

MEETING OF THE OIE TERRESTRIAL ANIMAL HEALTH STANDARDS COMMISSION**Paris, 11–20 September 2018****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 Nations
 Viale delle Terme di Caracalla
 00153 Rome
 ITALY
 Tel: +39 06 570 52447
 Mail: etienne.bonbon@fao.org
 Mail : e.bonbon@oie.int

Dr Lucio Ignacio Carbajo Goñi
Attaché
 Ministry of Agriculture, Food and Environment
 Spanish Embassy in Brazil
 SPAIN
 Mail: lcarbajo@mapama.es
 Mail: lcg958@gmail.com

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
 Mail:
gmfunes@magyp.gob.ar

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
 Mail: hammami.salah@iresa.agrinet.tn
 Mail: saleehammami@yahoo.fr

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
 Mail: masatsuqu_okita130@maff.go.jp

Dr Bernardo Todeschini
 Federal Superintendent of Agri-
 for Rio Grande do Sul
 Ministry of Agriculture, Livestoc
 and Food Supply
 BRAZIL
 Mail: bernardo.todeschini@agri

OIE HEADQUARTERS

Dr Jae Myong Lee
 Chargé de mission
 Standards Department
 Mail: j.lee@oie.int

Dr Kiyokazu Murai
 Chargé de mission
 Standards Department
 Mail: k.murai@oie.int

Dr Patricia Pozzetti
 Chargée de mission
 Standards Department
 Mail: p.pozzetti@oie.int

Dr Leopoldo Stuardo
 Chargé de mission
 Standards Department
 Mail: l.stuardo@oie.int

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Adopted agenda

- 1. Welcome and orientation**
- 2. Adoption of the agenda**
- 3. Cooperation with other Specialist Commissions**
- 4. Examination of Member Countries' comments at the 86th General Session**
 - 4.1. Zoning and compartmentalisation (Chapter 4.3.)
 - 4.2. Vaccination (Chapter 4.17.)
 - 4.3. The role of Veterinary Services in food safety systems (Chapter 6.2.)
 - 4.4. Guiding principles for the use of measures to assess animal welfare (Article 7.1.4.)
 - 4.5. Animal welfare and pig production systems (Chapter 7.13.)
 - 4.6. Infection with *Burkholderia mallei* (Glanders) (Chapter 12.10.)
- 5. Texts circulated for Member Countries' comments at the September 2017 and February 2018 meetings**
 - 5.1. Glossary
 - 5.2. Animal health surveillance (Chapter 1.4.)
 - 5.3. Procedures for self-declaration and for official recognition by the OIE (Chapter 1.6.)
 - 5.4. Draft new chapter on official control of listed and emerging diseases (Chapter 4.Y.)
 - 5.5. Draft new chapter on introduction to recommendations for disease prevention and control (Chapter 4.Z.)
 - 5.6. Draft new chapter on animal welfare and laying hen production systems (Chapter 7.Z.)
 - 5.7. Draft new chapter on killing of reptiles for their skins, meat and other products (Chapter 7.Y.)
 - 5.8. Infection with rabies virus (Chapter 8.14.)
 - 5.9. Infection with lumpy skin disease virus (Chapter 11.9.)
 - 5.10. Infection with African swine fever virus (Articles 15.1.1bis., 15.1.2., 15.1.3., 15.1.22.)
 - 5.11. Infection with classical swine fever virus (Chapter 15.2.)

Annex 2 (contd)**6. New amendments or draft new chapters proposed for the *Terrestrial Code***

- 6.1. Harmonisation of the *Terrestrial Code* chapters on diseases with official status recognition by the OIE
- 6.2. Veterinary legislation (Chapter 3.4.)
- 6.3. Collection and processing of bovine, small ruminant and porcine semen (Chapter 4.6.)
- 6.4. Infection with avian influenza viruses (Chapter 10.4.) including review of the report of the *ad hoc* Group on Avian influenza (June 2018)

7. Other issues

- 7.1. Update of the Code Commission's work programme
 - a) Veterinary Services (Chapter 3.1.) and Evaluation of Veterinary Services (Chapter 3.2.)
 - b) Notification of diseases, infections and infestations, and provision of epidemiological information (Chapter 1.1.)
 - c) Infection with Rift Valley fever virus (Chapter 8.15.)
 - d) Stray dog population control (Chapter 7.7.)
 - e) Infection with rinderpest virus (Chapter 8.16.)
 - f) Request for international trade standards for animal serum products used in cell culture media
 - g) Action arising from February 2018 meeting (definition of "epidemiological unit")
 - h) Revision of Chapter 7.5. Slaughter of animals and Chapter 7.6. Killing for disease control purposes
 - i) Report of the meeting of the *ad hoc* Group on Animal African trypanosomoses (March 2018)
 - j) OIE list of notifiable diseases.
 - 7.2. Date of next meetings
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CHAPTER 14.4.

**INFECTION WITH ~~CHLAMYDOPHILA~~ CHLAMYDIA
ABORTUS
(ENZOOTIC ABORTION OF EWES,
OVINE CHLAMYDIOSIS)**

Article 14.4.1.

General provisions

For the purposes of the *Terrestrial Code*, enzootic abortion of ewes (EAE), also known as ovine chlamydiosis or ovine enzootic abortion, is an *infection* of domestic sheep and goats by the bacterium ~~*Chlamydo*~~ *Chlamydia* *abortus*.

Susceptible animals become infected through ingestion of infectious materials. In lambs and non-pregnant ewes, the *infection* remains latent until conception. Ewes exposed to *infection* late in pregnancy may not exhibit signs of *infection* until the subsequent pregnancy. Countries should take account of these risk factors.

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

[...]

CHAPTER 6.2.

THE ROLE OF THE VETERINARY SERVICES IN FOOD SAFETY SYSTEMS

[...]

Article 6.2.4.

Roles and responsibilities of Veterinary Services in a food safety system

1. Roles and responsibilities of Veterinary Services

Veterinary Authorities or other *Competent Authorities* should provide an appropriate institutional environment to allow *Veterinary Services* to implement the necessary policies and standards, and ensure adequate resources for them to carry out their tasks in a sustainable manner. *Veterinary Services* should have a clear chain of command and respective roles and responsibilities should be clearly defined and well documented.

Veterinary Services should be fully involved, in accordance with their mandate and organisational structure at the national level, in the design and implementation of a risk-based food safety system. In the implementation of food safety systems for food of animal origin, *Veterinary Services* should retain responsibility for verification and audit and facilitate a flexible approach to operational activities.

