect and remove dead layer pullets and laying hens, and dispose of them in accordance with Chapter 4.13.;~~
- ~~to identify sick or injured layer pullets and laying hens, and treat or euthanased them in accordance with Article 7.Z.24.;~~
- to detect and correct any animal welfare or health problems in the flock; and
- to detect and correct malfunctioning equipment and other facility problems with the facility.
- ~~to identify sick or injured pullets and hens and to treat or cull kill them in accordance with Article 7.Z.24.;~~

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

When layer pullets and laying hens are handled, particularly when birds are placed into or removed from the poultry house, they should not be injured, and should be held in postures a manner that minimises 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 distance that over which layer pullets and laying hens are carried should be minimised. Laying hens are prone to bone fractures when not handled properly.

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

Article 7.Z.29.

Protection from predators

Layer pullets and laying 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.

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

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CHAPTER 10.4.

INFECTION WITH HIGH PATHOGENICITY AVIAN
INFLUENZA VIRUSES

Article 10.4.1.

General provisions⁷

- 1) This chapter deals with the *listed disease*, *infection* with 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 that has been determined as high pathogenicity in accordance with the *Terrestrial Manual*.
 - b) An occurrence of *infection* with a high pathogenicity avian influenza virus is defined by the isolation and identification of the virus or the detection of specific viral ribonucleic acid, in one or more samples from *poultry*.
 - c) *Poultry* means all domesticated birds used for the production of *meat* or eggs for human consumption, for the production of other commercial products, or for breeding of 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*.
 - d) 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, racing, exhibitions, zoological collections, competitions, breeding or selling, as well as pet birds, are not considered *poultry*.
 - e) The *incubation period* at the *flock-level* for high pathogenicity avian influenza is 14 days.
- 3) Although the objective of this chapter is to mitigate animal and public health risks posed by *infection* with high pathogenicity avian influenza viruses, other influenza A viruses of avian host origin (i.e. low pathogenicity avian influenza viruses) may have the potential to exert a negative impact on animal and public health. A sudden and unexpected increase in virulence of low pathogenicity avian influenza viruses in *poultry* is notifiable as an *emerging disease* in accordance with Article 1.1.4. *Infection* of domestic and *captive wild* birds with low pathogenicity avian influenza viruses having proven natural transmission to humans associated with severe consequences is also notifiable as an *emerging disease* with public health impact in accordance with Article 1.1.4. Occurrences of *infection* with avian influenza viruses of high pathogenicity in birds other than *poultry*, including *wild* birds, are notifiable in accordance with Article 1.3.6.
- 4) A *notification of infection* with avian influenza viruses of high pathogenicity in birds other than *poultry*, including *wild* birds, or of low pathogenicity avian influenza viruses in *poultry* (as described in point 2) c)) does not affect the high pathogenicity avian influenza status of the country or *zone*. A Member Country should not impose bans on the trade of *poultry commodities* in response to such *notifications*, or to other information on the presence of any influenza A virus in birds other than *poultry*, including *wild* birds.
- 5) This chapter includes *monitoring* considerations for low pathogenicity avian influenza viruses because some, especially H5 and H7 subtypes, have the potential to mutate into high pathogenicity avian influenza viruses.

Annex 13 (contd)

- 6) The use of *vaccination* against avian influenza may be recommended under specific conditions. Any vaccine used should comply with the standards described in the *Terrestrial Manual*. *Vaccination* will not affect the high pathogenicity avian influenza status of a free country or *zone* if *surveillance* supports the absence of *infection*, in accordance with Article 10.4.22., in particular point 2. *Vaccination* is an effective complementary control tool that can be used when a *stamping-out policy* alone is not sufficient. Whether to vaccinate or not should be decided by the *Veterinary Authority* on the basis of the avian influenza situation as well as the ability of the *Veterinary Services* to implement the *vaccination* strategy, as described in Chapter 4.18.
- 7) Standards for diagnostic tests and vaccines, including pathogenicity testing, are described in the *Terrestrial Manual*.

Article 10.4.1bis.

Safe commodities

When authorising importation or transit of the following *commodities*, *Veterinary Authorities* should not require any conditions related to high pathogenicity avian influenza, regardless of the high pathogenicity avian influenza status of the *exporting country or zone*:

- 1) heat-treated *poultry meat products* in a hermetically sealed container with an F_0 value of 3 or above;
- 2) extruded dry pet food and coated ingredients after extrusion;
- 3) rendered *meat* and bone meal, blood meal, feather meal, and *poultry* oil;
- 4) washed and steam-dried feathers and down from *poultry* and other birds.

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.

Country or zone free from high pathogenicity avian influenza

A country or *zone* may be considered free from high pathogenicity avian influenza when:

- *infection* with high pathogenicity avian influenza viruses in *poultry* is a *notifiable disease* in the entire country;
- absence of *infection* with high pathogenicity avian influenza viruses, based on *surveillance*, in accordance with Chapter 1.4. and Articles 10.4.20. to 10.4.22ter., has been demonstrated in the country or *zone* for the past 12 months;
- an awareness programme is in place related to *biosecurity* and management of avian influenza viruses;
- *commodities* are imported in accordance with Articles 10.4.3. to 10.4.17bis.

Surveillance should be adapted to parts of the country or existing *zones* depending on historical or geographical factors, industry structure, population data and proximity to recent *outbreaks* or the use of *vaccination*.

Article 10.4.2bis.

Compartment free from high pathogenicity avian influenza

The establishment of a *compartment* free from high pathogenicity avian influenza should be in accordance with relevant requirements of this chapter and the principles described in Chapters 4.4. and 4.5.

Article 10.4.2ter.

Establishment of a containment zone within a country or zone free from high pathogenicity avian influenza

In the event of an *outbreak* 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 purpose 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 4.4.7., the *surveillance* programme should take into account the density of *poultry* production, types of *poultry*, local management practices (including inter-premises movement patterns of *poultry*, people and equipment), relevant *biosecurity*, the presence and potential role of birds other than *poultry*, including *wild* birds, and the proximity of *poultry establishments* to permanent 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 10.4.2quater., once the *containment zone* is clearly established. It should be demonstrated that *commodities* for *international trade* have originated from outside the *containment zone* or comply with the relevant articles of this chapter.

Article 10.4.2quater.

Recovery of free status

If *infection* with high pathogenicity avian influenza virus has occurred in *poultry* in a previously free country or *zone*, the free status may be regained after a minimum period of 28 days (i.e. two *flock-level incubation periods*) after a *stamping-out policy* has been completed, provided that *surveillance* in accordance with Articles 10.4.20. to 10.4.22ter., in particular point 3 of Article 10.4.22., has been carried out during that period and has demonstrated the absence of *infection*.

If a *stamping-out policy* is not implemented, Article 10.4.2. applies.

Article 10.4.3.

Recommendations for importation from a country, zone or compartment free from high pathogenicity avian influenzaFor 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) the *poultry* originated from a country, *zone* or *compartment* free from high pathogenicity avian influenza;
- 3) the *poultry* originated from a *flock* that was monitored for avian influenza viruses and was found to be negative;
- 4) the *poultry* are transported in new or appropriately sanitised *containers*.

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

Annex 13 (contd)

Article 10.4.4.

Recommendations for the importation of live birds other than poultry

Regardless of the high pathogenicity 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 avian influenza;
- 2) the birds had been kept in isolation facilities approved by the *Veterinary Services* since they were hatched or for at least 28 days (i.e. two *flock-level incubation periods*) prior to shipment and showed no clinical signs of avian influenza during the isolation period;
- 3) a statistically appropriate sample of the birds was subjected, with negative results, to a diagnostic test for avian influenza within 14 days prior to shipment;
- 4) the birds are transported in new or appropriately sanitised *containers*.

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

Article 10.4.5.

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

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

- 1) the day-old live *poultry* had been kept in a country, *zone* or *compartment* free from high pathogenicity avian influenza since they were hatched;
- and
- a) the day-old live *poultry* were derived from parent *flocks* that were monitored for avian influenza viruses and were found to be negative at the time of collection of the eggs from which the day-old *poultry* hatched; or
 - b) the day-old live *poultry* that hatched from eggs that had had their surfaces sanitised in accordance with point 4 d) of Article 6.5.5.;

AND

- 2) the day-old live *poultry* were transported in new or appropriately sanitised *containers*.

If the day-old live *poultry* or the parent *flocks* have been vaccinated against avian influenza, the nature of the vaccine used and the date of *vaccination* should be stated in the *international veterinary certificate*.

Article 10.4.6.

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

Regardless of the high pathogenicity 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 avian influenza;
- 2) the birds were hatched and kept in isolation facilities approved by the *Veterinary Services*;

Annex 13 (contd)

- 3) a statistically appropriate sample of the parent *flock* birds were subjected, with negative results, to a diagnostic test for avian influenza at the time of collection of the eggs;
- 4) the birds were transported in new or appropriately sanitised *containers*.

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 stated in the *international veterinary certificate*.