Veterinary Services Authorities or other Competent Authorities should retain overall responsibility for the delivery and performance of any activities delegated to third party providers.

Where relevant, *Veterinary Services* should have an active role in other food safety-related activities, such as investigations of foodborne disease *outbreaks*, food defense, disaster management, and identifying emerging *risks*. In addition, *Veterinary Services* should have an active role in the development and management of coordinated *surveillance* and control programmes for foodborne pathogens of animal origin important for public health importance.

In order for *Veterinary Services* to make the best possible contribution to ensuring food safety, the education and training of *veterinarians* and *veterinary paraprofessionals* should include appropriate training in food safety systems and ongoing professional development.

2. Activities of Veterinary Services throughout the food chain

Depending on the responsibilities of the *Competent Authority*, the responsibilities of the *Veterinary Services* may be limited to the first part of the food chain, while in other cases the *Veterinary Services* may be responsible for the whole food chain.

a) Primary production

Through their presence on farms and collaboration with farmers, *Veterinary Services* play a key role in ensuring that *animals* are healthy and kept under good sanitary and hygienic conditions, as well as in *biosecurity* and early detection, *surveillance* and treatment of animal diseases, including conditions of public health significance.

Veterinary Services provide direction to farmers on practices that prevent or minimise physical and chemical hazards (for example, mycotoxins, environmental contaminants and pesticide residues) in primary production, including *feed*.

Veterinary Services play a central role in ensuring the responsible and prudent use of *veterinary medicinal products*, including *antimicrobial agents* in accordance with Chapter 6.10. in animal husbandry. This helps to minimise the likelihood of noncompliant levels of veterinary drug residues in food of animal origin and the development of antimicrobial resistance.

Annex 4 (contd)

Veterinary Services also play an important role in ensuring traceability throughout the food chain by verifying *animal identification* in accordance with Chapters 4.1. and 4.2.

b) Slaughter, processing and distribution

Activities at the *slaughterhouse/abattoir* should be designed and implemented according to an integrated, risk-based approach in accordance with Chapter 6.3. *Veterinary Services* have an essential role in ensuring that these activities, including *meat* inspection, minimise foodborne *risks* to public health. This may be provided by supervision and verification of process control and direct involvement in operational activities such as ante- and post-mortem inspection. *Slaughterhouse/abattoir* inspection of live animals and their carcasses plays a key role both in the *surveillance* network for animal diseases and zoonoses, and in ensuring the safety and suitability of *meat* and by-products for their intended uses. Control or reduction of biological hazards of public health and animal health importance by ante- and post-mortem *meat* inspection is a core responsibility of *Veterinary Services*.

Veterinary Services may be responsible for overseeing the control measures during processing and distribution of food of animal origin. They also play an important role in raising the awareness of food producers, processors and distributors regarding measures required to assure food safety.

c) Assurance schemes and certification of food of animal origin for international trade

Veterinary Services have an important role in overseeing assurance schemes and an essential role in certifying that food of animal origin complies with animal health and food safety standards.

Other ~~Competent Authorities~~ responsible agencies may also be involved in providing assurances and certification of food of animal origin (for example, pasteurisation of *milk products*) for *international trade*.

3. Foodborne disease outbreaks

Veterinary Services play a key role in the investigation of, and response to, foodborne disease *outbreaks* which may be attributable to or involve animal products, including the implementation of control measures. This work should be carried out in close collaboration with public health professionals, analysts, epidemiologists, food producers, processors and traders and any others involved.

Because of the global nature of the food trade, *Veterinary Services* should work with other national agencies in reporting to international emergency foodborne disease networks, such as the International Network of Food Safety Authorities (INFOSAN), and in utilising such information for preparedness.

CHAPTER 7.1.

**INTRODUCTION TO THE
RECOMMENDATIONS FOR ANIMAL WELFARE**

[...]

Article 7.1.4

Guiding principles for the use of measures to assess animal welfare

[...]

- 5) Users of the standard should select the most appropriate animal-based measures for their farming system or environment, from among those listed in the standard. Outcomes can be measured by an assessment of individuals or animal groups, or a representative sample of those, using data from *establishments*, transport or *slaughterhouses/abattoirs*. To guide users, *Competent Authorities* should collect all relevant data that can be used to set target values.

[...]

CHAPTER 7.13.

ANIMAL WELFARE AND
PIG PRODUCTION SYSTEMS

[...]

Article 7.13.4.

Criteria (or measurables) for the welfare of pigs

The following outcome-based criteria (or measurables), specifically animal-based criteria, can be useful indicators of *animal welfare*. The use of these indicators and their appropriate thresholds should be adapted to the different situations in which pigs are managed such as regional differences, *herd* health, pig breed or crossbreed, and climate. Consideration should also be given to the resources provided and the design of the systems. These criteria can be considered as tools to monitor the efficiency of design and management, given that they can affect *animal welfare*.

1. Behaviour

Certain behaviours appear to be indicators of good animal welfare and health in pigs such as play and specific vocalisations.

Certain other behaviours could indicate an *animal welfare* and health problem. These include sudden immobility, escape attempts, changes in *feed* and water intake, altered locomotory behaviour or posture, altered lying time, postures and patterns, altered respiratory rate and panting, coughing, shivering and huddling, high-pitched vocalisations and increased call rate, increased agonistic (including aggression), stereotypic, apathetic or other abnormal behaviours.

Environments that induce stereotypies typically also reduce animal welfare. Although stereotypies are generally held to indicate poor welfare, there are some instances where there is a poor association between stereotypies and stress. For example, frustration-induced stress may be somewhat rectified if the behaviour itself reduces the underlying motivation. Within a group, individuals that perform stereotypies may thus be coping more successfully than those that do not. Nevertheless, stereotypies indicate either a present problem for the animal or a past problem that has resolved. As with other indicators, caution should be used when using stereotypies as a welfare measure in isolation from other indicators.

[...]

Article 7.13.15.

Air quality

Good air quality and ventilation are important for the welfare and health of pigs and reduce the risk of respiratory discomfort, diseases and abnormal behaviour. Dust, toxins, microorganisms and noxious gases, including ammonia, hydrogen sulphide, and methane caused by decomposing animal waste, can be problematic in indoor systems.

Air quality is influenced strongly by management and building design in housed systems. Air composition is influenced by stocking density, the size of the pigs, flooring, bedding, waste management, building design and ventilation system.

Proper ventilation, without draughts, particularly for young pigs, is important for effective heat dissipation in pigs and to prevent the build-up of effluent gases (e.g. ammonia and hydrogen sulphide), including those from manure and dust in the housing unit. The ammonia concentration in enclosed housing should not exceed 25 ppm. A useful indicator is that if air quality at the level of the pigs is unpleasant for humans it is most likely a problem for pigs.

Annex 6 (contd)

Animal-based criteria (or measurables): morbidity, mortality and culling rates, physical appearance (discharges from nose or eyes), behaviour (especially respiratory rate, coughing and tail biting), change in body weight and body condition.

[...]

GLOSSARY

EARLY DETECTION SYSTEM

~~means a system for the timely detection and identification of an incursion or emergence of diseases or infections in a country, zone or compartment. An early detection system should be under the control of the Veterinary Services and should include the following characteristics:~~

- ~~a) representative coverage of target animal populations by field services;~~
- ~~b) ability to undertake effective disease investigation and reporting;~~
- ~~c) access to laboratories capable of diagnosing and differentiating relevant diseases;~~
- ~~d) a training programme for veterinarians, veterinary paraprofessionals, livestock owners/keepers and others involved in handling animals for detecting and reporting unusual animal health incidents;~~
- ~~e) the legal obligation of private veterinarians to report to the Veterinary Authority;~~
- ~~f) a national chain command.~~

EARLY WARNING SYSTEM

means a system for the timely detection, identification and reporting and communication of an incursion or emergence of diseases, infections or infestations in a country, zone or compartment.

SANITARY MEASURE

means a measure, such as those described in various chapters of the *Terrestrial Code*, ~~destined~~ designed to protect animal or human health or life within the whole territory or a zone of ~~the~~ a Member Country from risks arising from the entry, establishment ~~and/or~~ spread of a hazard.

CHAPTER 1.4.

ANIMAL HEALTH SURVEILLANCE

Article 1.4.1.

Introduction and objectives

- 1) In general, *surveillance* is aimed at demonstrating the absence of *infection* or *infestation*, determining the presence or distribution of *infection* or *infestation* or detecting as early as possible exotic diseases or *emerging diseases*. Animal health *surveillance* is a tool to monitor disease trends, to facilitate the control of *infection or infestation disease* ~~*infection or infestation*~~, to provide data for use in *risk analysis*, for animal or public health purposes, to substantiate the rationale for *sanitary measures* and for providing assurances to trading partners. The type of *surveillance* applied depends on the objectives of the surveillance, the available data sources and the outputs needed to support decision-making. The general recommendations in this chapter may be applied to all *infections* or *infestations* and all susceptible species (including *wildlife*) and may be refined adapted to national or local settings. *Specific surveillance* is described in some *listed disease-specific* chapters.
- 2) *Wildlife* may be included in a *surveillance* system because they can serve as reservoirs of *infection* or *infestation* and as indicators of *risk* to humans and domestic *animals*. However, the presence of an *infection* or *infestation* in *wildlife* does not mean it is necessarily present in domestic *animals* in the same country or *zone*, or vice versa. *Surveillance* in *wildlife* presents challenges that may differ significantly from those in *surveillance* in domestic *animals*.
- 3) Prerequisites to enable a Member Country to provide information for the evaluation of its *animal health status* are:
 - a) that the Member Country complies with the provisions of Chapters 3.1. to 3.4. on *Veterinary Services*;
 - b) that, where possible, *surveillance* data be complemented by other sources of information, such as scientific publications, research data, population demographic data, animal production data, documented field observations and other data;
 - c) that transparency in the planning, execution and results of *surveillance* activities, is in accordance with Chapter 1.1.
- 4) The objectives of this chapter are to:
 - a) provide guidance on the design of a *surveillance* system and the type of output it should generate;
 - b) provide recommendations to assess the quality of *surveillance* systems.

Article 1.4.2.

Definitions

The following definitions apply for the purposes of this chapter:

Bias: means a tendency of an estimate to deviate in one direction from a true *population* parameter.

Confidence: means the probability that the type of *surveillance* applied would detect the presence of *infection* or *infestation* if the *population* were infected and is equivalent to the sensitivity of the *surveillance*. Confidence depends on, among other parameters, the assumed prevalence of *infection* or *infestation*.

Annex 8 (contd)

Probability sampling: means a sampling strategy in which every unit is chosen at random and has a known non-zero probability of inclusion in the sample.

Sample: means the group of elements (sampling units) drawn from a *population*, on which tests are performed or parameters measured to provide *surveillance* information.

Sampling unit: means the unit that is sampled, ~~either in a random survey or in non-random surveillance~~. This may be an individual *animal* or a group of *animals*, such as an *epidemiological unit*. **Together, they comprise the sampling frame.**

Sensitivity: means the proportion of infected sampling units that are correctly identified as positive.

Specificity: means the proportion of uninfected sampling units that are correctly identified as negative.

Study population: means the *population* from which *surveillance* data are derived. This may be the same as the target *population* or a subset of it.

Surveillance system: means the use of one or more *surveillance* components to generate information on the health status of animal *populations*.

Survey: means a component of a *surveillance* system to systematically collect information with a predefined goal on a sample of a defined *population* group, within a defined period.

Target population: means the *population* to which conclusions are to be inferred.

Test: means a procedure used to classify a unit as either positive, negative or suspect with respect to an *infection* or *infestation*.

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 *infection* or *infestation* 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, **and** 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;

Annex 8 (contd)

- husbandry practices and production systems;
- accessibility of target *population*;
- geographical factors;
- environmental factors, including climate conditions.

Surveillance should be carried out at a frequency that reflects the epidemiology of the infection or infestation and the risk of its introduction and spread.

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.

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*.

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, at least at what is judged to be the most significant level of clustering for the particular animal population and infection or infestation.

ebis) Diagnostic tests

Surveillance involves the detection of infection or infestation according to appropriate case definitions. Tests used in surveillance may range from detailed laboratory examinations to clinical observations and the analysis of production records.

The performance of a test at the population level (including field observations) may be described in terms of its sensitivity, specificity and predictive values. Imperfect sensitivity or specificity, as well as prevalence, will have an impact on the conclusions drawn from surveillance. Therefore, these parameters 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.

f) 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.

Annex 8 (contd)

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 ~~should only~~ 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.

g) 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.

h) 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.