Article 10.4.7.

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

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

- 1) the hatching eggs came from a country, *zone* or *compartment* free from high pathogenicity avian influenza;
- 2) a) the hatching eggs were derived from parent *flocks* that were monitored for avian influenza viruses and were found to be negative at the time of collection of the hatching eggs; or
 - b) the hatching eggs have had their surfaces sanitised in accordance with point 4 d) of Article 6.5.5.;
- 3) the hatching eggs are transported in new or appropriately sanitised packaging materials and *containers*.

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

Article 10.4.8.

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

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

- 1) a statistically appropriate sample of the parent *flocks* birds was subjected, with negative results, to a diagnostic test for avian influenza 14 days prior to and at the time of collection of the hatching eggs;
- 2) the hatching eggs have had their surfaces sanitised in accordance with point 4 d) of Article 6.5.5.;
- 3) the hatching eggs are transported in new or appropriately sanitised packaging materials and *containers*.

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

Article 10.4.9.

Recommendations for importation from a country, zone or compartment free from high pathogenicity avian influenzaFor poultry semen

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

- 1) showed no clinical signs of avian influenza on the day of semen collection;
- 2) were kept in a country, *zone* or *compartment* free from high pathogenicity avian influenza.

Annex 13 (contd)

Article 10.4.10.

Recommendations for the importation of semen from birds other than poultry

Regardless of the high pathogenicity 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 facilities approved by the *Veterinary Services* for at least 28 days (i.e. two *flock-level incubation periods*) prior to semen collection;
- 2) showed no clinical signs of avian influenza during the isolation period;
- 3) were subjected, with negative results, to a diagnostic test for avian influenza within 14 days prior to semen collection.

Article 10.4.11.

Recommendations for importation from a country, zone or compartment free from high pathogenicity avian influenzaFor eggs for human consumption

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

- 1) the eggs for human consumption were produced and packed in a country, *zone* or *compartment* free from high pathogenicity avian influenza;
- 2) the eggs for human consumption were transported in new or appropriately sanitised packaging materials and *containers*.

Article 10.4.12.

Recommendations for the importation of egg products from poultry

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

- 1) the egg products are derived from eggs which meet the requirements of Article 10.4.11.; or
- 2) the egg products have been processed to ensure the inactivation of high pathogenicity avian influenza viruses, in accordance with Article 10.4.18.;

AND

- 3) the necessary precautions were taken to avoid contact of the egg products with any source of high pathogenicity avian influenza viruses.

Article 10.4.13.

Recommendations for importation from a country, zone or compartment free from high pathogenicity avian influenzaFor 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 originated from a country, *zone* or *compartment* free from high pathogenicity avian influenza;
- 2) which were slaughtered in an approved *slaughterhouse/abattoir* in a country, *zone* or *compartment* free from high pathogenicity avian influenza and were subjected to ante- and post-mortem inspections in accordance with Chapter 6.3., with favourable results.

Annex 13 (contd)

Article 10.4.14.

Recommendations for the importation of meat products from poultry

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

- 1) the *meat products* from *poultry* are derived from *fresh meat* which meets the requirements of Article 10.4.13.; or
- 2) the *meat products* from *poultry* have been processed to ensure the inactivation of high pathogenicity avian influenza viruses in accordance with Article 10.4.19.;

AND

- 3) the necessary precautions were taken to avoid contact of the *meat products* from *poultry* with any source of high pathogenicity avian influenza viruses.

Article 10.4.15.

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 high pathogenicity 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 a country, *zone* or *compartment* free from high pathogenicity avian influenza and were obtained 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 viruses using:
 - a) moist heat treatment for 30 minutes at 56°C; or
 - b) heat treatment where the internal temperature throughout the product reached at least 74°C; or
 - c) any equivalent treatment that has been demonstrated to inactivate avian influenza viruses;

AND

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

Article 10.4.16.

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

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

- 1) these *commodities* originated from *poultry* as described in Article 10.4.13. and were processed in a country, *zone* or *compartment* free from high pathogenicity avian influenza; or

Annex 13 (contd)

- 2) these *commodities* have been processed to ensure the inactivation of high pathogenicity avian influenza viruses using one of the following:
 - a) fumigation with formalin (10% formaldehyde) for 8 hours;
 - b) irradiation with a dose of 20 kGy;
 - c) any equivalent treatment which has been demonstrated to inactivate avian influenza viruses;

AND

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

Article 10.4.17.

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

Regardless of the high pathogenicity 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 inactivation of high pathogenicity avian influenza viruses using one of the following:
 - a) fumigation with formalin (10% formaldehyde) for 8 hours;
 - b) irradiation with a dose of 20 kGy;
 - c) any equivalent treatment which has been demonstrated to inactivate avian influenza viruses;
- 2) the necessary precautions were taken to avoid contact of the *commodity* with any source of high pathogenicity avian influenza viruses.

Article 10.4.17bis.

Recommendations for the importation of scientific specimens, skins and trophies of birds other than poultry

Regardless of the high pathogenicity 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 inactivation of high pathogenicity avian influenza viruses in accordance with Article 10.4.19bis.;

AND

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

Article 10.4.18.

Procedures for the inactivation of high pathogenicity avian influenza viruses in egg products from poultry

The following time/temperature combinations are suitable for the inactivation of high pathogenicity avian influenza viruses present in egg products:

Annex 13 (contd)

	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

These time/temperature combinations are indicative of a range that achieves a 7-log₁₀ reduction of avian influenza virus infectivity. These are examples for a variety of egg products but, when supported by scientific evidence, variations of these time/temperature combinations may be used, and they may be used for other egg products, if they achieve equivalent inactivation of the virus.

Article 10.4.19.

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

The following time/temperature combinations are suitable for the inactivation of high pathogenicity avian influenza viruses in *meat products*.

	Core temperature (°C)	Time
Meat products from poultry	60.0	507 seconds
	65.0	42 seconds
	70.0	3.5 seconds
	73.9	0.51 second

These time/temperature combinations are indicative of a range that achieves a 7-log₁₀ reduction of avian influenza virus infectivity. When supported by scientific evidence, variations of these time/temperature combinations may be used if they achieve equivalent inactivation of the virus.

Article 10.4.19bis.

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

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

- 1) boiling in water for an appropriate time to ensure that any material other than bone, claws or beaks is removed; or

Annex 13 (contd)

- 2) soaking, with agitation, in a 4% (w/v) solution of washing soda (sodium carbonate- Na_2CO_3) maintained at pH 11.5 or above for at least 48 hours; 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, treatment for at least 28 days with salt (NaCl) containing 2% washing soda (sodium carbonate- Na_2CO_3); 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 10.4.20.

Principles of surveillance for avian influenza

Article 10.4.20. defines the principles and Articles 10.4.21., 10.4.22., 10.4.22bis. and 10.4.22ter. provide guidance on avian influenza *surveillance* for the entire country, *zone* or *compartment* and are complementary to Chapter 1.4. These principles should be applied by Member Countries seeking to determine their high pathogenicity avian influenza status; they are also necessary to support *vaccination* programmes, to monitor low pathogenicity avian influenza viruses, especially H5 and H7, in *poultry* and to monitor avian influenza in *wild* birds.

The impact and epidemiology of avian influenza differ widely among different regions of the world and therefore it is impossible to provide detailed recommendations for all situations. Variables such as the frequency of contacts between *poultry* and *wild* birds, different *biosecurity* levels and production systems, and the commingling of different susceptible species including domestic waterfowl, may require different *surveillance* strategies to address each situation. Furthermore, domestic waterfowls typically do not show clinical signs and have longer infective periods than gallinaceous *poultry*. It is therefore incumbent upon the Member Country to provide scientific data that explain the epidemiology of avian influenza in the region of concern and also to demonstrate how all the risk factors have been taken into account. Member Countries have flexibility to provide a science-based approach to demonstrate absence of *infection* with avian influenza viruses at an appropriate level of confidence, as described in Chapter 1.4.

There is an increased recognition of the value of the application of sequencing technologies and phylogenetic analyses to determine routes of introduction, transmission pathways and epidemiological patterns of *infection*. When avian influenza viruses are detected, Member Countries should apply these technologies, when possible, to enhance the evidence used to develop specific *surveillance* strategies and control activities.

A *monitoring* system for low pathogenicity avian influenza viruses in *poultry* should be in place for the following reasons:

- 1) Some H5 and H7 low pathogenicity avian influenza viruses have the potential to mutate into high pathogenicity avian influenza viruses and currently it is not possible to predict whether and when this mutation will occur.
- 2) The detection of sudden and unexpected increases in virulence of low pathogenicity avian influenza viruses in *poultry*, in order to fulfil notification obligations of an *emerging disease* in accordance with Article 1.1.4.
- 3) The detection, in domestic and *captive wild* birds, of low pathogenicity avian influenza viruses that have been proven to be transmitted naturally to humans with severe consequences, as in order to fulfil notification obligations of an *emerging disease*, in accordance with Article 1.1.4.

Article 10.4.21.

Surveillance for early warning of high pathogenicity avian influenza

- 1) An ongoing *surveillance* programme for avian influenza should be in place and be designed to detect the presence of *infection* with high pathogenicity avian influenza viruses in the country or *zone* in a timely manner.

- 2) The high pathogenicity avian influenza *surveillance* programme should include the following.
- a) An *early warning system* for reporting suspected cases, in accordance with Article 1.4.5. throughout the production, marketing and processing chain. Farmers and workers who have day-to-day contact with *poultry*, as well as diagnosticians, should report promptly any suspicion of avian influenza to the *Veterinary Authority*. All suspected cases of high pathogenicity avian influenza should be investigated immediately. Given that suspicion cannot always be resolved by epidemiological and clinical investigation, samples should be taken and submitted to a *laboratory* for appropriate tests.
 - b) Implementation, as relevant, of regular and frequent clinical inspection, or serological and virological testing, of high-risk groups of *animals*, such as those adjacent to a country or *zone* infected with high pathogenicity avian influenza, places where birds and *poultry* of different origins are mixed, such as live bird markets, and *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) Immediate investigation of the presence of antibodies against influenza A viruses that have been detected in *poultry* and are not a consequence of *vaccination*. In the case of single or 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*.

Article 10.4.22.

Surveillance for demonstrating freedom from high pathogenicity avian influenza

1. A Member Country declaring freedom of the entire country, a *zone* or a *compartment* from high pathogenicity avian influenza in *poultry* should provide evidence of an effective *surveillance* programme.

Transparency in the application of different methodologies is essential to ensure consistency in decision-making, ease of understanding, fairness and rationality. The assumptions made, the uncertainties, and the effect of these on the interpretation of the results, should be documented.

The design of the *surveillance* programme will depend on the epidemiological circumstances and it should be planned and implemented in accordance with this chapter and Article 1.4.6. 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.

The *surveillance* programme should demonstrate absence of *infection* with high pathogenicity avian influenza viruses during the preceding 12 months in susceptible *poultry* populations (vaccinated and non-vaccinated).

The design of the sampling strategy should include an epidemiologically appropriate design prevalence. The design prevalence and desired level of confidence in the results will determine the sample size. The Member Country should justify the choice of design prevalence and confidence level used on the basis of the stated objectives of the *surveillance* and the epidemiological situation.

The sampling strategy may be risk-based if scientific evidence is available, and provided, for the quantification of risk factors. Specific risks could include those 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, the presence of more than one species at the *establishment* and poor *biosecurity* in place.

Data from different *surveillance* activities can be included to increase the sensitivity of the *surveillance* estimates and hence the confidence in freedom from disease. If this is to be done, a probabilistic approach is required to combine data from structured (e.g. surveys and active *surveillance*) and non-structured (e.g. passive *surveillance*) sources. It is necessary to quantify the sensitivity of each activity, in order to be able to quantify the sensitivity of the overall *surveillance* system and estimate the probability of disease freedom.

Annex 13 (contd)

The *surveillance* programme should include *surveillance* for high pathogenicity avian influenza viruses in *wild birds* and *monitoring* of low pathogenicity avian influenza viruses in *poultry*, in order to ensure that *biosecurity* and control measures are fit for purpose.

Documentation of 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 practise 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. Based on the epidemiology of avian influenza in the country, *zone* or *compartment*, a decision may be reached to vaccinate only certain species or other *poultry subpopulations*.

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

Member Countries seeking the demonstration of freedom from high pathogenicity avian influenza in vaccinated population should refer to Chapter on Avian Influenza (*infection* with avian influenza viruses) of the *Terrestrial Manual*, including virus or serological DIVA approaches.

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

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:

- a) *establishments* in the proximity of the *outbreaks*;
- b) *establishments* epidemiologically linked to the *outbreaks*;
- c) *poultry* used to re-populate affected *establishments*;
- d) any *establishments* where preventive depopulation has been carried out.

Article 10.4.22bis.

Surveillance of wild bird populations

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

Active *surveillance* in *wild birds* may be necessary for detection of some strains of high pathogenicity avian influenza viruses that produce *infection* without mortality in *wild birds*. Furthermore, it increases knowledge of the ecology and evolution of avian influenza viruses.

Annex 13 (contd)

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

Surveillance in *wild* birds should be enhanced by raising awareness, and by 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 10.4.22ter.

Monitoring of low pathogenicity avian influenza in poultry populations

Outbreaks of low pathogenicity avian influenza viruses can be managed at the *establishment* level; however, spread to other *poultry establishments* increases the risk of virus mutation, particularly if it is not detected and managed. Therefore, a *monitoring* system that includes awareness and reporting should be in place.

Monitoring the presence of low pathogenicity avian influenza viruses can be achieved through a combination of clinical investigation when *infection* is suspected because of changes in production parameters, such as reductions in egg production or *feed* and water intake, and active serological and virological *surveillance*.

Serological and virological *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 whether there is clustering of infected *flocks* regardless of whether the seropositive birds are still present at the *establishment* or whether active virus *infection* has been detected.

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.

This chapter deals with the listed disease, infection with high pathogenicity avian influenza viruses.

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 that has been determined as high pathogenicity index (IVPI); in accordance with the *Terrestrial Manual*.
 - 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 An occurrence of infection with a high pathogenicity avian influenza virus; is defined by the isolation and identification of the virus as such or the detection of specific viral ribonucleic acid has been detected, in one or more samples from poultry or a product derived from poultry.

Annex 14 (contd)

- 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'.

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 to be *poultry*.

- c) *Poultry* means all domesticated birds used for the production of *meat* or eggs for human consumption, for the production of other commercial products, or for breeding of 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*.
- d) 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 racing, exhibitions, zoological collections, competitions or for breeding or selling these categories of birds, as well as pet birds, are not considered *poultry*.
- e) ~~the~~ 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.

Although the objective of this chapter is to mitigate animal and public health risks posed by infection with high pathogenicity avian influenza viruses, other influenza A viruses of avian host origin (i.e. low pathogenicity avian influenza viruses) may have the potential to exert a negative impact on animal and public health. A sudden and unexpected increase in virulence of low pathogenicity avian influenza viruses in *poultry* is notifiable as an emerging disease in accordance with Article 1.1.4. Infection of domestic and captive wild birds with low pathogenicity avian influenza viruses having proven natural transmission to humans associated with severe consequences is also notifiable as an emerging disease with public health impact in accordance with Article 1.1.4. Occurrences of infection with avian influenza viruses of high pathogenicity in birds other than *poultry*, including wild birds, are notifiable in accordance with Article 1.3.6.

- 4) A notification of infection with avian influenza A viruses of high pathogenicity in birds other than *poultry*, including wild birds, or of low pathogenicity avian influenza viruses in *poultry* (as described in point 2) c)) does not affect the high pathogenicity avian influenza status of the country or zone. A Member Country should not impose bans on the trade in *poultry* and of *poultry* commodities in response to such notifications, 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.
- 5) This chapter includes monitoring considerations for low pathogenicity avian influenza viruses because some, especially H5 and H7 subtypes, have the potential to mutate into high pathogenicity avian influenza viruses.

Annex 14 (contd)

- 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.
- 46) The use of vaccination against high pathogenicity avian influenza in *poultry* may be recommended under specified specific conditions, while not affecting the status of a free country or zone. If the Any vaccine complies used should comply with the standards described in the Terrestrial Manual. Vaccination will not affect the high pathogenicity avian influenza status of a free country or zone if surveillance supports the absence of *infection*, in accordance with Article 10.4.22., in particular point 2. Vaccination is an effective complementary control tool that can be used when a stamping-out policy alone is not sufficient. The decision whether Whether to vaccinate or not is to should be made decided by the Veterinary Authorities Authority based on on the basis of the avian influenza situation as well as the ability of the Veterinary Services to execute implement the proper vaccination strategy, as described in Chapter 4.1718. Any vaccine used should comply with the standards described in the Terrestrial Manual.
- 597) 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 importation or transit of the following commodities, Veterinary Authorities should not require any conditions related to high pathogenicity avian influenza-related conditions, regardless of the high pathogenicity avian influenza status of the exporting country or zone:

- 1) heat-treated poultry meat products in a hermetically sealed container with a an Fo-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) washed and steam-dried 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;~~

Annex 14 (contd)

- 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.

Article 10.4.234.

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;
- absence of *infection* with high pathogenicity avian influenza viruses, based on *surveillance*, in accordance with Chapter 1.4. and Articles 10.4.20. to 10.4.22ter., has been demonstrated in the country or *zone* for the past 12 months;
- ≡ 1) 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
- an awareness programme is in place related to biosecurity and management of avian influenza viruses;
- ≡ bird commodities are imported in accordance with Articles 10.4.53. to 10.4.2317bis.

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 *and* 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 10.4.32bis.

Compartment free from high pathogenicity avian influenza

The establishment of a *compartment* free from high pathogenicity avian influenza should follow be in accordance with the relevant requirements of this chapter and the principles described in Chapters 4.34. and 4.45.