2. Implementation of the surveillance system

a) Diagnostic tests

~~*Surveillance* involves the detection of *infection* or *infestation* according to appropriate case definitions. Tests used in *surveillance* may range from detailed laboratory examinations to clinical observations and the analysis of production records.~~

~~Tests should be chosen in accordance with the relevant chapters of the *Terrestrial Manual*.~~

- i) ~~Sensitivity and specificity: The performance of a test at the *population* level (including field observations) may be described in terms of its sensitivity, specificity and predictive values. Imperfect sensitivity or specificity, as well as prevalence, will have an impact on the conclusions from *surveillance*. Therefore, these parameters should be taken into account in the design of *surveillance* systems and analysis of *surveillance* data.~~

~~The sensitivity and specificity values of the tests used should be specified for each species in which they may be used and the method used to estimate these values should be documented in accordance with Chapter 1.1.6 of the *Terrestrial Manual*.~~

- ii) ~~Pooling: Samples from a number of *animals* or *units* may be pooled and subjected to a testing protocol. The results should be interpreted using sensitivity and specificity values that have been determined or estimated for that particular pool size and testing procedure.~~

b) Data collection and management

The success of a *surveillance* system is dependent on a reliable process for data collection and management. The process may be based on paper or electronic records. Even where data are collected for non-survey purposes (e.g. during disease control interventions, inspections for movement control or during disease eradication schemes), the consistency and quality of data collection and event reporting in a format that facilitates analysis is critical. Software may offer the possibility of extraction of multiple source data for aggregation and analysis. Factors influencing the quality of collected data include:

- the distribution of, and communication between, those involved in generating and transferring data from the field to a centralised location; this requires effective collaboration among all stakeholders, such as government or non-governmental organisations, and others, particularly for data involving *wildlife*;
 - the ability of the data processing system to detect missing, inconsistent or inaccurate data, and to address these problems;
 - maintenance of raw data rather than the compilation of summary data;
 - minimisation of transcription errors during data processing and communication.
3. Quality assurance
Surveillance systems should be subjected to periodic auditing to ensure that all components function and provide verifiable documentation of procedures and basic checks to detect significant deviations of procedures from those specified in the design, in order to implement appropriate corrective actions.

Article 1.4.4.

Surveillance methods

Surveillance systems routinely use ~~structured random and non-random~~ data collected by probability-based or non-probability-based methods, either alone or in combination. A wide variety of *surveillance* sources may be available. These vary in their primary purpose and the type of *surveillance* information they are able to provide.

1. Disease reporting systems

Disease reporting systems are based on reporting of animal health-related events to the *Veterinary Authority*. Data derived from disease reporting systems can be used in combination with other data sources to substantiate claims of *animal health status*, to generate data for *risk analysis* or for early warning and response. Effective laboratory support is an important component of any reporting system. Reporting systems relying on laboratory confirmation of suspected clinical cases should use tests that have high specificity as described in the *Terrestrial Manual*.

Whenever the responsibility for disease reporting falls outside the scope of the *Veterinary Authority*, for example human cases of zoonotic diseases or *infections* or *infestations* in *wildlife*, effective communication and data sharing should be established with between the *Veterinary Authority* and other relevant authorities.

Participatory *surveillance* methods may be useful to collect epidemiological data that can support disease reporting systems.

2- Data generated by control programmes and health schemes

~~While focusing on the control or eradication of specific *infections* or *infestations*, control programmes or health schemes can be used to generate data that can contribute to other *surveillance* objectives.~~

2. Surveys

In addition to the principles in Article 1.4.3., the following should be considered when planning, implementing and analysing surveys.

Surveys may be conducted on the entire target *population* (i.e. a census) or on a sample.

The sources of data should be fully described and should include a detailed description of the sampling strategy used for the selection of *units* for testing. Also, consideration should be given to any biases that may be inherent in the survey design.

Annex 8 (contd)a) Survey design

The target and study *populations* should first be clearly defined. Depending on the design of the survey, appropriate sampling *units* should be defined for each stage.

The design of the survey will depend on the knowledge of the size, structure and distribution of the *population*, the epidemiology of the *infection* or *infestation* and the resources available.

Data on the size, structure and distribution of *wildlife populations* often do not exist. However, they should be estimated to the extent possible before the survey is designed. Expert opinion can be sought in the gathering and interpretation of such *population* data. Historical *population* data should be updated since these may not reflect current *populations*.

b) Samplingi) Objective

The objective of **probability** sampling from a *population* is to select a subset of units that is representative of the *population* of interest with respect to the objective of the study, taking into account practical constraints imposed by different environments and production systems so that data from the study *population* can be extrapolated to the target *population* in a statistically-valid manner. When selecting *epidemiological units* within a *population*, **probability-based** sampling, such as a simple random selection, should be used.

Where **probability-based** sampling is not feasible, non-probability-based methods may be applied and should provide the best practical chance of generating a sample that **is can be considered as representative of the target *population*. The objective of non-probability based sampling should be to maximise the likelihood of detection of the *infection* or *infestation*.** However, this type of sampling may **not only** be representative of the study and target *population*, **unless if** risk factors are weighted, **and** ~~†~~**Those weights should be underpinned by relevant scientific evidence and should capture the relative differences in risk and proportion between the *subpopulation* and the *population*.**

The sampling method used at all stages should be fully documented.

ii) Sample size

In surveys conducted to demonstrate the presence or absence of an *infection* or *infestation* the method used to calculate sample size depends on the size of the *population*, the design of the survey, the expected *prevalence* and possible clustering, the level of confidence desired of the survey results and the performance of the tests used.

In addition, for surveys designed to estimate a parameter (e.g. *prevalence*) consideration should be given to the desired precision of the estimate.

iii) Sample selection

== **probability-based sampling methods, such as:**

- **simple random selection;**
- **cluster sampling;**
- **stratified sampling;**
- **systematic sampling; **or****
- **risk-based sampling.**

— non-probability-based sampling methods, depending on:

- convenience;
- expert choice;
- quota;
- risk.

3. Risk-based methods

Surveillance activities targeting selected *subpopulations* in which an *infection* or *infestation* is more likely to be introduced or found, or more likely to spread, or cause other consequences (e.g. large economic losses or trade restrictions) are useful to increase the efficiency of detection and can contribute to early detection, freedom claims, disease control activities, and estimation of *prevalence*. Risk-based methods can be used for both probability-based and non-probability-based selection of sampling units methods and data collection. The effect of the selection (i.e. its impact on probability of detection) should be estimated.

Risk-based methods should be based on risk assessment and are useful to optimise the use of *surveillance* resources.