Article 10.4.32ter.

Establishment of a containment zone within a country or zone free from high pathogenicity avian influenza

In the event of an 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 4.34.7., the *surveillance* programme should take into account the density of *poultry* production, types of *poultry*, local management practices (including inter-premises movement patterns of *poultry*, people and equipment), relevant *biosecurity*, and the presence and potential role of birds other than *poultry*, including *wild birds*, and the proximity of *poultry establishments* to perennial permanent 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 10.4.32quater., once the *containment zone* is clearly established. It should be demonstrated that *commodities for international trade* either have originated from outside the *containment zone* or comply with the relevant articles of this chapter.

Article 10.4.32quater.

Recovery of free status

If infection with high pathogenicity avian influenza virus has occurred in *poultry* in a previously free country or zone, the free status can may be regained after a minimum period of 28 days (i.e. two flock-level incubation periods) after a *stamping-out policy* has been completed, provided that *surveillance* in accordance with Articles 10.4.2720. to 10.4.3322ter., in particular point 3 of Article 10.4.3022., has been carried out during that period and has demonstrated the absence of *infection*.

If a *stamping-out policy* is not implemented, Article 10.4.32. applies.

Article 10.4.53.

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;
- ~~b3) the poultry originated from a flock free from infection with any H5 or H7 that was monitored for avian influenza A viruses and was found to be negative;~~

Annex 14 (contd)

34) the *poultry* are transported in new or appropriately ~~sanitized~~ ~~sanitised~~ *containers*.

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

Article 10.4.64.

Recommendations for the importation of live birds other than poultry

Regardless of the ~~avian influenza~~ ~~high pathogenicity 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 had been~~ kept in isolation ~~facilities~~ approved by the *Veterinary Services* since they were hatched or for at least 24 ~~28~~ days (~~i.e. two flock-level incubation periods~~) 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 appropriate~~ sample of the birds, ~~selected in accordance with the provisions of Article 40.4.29.~~, was subjected, ~~with negative results~~, to a diagnostic test ~~for avian influenza A viruses~~ within 14 days prior to shipment ~~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~~ ~~sanitised~~ *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 stated~~ in the *international veterinary certificate*.

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 10.4.85.

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:

Annex 14 (contd)

- 1) the day-old live poultry ~~were had been~~ kept in a country, zone or compartment free from ~~infection with~~ high pathogenicity avian influenza since they were hatched;
- 2) and
 - a) the day-old live poultry were derived from parent flocks ~~free from infection with any H5 or H7 that were monitored for avian influenza A viruses and were found to be negative~~ 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~~ had their surfaces ~~sanitized~~ sanitised in accordance with point 4 d) of Article 6.5.5.:

AND

- 23) the day-old live poultry ~~are were~~ transported in new or appropriately ~~sanitized~~ sanitised containers.

If the day-old live 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 stated in the international veterinary certificate.

Article 10.4.96.

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

Regardless of the ~~avian influenza~~ high pathogenicity 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 facilities approved by the *Veterinary Services*;
- 3) a statistically appropriate sample of the parent flock birds were subjected, with negative results, to a diagnostic test for avian influenza A viruses at the time of ~~the~~ collection of the eggs for H5 and H7 to demonstrate freedom from ~~infection with a virus which would be considered~~ avian influenza ~~in poultry~~;
- 4) the birds ~~are were~~ transported in new or appropriately ~~sanitized~~ sanitised containers.

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 stated 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.

Annex 14 (contd)

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 the *certificate*.

Article 10.4.117.

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 hatching eggs came from a country, zone or compartment free from ~~infection with~~ high pathogenicity avian influenza ~~viruses in poultry~~;
- 2) a) the hatching eggs were derived from parent *flocks* ~~free from infection with any H5 or H7 that were monitored for avian influenza A viruses and were found to be negative~~ 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 hatching eggs; or
 - b3) the hatching eggs have had their surfaces sanitized sanitised (in accordance with Chapter 6.5. point 4 d) of Article 6.5.5.);
- 34) the hatching eggs are transported in new or appropriately sanitized sanitised packaging materials and containers.

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 stated in the *international veterinary certificate*.

Article 10.4.128.

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

Regardless of the avian influenza high pathogenicity 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 appropriate sample of the parent *flocks* ~~birds from the parent flock birds were~~ was subjected, ~~with negative results,~~ to a diagnostic test for avian influenza A viruses ~~seven 14~~ days prior to and at the time of ~~the~~ collection of the hatching eggs for H5 and H7 ~~to demonstrate freedom from infection with a virus which would be considered avian influenza in poultry~~;
- 2) the hatching eggs have had their surfaces sanitized sanitised (in accordance with point 4 d) of Article 6.5.5. ~~Chapter 6.5.~~;
- 3) the hatching eggs are transported in new or appropriately sanitized sanitised packaging materials and containers.

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 stated in the *international veterinary certificate*.

Article 10.4.9.**Recommendations for importation from a country, zone or compartment free from high pathogenicity avian influenza**For poultry semen

Annex 14 (contd)

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

- 1) showed no clinical signs of avian influenza on the day of semen collection;
- 2) were kept in a country, zone or compartment free from high pathogenicity avian influenza.

Article 10.4.10.

Recommendations for the importation of semen from birds other than poultry

Regardless of the high pathogenicity 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 facilities approved by the Veterinary Services for at least 28 days (i.e. two flock-level incubation periods) prior to semen collection;
- 2) showed no clinical signs of avian influenza during the isolation period;
- 3) were subjected, with negative results, to a diagnostic test for avian influenza within 14 days prior to semen collection.

Article 10.4.13.

Recommendations for importation from a country, zone or compartment free from avian influenzaFor 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 10.4.1411.

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 for human consumption 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.);
- 23) the eggs for human consumption ~~are~~ were transported in new or appropriately ~~sanitized~~ sanitised packaging materials and containers.

Article 10.4.1512.

Recommendations for the importation of egg products of from poultry

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

Annex 14 (contd)

- 1) the **commodity egg products** ~~is are~~ derived from eggs which meet the requirements of Articles ~~10.4.13. or 10.4.14.11.~~; or
- 2) the **commodity egg products** ~~has have~~ been processed to ensure the ~~destruction~~ inactivation of high pathogenicity avian influenza viruses, in accordance with Article 10.4.2518.;

AND

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

Article 10.4.16.

Recommendations for importation from a country, zone or compartment free from avian influenzaFor poultry semen

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

- 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 poultryFor 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 21 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 10.4.1913.

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~~ were slaughtered in an approved slaughterhouse/abattoir in a country, zone or compartment free from ~~infection with~~ high pathogenicity avian influenza viruses ~~in poultry~~ and ~~have been~~ were 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 favourable results.

Article 10.4.2014.

Recommendations for the importation of meat products of from poultry

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

- 1) the commodity meat products from poultry ~~is are~~ derived from *fresh meat* which meets the requirements of Article 10.4.1913.; or
- 2) the commodity meat products from poultry ~~has have~~ been processed to ensure the ~~destruction~~ inactivation of high pathogenicity avian influenza viruses in accordance with Article 10.4.2619.;

AND

- 3) the necessary precautions were taken to avoid contact of the commodity meat products from poultry with any source of high pathogenicity avian influenza viruses.

Article 10.4.2115.

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 high pathogenicity 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 a country, zone or compartment free from high pathogenicity avian influenza and were obtained 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 viruses using:
 - a) moist heat treatment for 30 minutes at 56°C; or
 - b) heat treatment where the internal temperature throughout the product reaches reached at least 74°C; or
 - c) any equivalent treatment that has been demonstrated to inactivate avian influenza viruses;

Annex 14 (contd)AND

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

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;~~~~

AND

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

Article 10.4.2216.

Recommendations for the importation of feathers and down of from 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 10.4.1913, 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 viruses 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) irradiation with a dose of 20 kGy;~~
 - ~~c) any equivalent treatment which has been demonstrated to inactivate avian influenza viruses;~~~~

AND

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

Article 10.4.23.17.

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

Regardless of the ~~avian influenza~~ high pathogenicity 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 viruses 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_e) any equivalent treatment which has been demonstrated to inactivate avian influenza viruses;
- 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 viruses in poultry.

Article 10.4.17bis.

Recommendations for the importation of scientific specimens, skins and trophies of birds other than poultry

Regardless of the high pathogenicity 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 inactivation of high pathogenicity avian influenza viruses in accordance with Article 10.4.19bis.;

AND

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

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:~~

- ~~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

Annex 14 (contd)

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

Article 10.4.2518.

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

The following times for industry standard temperatures time/temperature combinations 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 These time/temperature combinations are indicative of a range that achieves a 7-log₁₀ kill reduction of avian influenza virus infectivity. These are listed as examples in for a variety of egg products, but, when supported by scientifically documented scientific evidence, variances variations from of these times and temperatures time/temperature combinations may be used, and they may be used for additional other egg products, may also be suitable when if they achieve equivalent inactivation of the virus.