4. Ante-mortem and post-mortem inspection

Inspection of *animals* at *slaughterhouses/abattoirs* may provide valuable *surveillance* data. The sensitivity and specificity of *slaughterhouse/abattoir* inspection for detecting the presence of specified diseases will be influenced by:

- a) clinical and pathological signs;
- b) the training, experience and number of the inspection staff;
- c) the extent to which the Competent Authority is involved involvement of the *Competent Authority* in the supervision of ante-mortem and post-mortem inspection, including reporting systems;
- d) the quality of construction of the *slaughterhouse/abattoir*, speed of the slaughter chain, lighting quality, etc.; and
- e) independence of the inspection staff.

Slaughterhouse/abattoir inspections are likely to provide good coverage for particular age groups and geographical areas only. *Slaughterhouse/abattoir surveillance* data may only be representative of a particular *subpopulation* (e.g. only *animals* of a particular class and age are likely to be slaughtered for human consumption in significant numbers). Such limitations should be recognised when analysing *surveillance* data.

The usefulness of data generated by *slaughterhouse/abattoir* inspections is dependent on effective *animal traceability* that relates *animals* to their *herd* or *flock* or locality of origin.

5. Laboratory investigation records

~~Laboratory investigation records may provide useful data for surveillance. Multiple sources of data such as national, accredited, university and private sector laboratories should be integrated in order to increase the coverage of the surveillance system.~~

~~Valid analysis of data from different laboratories depends on the existence of standardised diagnostic procedures and standardised methods for data recording and interpretation as well as a mechanism to ensure the traceability of specimens to herd or flock or locality of origin.~~

Annex 8 (contd)

6. Biological specimen banks

~~Specimen banks consist of stored specimens, gathered through representative sampling or opportunistic collection. Specimen banks may contribute to retrospective studies, including providing support for claims of historical freedom from *infection* or *infestation*, and may allow certain studies to be conducted more quickly and at lower cost than other approaches.~~

57. Surveillance of Ssentinel units

Surveillance of Ssentinel units involve the identification and regular testing of one or more *animals* of known health or immune status in a specified geographical location to detect the occurrence of *infection* or *infestation*. Sentinel units provide the opportunity to target *surveillance* depending on the risk of introduction or re-emergence, likelihood of *infection* or *infestation*, cost and other practical constraints. Sentinel units may provide evidence of freedom from or distribution of, *infection* or *infestation*, or of their distribution.

68. Clinical observations surveillance

Clinical observations of *animals* in the field are an important source of *surveillance* data. The sensitivity and specificity of clinical observations are highly dependent on the criteria used to define a suspected case. In order to allow comparison of data, the case definition should be standardised. Training of potential field observers in the application of the case definition and reporting is important. Ideally, both the number of positive observations and the total number of observations should be recorded.

79. Syndromic data surveillance

Systematic analysis of health data, including morbidity and mortality rates, production records and other parameters can be used to generate signals that may be indicative of changes in the occurrence of *infection* or *infestation*. Software may offer the prospect of extraction of syndromic data for aggregation and analysis.

84. Other useful data sourcesa) Data generated by control programmes and health schemes

While focusing on the control or eradication of specific *infections* or *infestations*, control programmes or health schemes can be used to generate data that can contribute to other *surveillance* objectives.

b) Laboratory investigation records

Laboratory investigation records may provide useful data for *surveillance*, in particular for retrospective studies. Multiple sources of data such as national, accredited, university and private sector *laboratories* should be integrated in order to increase the coverage of the *surveillance* system.

Valid analysis of data from different *laboratories* depends on the existence of quality control and quality assurance systems, including standardised diagnostic procedures and standardised methods for data recording and interpretation as well as a mechanism to ensure the traceability of specimens to *herd* or *flock* or locality of origin.

c) Biological specimen banks

Specimen banks consist of stored specimens, gathered through representative sampling or opportunistic collection. Specimen banks may contribute to retrospective studies, including providing support for claims of historical freedom from *infection* or *infestation*, and may allow certain studies to be conducted more quickly and at lower cost than other approaches.

d) Wildlife data

Specimens for *surveillance* from *wildlife* may be available from sources such as hunters and trappers, road-kills, *wild animal meat* markets, sanitary inspection of hunted *animals*, morbidity and mortality observations by the general public, *wildlife* rehabilitation centres, *wildlife* biologists and *wildlife* agency field personnel, farmers and other landholders, naturalists and conservationists. *Wildlife* data such as census data, trends over time, and reproductive success can be used in a manner similar to farm production records for epidemiological purposes.

eb) Public health data

For zoonotic diseases public health data may be an indicator of a potential change in the *animal health status*. The *Veterinary Authority* should coordinate with human health authorities and share data for integration into *specific surveillance* systems.

fe) Environmental data

Relevant environmental data such as rainfall, temperature, extreme climatic events, presence and abundance of potential *vectors* as described in Chapter 1.5., should also be integrated into the *surveillance* system.

ge) Additional supporting data such as:

- i) data on the epidemiology of the *infection* or *infestation*, including host *population* distribution;
- ii) data on animal movements, including transhumance and natural *wildlife* migrations;
- iii) trading patterns for *animals* and animal products;
- iv) national animal health regulations, including information on compliance and effectiveness;
- v) history of imports of potentially infected material;
- vi) *biosecurity* in place; and
- vii) the *risk* of introduction of *infection* or *infestation*.

9. Combination and interpretation of surveillance results

Depending on the objective of surveillance, the combination of multiple sources of data may provide an indication of the overall sensitivity of the system and may increase the confidence in the results. The methodology used to combine the evidence from multiple data sources should be scientifically valid, and fully documented, including references to published material.

Surveillance information gathered from the same country, zone or compartment at different times may provide cumulative evidence of animal health status. Repeated surveys may be analysed to provide a cumulative level of confidence. However, the combination of data collected over time from multiple sources may be able to achieve an equivalent level of confidence.

Analysis of surveillance information gathered intermittently or continuously over time should, where possible, incorporate the time of collection of the information to take the decreased value of older information into account. The sensitivity and specificity of tests used and completeness of data from each source should also be taken into account for the final overall confidence level estimation.

In assessing the efficiency of the surveillance system based on multiple sources, the Veterinary Authority should consider the relative contribution of each component to the overall sensitivity, while considering the primary objective of each surveillance component.

Results from animal health surveillance systems are subject to one or more potential biases. When assessing the results, care should be taken to identify potential biases that can inadvertently lead to an over-estimate or an under-estimate of the parameters of interest.

Annex 8 (contd)

Article 1.4.5:

Considerations in survey design

In addition to the principles in Article 1.4.3., the following should be considered when planning, implementing and analysing surveys:

1- Types of surveys

Surveys may be conducted on the entire target *population* (i.e. a census) or on a sample.