Article 10.4.2619.

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

The following times for industry standard temperatures time/temperature combinations are suitable for the inactivation of high pathogenicity avian influenza viruses in meat products.

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

The listed temperatures These time/temperature combinations are indicative of a range that achieves a 7-log₁₀ kill reduction of avian influenza virus infectivity. Where scientifically documented When supported by scientific evidence, variances from variations of these times and temperatures time/temperature combinations may also be suitable used when if they achieve the equivalent inactivation of the virus.

Article 10.4.2619bis.

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

For the inactivation of high pathogenicity avian influenza viruses in scientific specimens and in 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 material 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 treatment 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 10.4.2720.

Introduction to Principles of surveillance of high pathogenicity for 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., Article 10.4.20. defines the principles and Articles 10.4.21., 10.4.22., 10.4.22bis. and 10.4.22ter. provide guidance on avian influenza surveillance for the entire country, zone or compartment and are complementary to Chapter 1.4. applicable to These principles should be applied by Member Countries seeking to determine their high pathogenicity avian influenza status.; Surveillance is they are also necessary to support vaccination programmes, to monitor general situation of H5 and H7 low pathogenicity avian influenza viruses, especially H5 and H7, in poultry and for to monitoring monitor 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 among 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 between poultry with and wild birds, different biosecurity levels and production systems, and the commingling of different susceptible species including domestic waterfowl, may require specific different surveillance strategies to address each specific situation. Furthermore, domestic waterfowls typically do not show clinical signs and have longer infective periods than gallinaceous poultry. It is therefore incumbent upon the Member Country to provide scientific data that explains the epidemiology of avian influenza in the region concerned of concern and also demonstrates to demonstrate how all the risk factors are managed have been taken into account. 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. Member Countries have flexibility to provide a science-based approach to demonstrate absence of infection with avian influenza viruses at an appropriate level of confidence, as described in Chapter 1.4.

Annex 14 (contd)

There is an increased recognition of the value of the application of sequencing technologies and phylogenetic analyses to determine routes of introduction, transmission pathways and epidemiological patterns of *infection*. When avian influenza viruses are detected, Member Countries should apply these technologies, when possible, to enhance the evidence used to develop specific *surveillance* strategies and control activities.

A monitoring system for low pathogenicity avian influenza viruses in *poultry* should be in place for the following reasons:

- 1) *Surveillance* of Some H5 and H7 low pathogenicity avian influenza viruses in *poultry* is relevant as they might have the potential to mutate into high pathogenicity avian influenza viruses. There is and currently no scientific evidence it is not possible to predict if whether and when this mutation might will occur. Outbreaks of low pathogenicity viruses can be managed at establishment level however spread to other *poultry establishments* increases the risk of virus mutation, if it is not detected and managed. Therefore, a system should be in place to detect clusters of infected *poultry establishments* where H5 and H7 low pathogenicity viruses spread between *poultry establishments*.
- 2) The detection of sudden and unexpected increases in virulence of low pathogenicity avian influenza viruses in *poultry*, in order to fulfil notification obligations of an *emerging disease* in accordance with Article 1.1.4.
- 3) The detection, in domestic and *captive wild* birds, of low pathogenicity avian influenza viruses that have been proven to be transmitted naturally to humans with severe consequences, as in order to fulfil notification obligations of an *emerging disease*, in accordance with Article 1.1.4.

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 10.4.2821.

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

- 1) ~~An ongoing~~ *Surveillance* programme for avian influenza should be in the form of a continuing programme place and be 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;
 - c) a system for recording, managing and analysing diagnostic and *surveillance* data should be in place.
- 2) The *high pathogenicity* avian influenza *surveillance* programme should include the following:
 - a) ~~include an~~ An early warning system for reporting suspected cases, 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 Given that 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 implementation, when as relevant, of regular and frequent clinical inspection, and or serological and virological testing, of high-risk groups of animals, such as those adjacent to an country or zone infected with high pathogenicity avian influenza infected country or zone, places where birds and poultry of different origins are mixed, such as live bird markets, and 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 Immediate investigation of the presence of antibodies against influenza A viruses, which that have been detected in poultry and are not a consequence of vaccination, be immediately investigated. In the case of single or 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.~~

Annex 14 (contd)

~~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.~~

~~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;~~

Annex 14 (contd)

- e) 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 10.4.3022.

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 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.

Transparency in the application of different methodologies is essential to ensure consistency in decision-making, ease of understanding, fairness and rationality. The assumptions made, the uncertainties, and the effect of these on the interpretation of the results, should be documented.

The strategy and design of the *surveillance* programme will depend on the prevailing epidemiological circumstances and it should be planned and implemented according to general conditions and methods described in in accordance with 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.

The surveillance programme should demonstrate absence of infection with high pathogenicity avian influenza viruses during the preceding 12 months in susceptible poultry populations (vaccinated and non-vaccinated).

Annex 14 (contd)

The design of the sampling strategy should include an epidemiologically appropriate design prevalence. The design prevalence and desired level of confidence in the results will determine the sample size. The Member Country should justify the choice of design prevalence and confidence level used on the basis of the stated objectives of the surveillance and the epidemiological situation.

This surveillance may be targeted to poultry population at The sampling strategy may be risk-based if scientific evidence is available, and provided, for the quantification of risk factors. Specific risks could include those 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 at 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.

Data from different surveillance activities can be included to increase the sensitivity of the surveillance estimates and hence the confidence in freedom from disease. If this is to be done, a probabilistic approach is required to combine data from structured (e.g. surveys and active surveillance) and non-structured (e.g. passive surveillance) sources. It is necessary to quantify the sensitivity of each activity, in order to be able to quantify the sensitivity of the overall surveillance system and estimate the probability of disease freedom.

The surveillance programme should include surveillance for high pathogenicity avian influenza viruses in wild birds and monitoring of low pathogenicity avian influenza viruses in poultry, in order to ensure that biosecurity and control measures are fit for purpose.

Documentation for of 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 practise 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 may be reached to vaccinate only certain species or other poultry subpopulations.

In all vaccinated flocks there is a need to perform virological and serological tests to ensure the absence of virus circulation. The use of sentinel poultry may provide further confidence of in the absence of virus circulation. The tests have to should be repeated at least every six months or at shorter intervals at a frequency, 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 on Avian Influenza (infection with avian influenza viruses) of the Terrestrial Manual, including virus or serological DIVA approaches.

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

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:

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

Article 10.4.3022bis.

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 because infection with high pathogenicity avian influenza is usually can be associated with mortality in some species. 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 viruses that produce infection without mortality in wild birds. Furthermore, it increases knowledge of the ecology and evolution of avian influenza viruses.

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

Surveillance in wild birds should be enhanced by raising awareness, raising and by 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 10.4.3022ter.

Monitoring of H5 and H7 low pathogenicity avian influenza in poultry populations

Outbreaks of low pathogenicity avian influenza viruses can be managed at the establishment level; however, spread to other poultry establishments increases the risk of virus mutation, particularly if it is not detected and managed. Therefore, a monitoring system that includes awareness and reporting should be in place.

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

Serological and virological 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 whether there is clustering of infected flocks regardless of whether the seropositive birds are still present on at the establishment or whether active virus infection has been detected.

Annex 14 (contd)

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 21-28 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.

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.~~

1. 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.~~

Annex 14 (contd)