Surveys conducted in order to document freedom from *infection* or *infestation* should be conducted using probability based sampling methods so that data from the study *population* can be extrapolated to the target *population* in a statistically valid manner.

The sources of data should be fully described and should include a detailed description of the sampling strategy used for the selection of *units* for testing. Also, consideration should be given to any biases that may be inherent in the survey design.

2- Survey design

The target and study *populations* should first be clearly defined. Depending on the design of the survey, appropriate sampling *units* should be defined for each stage.

The design of the survey will depend on the knowledge of the size, structure and distribution of the *population*, the epidemiology of the *infection* or *infestation* and the resources available.

Data on the size, structure and distribution of *wildlife* populations often do not exist. However, they should be estimated to the extent possible before the survey is designed. Expert opinion can be sought in the gathering and interpretation of such *population* data. Historical *population* data should be updated since these may not reflect current *populations*.

3- Sampling

a) Objective

The objective of probability sampling from a *population* is to select a subset of units that is representative of the *population* of interest with respect to the objective of the study, taking into account practical constraints imposed by different environments and production systems. When selecting *epidemiological units* within a *population*, probability sampling, such as a simple random selection, should be used. Where probability sampling is not feasible, non-probability based methods may be applied and should provide the best practical chance of generating a sample that is representative of the target *population*. The objective of non-probability based sampling is to maximise the likelihood of detection of the *infection* or *infestation*. However, this type of sampling will not be representative of the study and target *population*.

The sampling method used at all stages should be fully documented.

b) Sample size

In surveys conducted to demonstrate the presence or absence of an *infection* or *infestation* the method used to calculate sample size depends on the size of the *population*, the design of the survey, the expected prevalence, the level of confidence desired of the survey results and the performance of the tests used.

In addition, for surveys designed to estimate a parameter (e.g. prevalence) consideration should be given to the desired precision of the estimate.

c) A sample may be selected by either:

i) probability based sampling methods, such as:

- simple random selection;
- cluster sampling;
- stratified sampling;
- systematic sampling; or

ii) non-probability based sampling methods, depending on:

- convenience;
- expert choice;
- quota;
- risk.

Article 1.4.5.

Early warning systems

An early warning system is essential for the timely detection, reporting and communication of occurrence, incursion or emergence of diseases, infections or infestations, and is an integral component of emergency preparedness. It should be under the control of the Veterinary Authority and should include the following:

- 1) appropriate coverage of target animal populations by the Veterinary Services;
- 2) laboratories capable of diagnosing and differentiating relevant infections or infestations;
- 3) training and awareness programmes for veterinarians, veterinary paraprofessionals, livestock owners or keepers and others involved in handling animals from the farm to the slaughterhouse/abattoir, for detecting and reporting unusual animal health incidents;
- 4) a legal obligation by veterinarians and other relevant stakeholders to report suspected cases or cases of notifiable diseases or emerging diseases to the Veterinary Authority, with following information including the description of the findings:
 - 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;
- 5) epidemiological investigations of suspected cases and cases conducted by the Veterinary Services, taking into account the following: in order to confirm the case and to acquire accurate knowledge of the situation for further action.

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.

- biosecurity to be observed when entering and leaving the establishment, premises or locality;
- clinical examinations to be undertaken (number and types of animals);
- samples to be taken from animals showing signs or not (number and types of animals), with specified sampling and sample handling equipment and sample handling procedures, including for the safety of the investigator and animal owners;
- procedure for submitting samples for testing;
- size of the affected establishment, premises or locality and possible entry pathways;
- investigation of the approximate numbers of similar or possibly susceptible animals in the establishment and its surroundings;
- details of any recent movements of possibly susceptible animals or vehicles or people to or from the affected establishments, premises or locality;

Annex 8 (contd)

~~any other relevant epidemiological information, such as presence of the suspected disease in *wildlife* or abnormal vector activity;~~

~~all suspected case investigations should provide a result, either positive or negative. Criteria should be established in advance for a case definition;~~

6) effective systems of communication between the *Veterinary Authority* and relevant stakeholders;

7) a national chain of command.

Early warning systems are an essential component of emergency preparedness.

When a case of a *listed disease* is detected, notification shall be made to the OIE in accordance with Chapter 1.1.

Article 1.4.6.

Surveillance to demonstrate freedom from an infection or infestation

~~This article provides general principles for declaring freedom from an *infection* or *infestation*, including for the recognition of historical freedom.~~

1. Demonstration of freedom

A *surveillance* system to demonstrate freedom from an *infection* and *infestation* should meet the following, in addition to the general principles outlined in Article 1.4.3.

~~Freedom implies the absence of the pathogenic agent *infection* or *infestation* in an animal population in the country, zone or compartment. Scientific methods cannot provide absolute certainty of this absence. Therefore, demonstrating freedom, except for historical freedom, involves providing sufficient evidence to demonstrate to a desired level of confidence (to a level of confidence acceptable to Member Countries) that *infection* or *infestation* with a specified pathogenic agent, if present, is present in less than a specified proportion of the population.~~

However, finding evidence of *infection* or *infestation* at any prevalence in the target population automatically invalidates any freedom claim unless otherwise stated in the relevant chapter of the *Terrestrial Code*. The implications for the status of domestic animals ~~of when~~ *infection* or *infestation* is present in *wildlife* in the same country or zone should be assessed in each situation, as indicated in the relevant chapter of the *Terrestrial Code*.

~~Evidence from probability-based and nonprobability risk-based data sources collection, as stated before, may increase the sensitivity of the surveillance level of confidence or be able to detect a lower prevalence with the same level of confidence as structured surveys.~~

2. Requirements to declare a country or a zone free from an infection or infestation

a) Prerequisites, unless otherwise specified in the relevant chapter of the *Terrestrial Code*:

- i) the *infection* or *infestation* has been a *notifiable disease*;
- ii) an early warning system has been in place for all relevant species;
- iii) measures to prevent the introduction of the *infection* or *infestation* have been in place;
- ~~iv) no vaccination against the disease has been carried out;~~
- iv) the *infection* or *infestation* is not known to be established in *wildlife* within the country or zone.

b) Historical freedom

Unless otherwise specified in the relevant chapter of the *Terrestrial Code*, a country or zone may be considered free without formally applying a pathogen-specific *surveillance* programme when:

- i) for at least the past 10 years:
 - ~~= no vaccination against the disease has been carried out;~~
 - the prerequisites listed in point a) are complied with for at least the past 10 years;
 - ii) the pathogenic agent is likely to produce identifiable clinical or pathological signs in susceptible animals;
 - iii) for at least 25 years there has been no occurrence of *infection* or *infestation* ~~or eradication has been achieved for the same length of time.~~
 - c) Where historical freedom cannot be ~~achieved~~ demonstrated:
 - i) the prerequisites listed in a) ~~are~~ have been complied with for at least as long as the surveillance has been in place;
 - ii) pathogen-specific *surveillance* has been applied as described in this chapter and in the relevant chapter of the *Terrestrial Code*, if it exists, and has not detected any occurrence of the *infection* or *infestation*.
3. Requirements to declare a compartment free from infection or infestation
- a) The prerequisites listed in points 2 a)i) to ~~iiiiv)~~ are complied with for at least as long as the surveillance has been in place;
 - b) ongoing pathogen-specific *surveillance* has been applied as described in this chapter and in the relevant chapter of the *Terrestrial Code*, if they it exists, and has not detected any occurrence of the *infection* or *infestation*.
4. Recommendations for the maintenance of freedom from infection or infestation

Unless otherwise specified in the relevant chapter of the *Terrestrial Code*, a country or *zone* that has achieved freedom in accordance with the provisions of the *Terrestrial Code* may maintain its free status provided that:

- a) the *infection* or *infestation* is a *notifiable disease*;
- b) an *early warning system* is in place for all relevant species;
- c) measures to prevent the introduction of the *infection* or *infestation* are in place;
- d) *surveillance* adapted to the likelihood of occurrence of *infection* or *infestation* is carried out. *Specific surveillance* may not need to be carried out if supported by a *risk assessment* addressing all identified pathways for introduction of the pathogenic agent and provided ~~it~~ the pathogenic agent is likely to produce identifiable clinical or pathological signs in susceptible *animals*;
- e) ~~vaccination against the disease is not applied;~~
- ef) the *infection* or *infestation* is not known to be established in *wildlife*. It can be difficult to collect sufficient epidemiological data to prove absence of *infection* or *infestation* in *wild animal populations*. In such circumstances, a range of supporting evidence should be used to make this assessment.

Article 1.4.7.

Surveillance considerations in support of disease control programmes

Surveillance is an important component in disease control programmes and can be used to determine the distribution and occurrence of *infection* or *infestation* or of other relevant health-related events. It can be used to assess progress and aid in decision-making in the control or eradication of selected *infections* or *infestations*.

Surveillance used to assess progress in control or eradication of selected *infections* or *infestations* should be designed to collect data about a number of variables such as:

Annex 8 (contd)

- 1) prevalence or incidence of *infection* or *infestation*;
- 2) morbidity and mortality;
- 3) frequency of *risk* factors and their quantification;
- 4) frequency distribution of results of the laboratory tests;
- 5) post-vaccination monitoring results;
- 6) frequency distribution of *infection* or *infestation* in *wildlife*.

The spatial and temporal distribution of these variables and other data such as *wildlife*, public health and environmental data as described in point 840) of Article 1.4.4. can be useful in the assessment of disease control programmes.

Article 1.4.8.

Early warning systems

~~An early warning system is essential for the timely detection, identification and reporting of occurrence, incursion or emergence of *infections* or *infestations*, and should include the following:~~

- 1) ~~appropriate coverage of target *animal* populations by the *Veterinary Services*;~~
- 2) ~~effective disease investigation and reporting;~~
- 3) ~~*laboratories* capable of diagnosing and differentiating relevant *infections* or *infestations*;~~
- 4) ~~training and awareness programmes for *veterinarians*, *veterinary paraprofessionals*, livestock owners or keepers and others involved in handling *animals* from the farm to the *slaughterhouse/abattoir*, for detecting and reporting unusual animal health incidents;~~
- 5) ~~a legal obligation by relevant stakeholders to report suspected cases or cases of *notifiable diseases* or *emerging diseases* to the *Veterinary Authority*;~~
- 6) ~~effective systems of communication between the *Veterinary Authority* and relevant stakeholders;~~
- 7) ~~a national chain of command.~~

~~*Early warning systems* are an essential component of emergency preparedness.~~

Article 1.4.9.

Combination and interpretation of surveillance results

~~Depending on the objective of *surveillance*, the combination of multiple sources of data may provide an indication of the overall sensitivity of the system and may increase the confidence in the results. The methodology used to combine the evidence from multiple data sources should be scientifically valid, and fully documented, including references to published material.~~

~~*Surveillance* information gathered from the same country, *zone* or *compartment* at different times may provide cumulative evidence of *animal health status*. Repeated surveys may be analysed to provide a cumulative level of confidence. However, the combination of data collected over time from multiple sources may be able to achieve an equivalent level of confidence.~~

~~Analysis of *surveillance* information gathered intermittently or continuously over time should, where possible, incorporate the time of collection of the information to take the decreased value of older information into account. The sensitivity and specificity of tests used and completeness of data from each source should also be taken into account for the final overall confidence level estimation.~~

Annex 8 (contd)

~~In assessing the efficiency of the *surveillance* system based on multiple sources, the *Veterinary Authority* should consider the relative contribution of each component to the overall sensitivity, while considering the primary objective of each *surveillance* component.~~

~~Results from *animal health surveillance* systems are subject to one or more potential biases. When assessing the results, care should be taken to identify potential biases that can inadvertently lead to an over-estimate or an under-estimate of the parameters of interest.~~

SECTION 4.

~~GENERAL RECOMMENDATIONS: DISEASE PREVENTION AND CONTROL~~

CHAPTER 4.Z.

INTRODUCTION TO RECOMMENDATIONS FOR DISEASE PREVENTION AND CONTROL

Article 4.Z.1.

Effective prevention and control of contagious infectious transmissible animal diseases, including zoonoses, is a central mandate of the *Veterinary Services* of each Member Country.

~~From the extensive experience in combatting contagious animal diseases, *Veterinary Services* around the world, supported by significant progress in veterinary science, have developed and improved a number of tools to prevent, control and sometimes even eradicate them~~ infectious transmissible animal diseases.

The following chapters of this section describe these tools and the ~~different aspects of~~ recommendations for disease prevention and control ~~to that should~~ be implemented by the *Veterinary Services*.

To effectively prevent ~~effectively~~ introduction and transmission of contagious infectious animal diseases while minimising potential negative impacts of *sanitary measures*, *Veterinary Services* should consider ~~devising a set of developing~~ measures selected from based on the recommendations ~~described~~ in this section, taking into account various factors including their impact on trade, animal welfare, public health and environment. In parallel with disease-specific *sanitary measures*, *Veterinary Services* should ~~take into account~~ consider relevant commodity-based *sanitary measures*.