~~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:~~

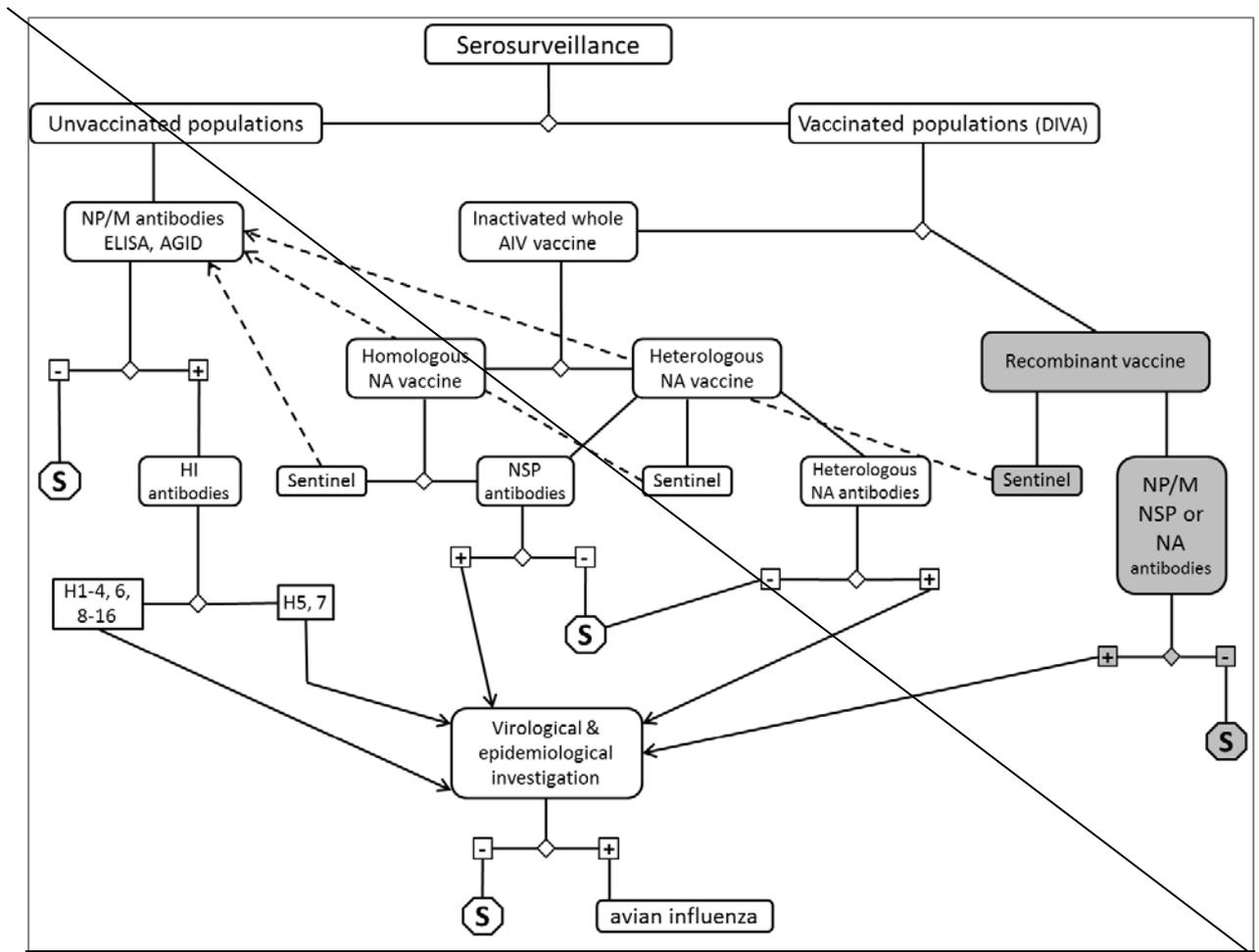
- ~~a) characterisation of the existing production systems;~~
- ~~b) results of clinical *surveillance* of the suspects and their cohorts;~~
- ~~c) quantification of *vaccinations* performed on the affected sites;~~
- ~~d) sanitary protocol and history of the affected *establishments*;~~
- ~~e) control 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*.

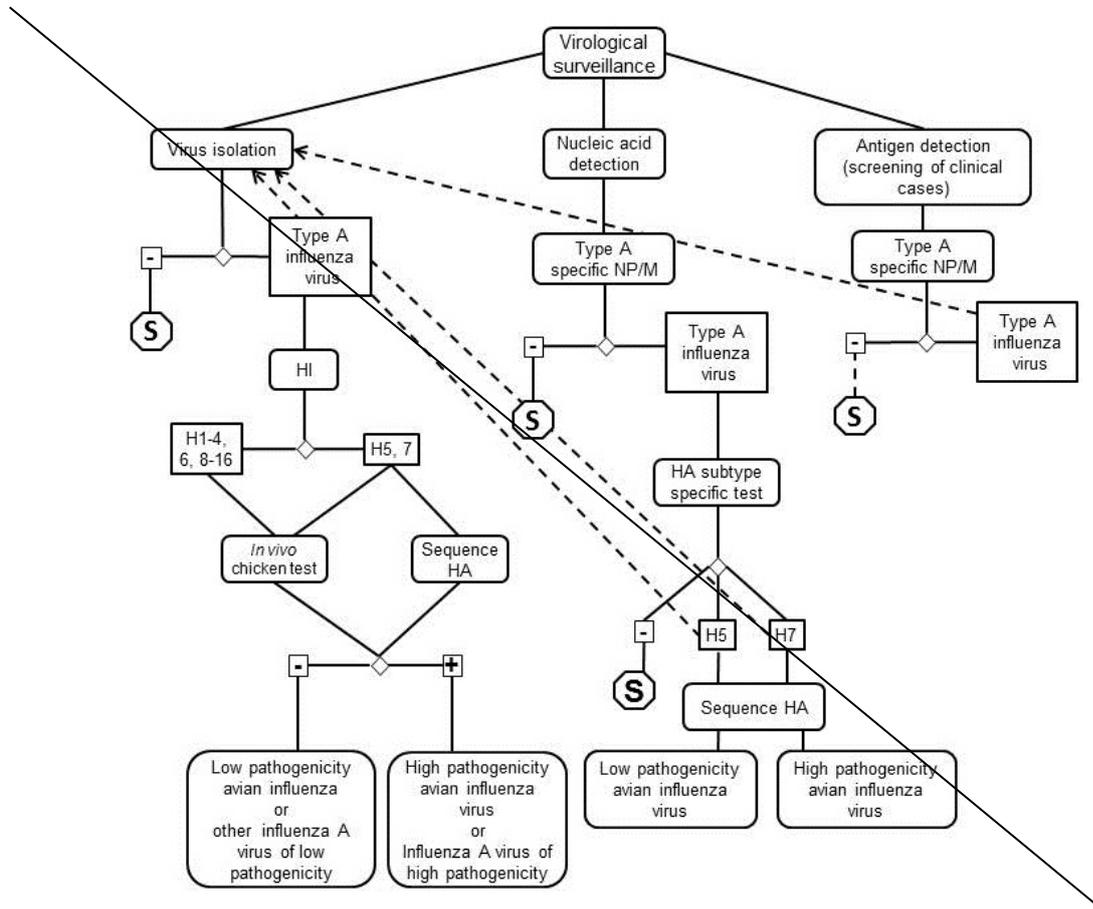
Key abbreviations and acronyms:	
AGID	Agar gel immunodiffusion
DIVA	Differentiating infected from vaccinated animals
ELISA	Enzyme-linked immunosorbent assay
HA	Haemagglutinin
HI	Haemagglutination inhibition
NA	Neuraminidase
NP/M	Nucleoprotein and matrix protein
NSP	Nonstructural protein
S	No evidence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

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



Annex 14 (contd)

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



CHAPTER 1.3.

**DISEASES, INFECTIONS AND INFESTATIONS
LISTED BY THE OIE**

[...]

Article 1.3.6.

The following are included within the category of avian diseases and *infections*:

- Avian chlamydiosis
- Avian infectious bronchitis
- Avian infectious laryngotracheitis
- Avian mycoplasmosis (*Mycoplasma gallisepticum*)
- Avian mycoplasmosis (*Mycoplasma synoviae*)
- Duck virus hepatitis
- Fowl typhoid
- Infection with high pathogenicity avian influenza viruses
- Infection with influenza A viruses of high pathogenicity in birds other than *poultry* including wild birds
- Infection with Newcastle disease virus
- Infectious bursal disease (Gumboro disease)
- Pullorum disease
- Turkey rhinotracheitis.

[...]

CHAPTER 14.7.

**INFECTION WITH
PESTE DES PETITS RUMINANTS VIRUS**

[...]

Article 14.7.3.

PPR-free country or zone free from PPR

A country or zone may be considered free from PPR when the relevant provisions of in point 2 of Article 1.4.6. and Chapter 1.6. have been complied with, and when within the proposed free country or zone for at least the past 24 months:

- 1) there has been no case of infection with PPRV;
 - 2) the Veterinary Authority has current knowledge of, and authority over, all domestic sheep and goats in the country or zone;
 - 3) appropriate surveillance has been implemented in accordance with:
 - a) Chapter Article 1.4.6. where historical freedom can be demonstrated; or
 - b) Articles 14.7.27. to 14.7.33. where historical freedom cannot be demonstrated;
 - 4) measures to prevent the introduction of the infection have been in place: in particular, the importations or movements of commodities into the country or zone have been carried out in accordance with this chapter and other relevant chapters of the Terrestrial Code;
 - 5) no vaccination against PPR has been carried out;
 - 56) no animals vaccinated against PPR have been introduced since the cessation of vaccination. [under study]
- ~~1) The PPR status of a country or zone should be determined on the basis of the following criteria, as applicable:~~
- ~~a) PPR is notifiable in the whole territory, and all clinical signs suggestive of PPR should be subjected to appropriate field or laboratory investigations;~~
 - ~~b) an ongoing awareness programme is in place to encourage reporting of all cases suggestive of PPR;~~
 - ~~c) systematic vaccination against PPR is prohibited;~~
 - ~~d) importation of domestic ruminants and their semen, oocytes or embryos is carried out in accordance with this chapter;~~
 - ~~e) the Veterinary Authority has current knowledge of, and authority over, all domestic sheep and goats in the country or zone;~~
 - ~~f) appropriate surveillance, capable of detecting the presence of infection even in the absence of clinical signs, is in place; this may be achieved through a surveillance programme in accordance with Articles 14.7.27. to 14.7.33.~~

Annex 16 (contd)

- 2) To qualify for inclusion in the list of PPR free countries or zones, a Member Country should either:
- a) apply for recognition of historical freedom as described in point 1) of Article 1.4.6.; or
 - b) apply for recognition of freedom and submit to the OIE:
 - i) a record of regular and prompt animal disease reporting;
 - ii) a declaration stating that:
 - there has been no *outbreak* of PPR during the past 24 months;
 - no evidence of PPRV *infection* has been found during the past 24 months;
 - no *vaccination* against PPR has been carried out during the past 24 months;
 - importation of domestic ruminants and their semen, oocytes or embryos is carried out in accordance with this chapter;
 - iii) supply documented evidence that *surveillance* in accordance with Chapter 1.4. is in operation and that regulatory measures for the prevention and control of PPR have been implemented;
 - iv) evidence that no animals vaccinated against PPR have been imported since the cessation of *vaccination*.

The Member Country will be included in the list only after the application and submitted evidence has been accepted by the OIE. Changes in the epidemiological situation or other significant events should be reported to the OIE in accordance with the requirements in Chapter 1.1.

The country or the zone will be included in the list of countries or zones free from PPR in accordance with Chapter 1.6.

Retention on the list requires annual reconfirmation of point 2) above annual reconfirmation of all points above and relevant points under point 4 of Article 1.4.6. Documented evidence should be resubmitted annually for that information in point 4 d) of Article 1.4.6. and points 1) to 3) above. Above be re-submitted annually and Any changes in the epidemiological situation or other significant events including those relevant to points 4 a) to 4 c) of Article 1.4.6. and points 4) and 5) above should be reported notified to the OIE in accordance with Chapter 1.1.

[...]

Article 14.7.7.

Recovery of free status

When ~~Should an~~ a PPR outbreak of PPR or PPRV infection occurs in a previously PPR free country or zone, its status may be restored and when a stamping-out policy is practised, the recovery period shall be six months after the slaughter of the last case disinfection of the last affected establishment, provided that: Article 14.7.32. has been complied with

- 1) a stamping-out policy has been implemented;
- 2) surveillance in accordance with Article 14.7.32. has been carried out with negative results.

If a stamping-out policy is not applied Otherwise, Article 14.7.3. applies.

The country or zone will regain PPR free status only after the submitted evidence has been accepted by the OIE.

[...]

Article 14.7.24.

Recommendations for importation from countries or zones considered infected with PPRVFor wool, hair, raw hides and skins from sheep and goats

Veterinary Authorities should require the presentation of an *international veterinary certificate* attesting that the products were adequately processed in accordance with one of the following procedures referred to in Article 8.8.34. in premises controlled and approved by the *Veterinary Authority* of the *exporting country*.

1. For wool and hair:

- a) industrial washing, which consists of the immersion of the wool in a series of baths of water, soap and sodium hydroxide (soda) or potassium hydroxide (potash);
- b) chemical depilation by means of slaked lime or sodium sulphide;
- c) fumigation with formaldehyde in a hermetically sealed chamber for at least 24 hours;
- d) industrial scouring which consists of the immersion of wool in a water-soluble detergent held at 60-70°C;
- e) storage of wool at 4°C for four months, 18°C for four weeks or 37°C for eight days;
- f) the necessary precautions were taken after processing to avoid contact of the *commodities* with any potential source of PPRV.

2. For raw hides and skins:

- a) treatment for at least 28 days with salt (NaCl) containing 2% sodium carbonate (Na₂CO₃);
- b) the necessary precautions were taken after processing to avoid contact of the *commodities* with any potential source of PPRV.

[...]

Article 14.7.34.

OIE endorsed official control programme for PPR

~~The objective of an OIE endorsed official control programme for PPR is for Member Countries to progressively improve the situation in their territories and eventually attain free status for PPR.~~

Member Countries may, on a voluntary basis, apply for endorsement of their *official control programme* for PPR in accordance with Chapter 1.6., when they have implemented measures in accordance with this article.

For a Member Country's *official control programme* for PPR to be endorsed by the OIE, the Member Country should provide a detailed official control programme for the control and eventual eradication of PPR in the country or zone. This document should address and provide documented evidence on the following:

1) epidemiology:

- a) the detailed epidemiological situation of PPR in the country, highlighting the current knowledge and gaps;
- b) the main livestock production systems and movement patterns of sheep and goats and their products within and into the country and, where applicable, the specific zone;

Annex 16 (contd)

- 2) surveillance and diagnostic capabilities:
- a) PPR surveillance in place, in accordance with Chapter 1.4. and Articles 14.7.27. to 14.7.33.;
 - b) diagnostic capability and procedures, including regular submission of samples to a laboratory that carries out diagnosis diagnostic testing and further characterisation of strains;
 - c) serosurveillance conducted in susceptible species, including wildlife, to serve as sentinels for PPRV circulation in the country;
- 3) vaccination strategies to reach the objectives:
- a) where vaccination is practised as a part of the official control programme for PPR, documented evidence (such as copies of national legislation, regulations and Veterinary Authority directives) that vaccination of selected populations is compulsory.;
 - b) and detailed information on vaccination campaigns, in particular on:
 - i) the strategy that is adopted for the vaccination campaign;
 - ii) target populations for vaccination;
 - iii) target geographical area for vaccination;
 - iv) monitoring of vaccination coverage, including serological monitoring of population immunity;
 - v) technical specification of the vaccines used and description of the vaccine licensing procedures in place;
 - vi) if relevant, proposed timeline for the transition to the use of vaccines fully compliant with the standards and methods described in the Terrestrial Manual;
 - vii) the proposed strategy and work plan including the timeline for the transition to the cessation of the use of vaccination;
- 4) the measures implemented to prevent the introduction of the pathogenic agent, and to ensure the rapid detection of, and response to, all PPR outbreaks in order to reduce outbreaks and to eliminate PPRV circulation in domestic sheep and goats in at least one zone in the country;
- 5) existence of an emergency preparedness plan and an emergency response plan to be implemented in case of PPR outbreaks;
- 46) the defined work plan and timelines of the official control programme;
- 57) performance indicators for assessing the effectiveness of the control measures to be implemented;
- 68) monitoring, evaluation and review assessment of the evolution and implementation of the official control programme to demonstrate the effectiveness of the strategies.;
- 7) existence of an emergency preparedness plan and of an emergency response plan to be implemented in case of PPR outbreaks.
- 1) submit documented evidence on the capacity of its Veterinary Services to control PPR; this evidence can be provided by countries following the OIE PVS Pathway;
 - 2) submit documentation indicating that the official control programme for PPR is applicable to the entire territory (even if it is on a zonal basis);
 - 3) have a record of regular and prompt animal disease reporting in accordance with the requirements in Chapter 1.1.;

Annex 16 (contd)

- 4) submit a dossier on the status of PPR in the country describing the following:
 - a) the general epidemiology of PPR in the country highlighting the current knowledge and gaps;
 - b) the measures implemented to prevent introduction of *infection*, the rapid detection of, and response to, all PPR *outbreaks* in order to reduce the incidence of *outbreaks* and to eliminate virus circulation in domestic sheep and goats in at least one *zone* in the country;
 - c) the main livestock production systems and movement patterns of sheep and goats and their products within and into the country and, where applicable, the specific *zone(s)*;
- 5) submit a detailed plan of the programme to control and eventually eradicate PPR in the country or *zone* including:
 - a) the timeline for the programme;
 - b) the performance indicators that will be used to assess the efficacy of the control measures;
- 6) submit evidence that PPR *surveillance* is in place, taking into account the provisions in Chapter 1.4. and the provisions on *surveillance* in this chapter;
- 7) have diagnostic capability and procedures in place, including regular submission of samples to a *laboratory*;
- 8) where *vaccination* is practised as a part of the *official control programme* for PPR, provide evidence (such as copies of legislation) that *vaccination* of sheep and goats in the country or *zone* is compulsory;
- 9) if applicable, provide detailed information on *vaccination* campaigns, in particular on:
 - a) the strategy that is adopted for the *vaccination* campaign;
 - b) monitoring of *vaccination* coverage, including serological monitoring of population immunity;
 - c) serosurveillance in other susceptible species, including *wildlife* to serve as sentinels for PPRV circulation in the country;
 - d) disease *surveillance* in sheep and goat populations;
 - e) the proposed timeline for the transition to the cessation of the use of *vaccination* in order to enable demonstration of absence of virus circulation;
- 10) provide an emergency preparedness and contingency response plan to be implemented in case of PPR *outbreak(s)*.

The Member Country's *official control programme* for PPR will be included in the list of programmes endorsed by the OIE only after the submitted evidence has been accepted by the OIE.

The country will be included in the list of countries having an OIE endorsed *official control programme* for PPR in accordance with Chapter 1.6.

Retention on the list of endorsed *official control programmes* for PPR requires an annual update on the progress of the *official control programme* and information on significant changes concerning the points above.

Changes in the epidemiological situation and other significant events should be reported to the OIE in accordance with the requirements in Chapter 1.1.

Annex 16 (contd)

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

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

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 captive or farmed free ranging, used for the production of meat, or other commercial products or purposes use 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 postnatally have an infective period of up to three months. 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.~~

Annex 17 (contd)

~~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.~~

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 F₀ 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 15.2.32.**Country or zone free from CSF Classical swine fever free country or zone**

A country or zone may be considered free from CSF when the relevant provisions in point 2 of Article 1.4.6. have been Article 15.2.2. is complied with, and when within the proposed CSF free country or zone for at least the past 12 months:

- 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;

Annex 17 (contd)

- 13) there has been no evidence case of infection with CSFV has been found in domestic and captive wild pigs during the past 12 months;
- 2) the Veterinary Authority has current knowledge of, and authority over, all domestic and captive wild pig herds in the country or zone;
- 3) the Veterinary Authority has current knowledge of the distribution, habitat and indication of disease occurrence through passive surveillance of wild and feral pigs in the country or zone;
- 4) appropriate surveillance has been implemented in accordance with:
- a) Article 1.4.6. where historical freedom can be demonstrated; or
- b) Articles 15.2.21. to 15.2.26. where historical freedom cannot be demonstrated;
- 5) measures to prevent the introduction of the infection have been in place: in particular, the importations or movements of commodities into the country or zone have been carried out in accordance with this chapter and other relevant chapters of the Terrestrial Code;
- 6) 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 3.8.3. 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.
- 7) the domestic and captive wild pig populations are separated by appropriate biosecurity, effectively implemented and supervised, from the wild and feral pig populations, based on the assessed likelihood of spread within the wild and feral pig populations, and surveillance in accordance with Article 15.2.26.

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.

The country or the zone will be included in the list of countries or zones free from CSF in accordance with Chapter 1.6.

Retention on the list requires annual reconfirmation of all points above and relevant points under point 4 of Article 1.4.6. Documented evidence should be resubmitted annually for that the information in points 1) to 5)3), 2) to or 53) above be re-submitted annually and, Any changes in the epidemiological situation or other significant events above should be reported notified to the OIE according to the requirements in in accordance with Chapter 1.1.

Article 15.2.43.

Compartment free from CSF Classical swine fever free compartment

The establishment and 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 4.4. and 4.5. Pigs in a the compartment free from CSF should be separated from any other pigs by the application of effective biosecurity

Article 15.2.54.

Establishment of a containment zone within a classical swine fever free country or zone previously 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 epidemiologically linked outbreaks, can be established, in accordance with Article 4.4.7. for the purpose of to minimising the impact on the entire rest of the country or zone.

Annex 17 (contd)

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~~ 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 15.2.65., 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 15.2.365. have been fulfilled.

The recovery of the CSF free status of the *containment zone* should follow the provisions of Article 15.2.65. and be achieved within 12 months of its approval.

Article 15.2.65.

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 recovered when where surveillance in accordance with Articles 15.2.263025. to 15.2.32. has been carried out with negative results either, and three months after:

- 1) three months after the disinfection of the last affected establishment, provided that a *stamping-out policy* without *vaccination* ~~is practised~~ has been implemented; or
- 2) when where a *stamping-out policy* with emergency *vaccination* is practised:
 - 2) a) three months after and the disinfection of the last affected establishment or and the slaughter of all vaccinated animals, whichever occurred last, provided that a *stamping-out policy* with emergency *vaccination* and *slaughter* of vaccinated animals has been implemented; or
 - 3) b) three months after the disinfection of the last affected establishment provided that a *stamping-out policy* with emergency *vaccination* without the *slaughter* of vaccinated animals when where there are means, validated according to Chapter 3.8.3. 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 15.2.65bis.

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.

Annex 17 (contd)

- 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 biosecure conditions** under the supervision of the **Veterinary Services Authority** 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 15.2.2318. 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 15.2.2217, or Articles 15.2.2419, to 15.2.2419ter, to destroy any residual virus CSFV potentially present.

Article 15.2.65ter.

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 15.2.54.;
- 2) the pigs should be transported under the supervision of the **Veterinary Services Authority** 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 15.2.2318. 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 15.2.2217, or Articles 15.2.2419, to 15.2.2419ter, to destroy any residual virus CSFV potentially present.

Article 15.2.76.

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:

Annex 17 (contd)

- 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 3.8.3. of the *Terrestrial Manual*, of distinguishing between vaccinated and infected pigs.

Article 15.2. ~~87~~.

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;
- 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 3.8.3. 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 3.8.3. of the *Terrestrial Manual*, of distinguishing between vaccinated and infected pigs.

Article 15.2. ~~108~~.

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:

Annex 17 (contd)

- 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 4.6. and 4.7.

Article 15.2. ~~119~~.

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 15.2.2621, to 15.2.3226., demonstrated that no case of CSF occurred in the past 12 months;
 - 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 elicited 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 4.6. and 4.7.

Article 15.2. ~~1210~~.

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

For in vivo derived embryos of domestic pigs

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

- 1) the donor females: ~~showed no clinical sign of CSF on the day of collection of the embryos~~;
 - 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;

Annex 17 (contd)

- 2) the semen used to fertilise the oocytes complied with the conditions in Articles 15.2.408. or Article 15.2.449., as relevant;
- 3) the embryos were collected, processed and stored in accordance with Chapters 4.8. and 4.10., as relevant.

Article 15.2.431.

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

For *in vivo* derived embryos of domestic pigs

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

- 1) the donor females:
 - 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 15.2.2621. to 15.2.3226., 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;~~
 - 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 3.8.3. of the Terrestrial Manual,~~ that any antibody is due to ~~was caused elicited by~~ the vaccine;
- 2) the semen used to fertilise the oocytes complied with the conditions in Article 15.2.8. or Article 15.2.9., as relevant;
- 3) the embryos were collected, processed and stored in accordance with Chapters 4.8. and 4.10., as relevant.

Article 15.2.442.

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 15.2.76. or Article 15.2.87.;
- 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 15.2.14.12bis.

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 derives complying complied complying with Article 15.2.87.;
- 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 15.2.87. 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;
- 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.;
- 2) 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 15.2.16.13.

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 15.2.14.12, or 15.2.14.12bis, or 15.2.15.;

Annex 17 (contd)

- 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. ~~1412, or 15.2. 1412bis, or 15.2.15;~~

OR

- 2) ~~have been were~~ processed in accordance with one of the processes in Article 15.2. ~~2318~~, 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:~~

- 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. ~~1914~~.**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. ~~2419bis~~, 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 15.2.2015.

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 15.2.2419ter. 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 15.2.2416.

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 15.2.2520. 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 15.2.2416bis.

Recommendations for the importation of other pig products commodities

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

- 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 that has been demonstrated inactivate 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 15.2.2217.

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.

Annex 17 (contd)Article 15.2. ~~2318~~.**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;~~
- ~~b) a 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:

- a) an *A_w* ~~a_w~~ value of not more than 0.93, or
- b) a pH value of not more than 6.0.

~~Hams should be subjected to a natural fermentation and maturation process for at least 190 days and loins for 140 days.~~

3. Dry cured ~~pork pig~~ meat

- ~~a) Italian style hams with bone in should be cured with salt and dried for a minimum of 313 days.~~
- ~~b) Spanish style *pork meat* with bone in should be cured with salt and dried for a minimum of 252 days for Iberian hams, 140 days for Iberian shoulders, 126 days for Iberian loin, and 140 days for Serrano hams.~~

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

Article 15.2. ~~2419~~.**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 ~~s~~ 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% Na₂HPO₄ and 2.8% Na₃PO₄ (weight/weight/weight), ~~and kept~~ either dry, or as or saturated brine (*a_w* < 0.80), and at a temperature of greater than 20°C or above ~~during this entire period.~~

Article 15.2. ~~2419~~bis.**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. ~~2419~~ter.**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;
- 3) any equivalent treatment that has been demonstrated to inactivate CSFV.

Article 15.2.2520.

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:

- 1) boiling in water for an appropriate time so as to ensure that any matter other than bone, tusks or teeth is removed;
- 2) gamma irradiation at a dose of at least 20 kiloGray at room temperature (20°C or higher);
- 3) soaking, with agitation, in a 4 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 15.2.2621.

Introduction to surveillance: introduction

Articles 15.2.2621. to 15.2.3226. 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.

Annex 17 (contd)

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

Article 15.2.2722.

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. Diagnosticicians 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. Chapter 1.9. 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 15.2.2823.

Surveillance strategies

1. Introduction

The population covered by *surveillance* aimed at detecting disease and *infection* should include domestic pig population and wild and feral 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 infection* 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.

Annex 17 (contd)

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*.

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.

Annex 17 (contd)

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.

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. 2924.

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. 3426.

Article 15.2. 3025.

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*.

Annex 17 (contd)

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. ~~3126~~.

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:
 - 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.

Article 15.2.32.

The use and interpretation of diagnostic tests in surveillance