Furthermore, although the general principles covering the measures described in this section are applicable to multiple diseases, *Veterinary Services* should adapt them to their circumstances, because characteristics of the pathogenic agents and the situations in which they occur differ between diseases and between countries ~~are different disease by disease and country by country~~. To this end, recommendations in this section should be read in conjunction with *listed disease-specific* recommendations in Sections 8 to 15.

Veterinary Services should ensure that any prevention and control programme be proportionate to the *risk*, practical and feasible within the national context and be based on *risk analysis*.

Prerequisites for ~~devising~~ developing such programmes ~~may~~ include:

- quality *Veterinary Services* including legislative framework, ~~and~~ *laboratory* capacity and adequate and committed funding;
- appropriate education and training to secure *veterinarians* and *veterinary paraprofessionals*;
- close link with research institutions;
- effective awareness of, and active cooperation with, private stakeholders;
- public-private partnerships;
- cooperation between *Veterinary Authorities* and other *Competent Authorities*;
- regional cooperation among *Veterinary Authorities* on transboundary animal diseases.

CHAPTER 7.Y.

KILLING OF REPTILES FOR THEIR SKINS, MEAT AND OTHER PRODUCTS

Article 7.Y.1.

Scope

The recommendations in this chapter address the need to ensure the welfare of chelonians, crocodylians, lacertilians and ophidians, during the process of *killing* them for their skins, *meat* and other products.

Article 7.Y.2.

Definitions

Some of the definitions in this chapter differ from those in the Glossary and Chapter 7.5., as they are adapted to reptiles, given the specific characteristics of these animals.

For the purposes of this chapter:

Restraint: means any acceptable physical or chemical method of reducing, or eliminating, voluntary or reactive movement of the reptile, to facilitate efficient stunning or *killing*.

Stunning: means the procedure that causes immediate loss of unconsciousness until the animal-reptile is dead, or causes the absence of pain, distress and suffering until the onset of unconsciousness, according to the outcomes defined in this chapter for the species covered.

Unconsciousness: means the state of unawareness caused by temporary or permanent disruption of brain function.

Pithing: means a method carried out by inserting a rod or probe through the foramen magnum (or the hole from a penetrative captive bolt or gunshot), into the brain to ensure thorough brain destruction.

Article 7.Y.3.

General considerations

Because of the anatomy and physiology of reptiles, specific various factors should be considered when choosing the appropriate restraining, stunning and killing method. Such factors include the size of the reptile animal, tolerance and intolerance of certain species to particular methods, reptile animal handling and restraint, ease of access to veins and safety of the animal handlers.

1. Animal welfare plan

Facilities in which reptiles are killed should have an *animal welfare* plan and associated procedures. The purposes of such a plan should be to maintain good *animal welfare* at all stages of handling of ~~animals~~ reptiles until their *death*.

The *animal welfare* plan should contain standard operating procedures for each step of reptile animal handling to ensure that it is properly implemented, based on relevant recommendations in this chapter, including criteria indicators shown in Article 7.Y.56. It should also include corrective actions to address specific risks, for example, power failures or other circumstances that could negatively affect the welfare of reptiles animals.

Annex 10 (contd)2. Competency and training of the personnel

Animal handlers should be competent in handling and moving, stunning and verifying monitoring effective stun, and killing of reptiles, as well as in recognising species and understanding relevant behaviours of these animals and the underlying *animal welfare* and technical principles necessary to carry out their tasks.

There should be sufficient number of personnel, who should be trained, competent and familiar with the recommendations outlined in this chapter and their application within the national context.

The manager of the facility should ensure that personnel are competent and carry out their tasks in accordance with the guiding principles for *animal welfare* in Article 7.1.2.

The manager of the facility should ensure that personnel are physically and mentally able to carry out their tasks through the period of their work shift.

Competence may be gained through formal training or practical experience. This competence should be verified by the *Competent Authority* or an independent body accredited by it.

3. Source of animals

Animals Reptiles should be acquired legally in accordance with all national jurisdictions legislation, including those of the importation and exportation countries and international treaties, including the Convention on International Trade in Endangered Species of Wild Fauna and Flora (CITES).

Relevant documentation related to the source of the animals should accompany the animals.

When moving reptiles If animals captured in the wild are to be used, capture and transport techniques should not compromise be humane and give due regard to human and animal health, welfare and safety.

4.3. Behaviour Behavioural considerations for handling, restraining, stunning and killing

Handling, restraining, stunning and *killing* methods should take into account specific reptile behaviours indicating fear, pain or distress, such as well as:

- reptiles are sensitive to and will respond sensitivity and responsiveness to visual, and-tactile, auditory, olfactory and vibrational stimuli as well as noise and vibrations;
- ability to escape handling and restraint the restraint and handling of reptiles can be difficult because of their agility and strength;
- ability to reptiles can inflict significant bite wounds to handlers, and frequently with wound infection or envenomation are not uncommon;
- low body temperatures may result in slow movements, torpor and slow movements, torpor and reduced responsiveness due to low body temperatures or slow metabolic rates, which may result in slow movements, and that should not be regarded as indicators of quiescence or unconsciousness;
- absence of vocalisation, is common or normal which is typical in reptiles, even in highly traumatic situations.

Article 7.Y.4.Source and transportation of reptiles

Reptiles should be acquired legally, in accordance with all national legislation, including those of the importation and exportation countries, and with international treaties, including the Convention on International Trade in Endangered Species of Wild Fauna and Flora (CITES).

Relevant documentation related to the source of the animals should accompany the animals.

When moving reptiles, capture and transport techniques should not compromise human and animal health, welfare and safety.

Article 7.Y.45.

Selection of a killing process

In the case of reptiles, the *killing* process should involve either stunning followed by a killing method or direct killing method. Where stunning is used, death should be ensured ~~may involve a stunning and a subsequent killing step or a direct killing method should involve either prior stunning followed by a killing method or an instantaneous method of killing. When prior stunning is used and the stunning is not irreversible, reptiles should be killed before consciousness is recovered.~~

Criteria which may influence the choice of methods used in the *killing* process include:

- ≡ species and size of the reptile;
- level of knowledge and skill required to perform the procedure effectively;
- safety of the operator;
- compatibility with processing requirements and reptile animal product purposes;
- in the case of the use of drugs, the drug availability, licensing and use requirements, possible human abuse, and implications for other product uses such as consumption by reptile animal or humans;
- ability to maintain equipment in proper working order;
- cost of the method.

The *killing* process used should:

- avoid ~~excitement~~ agitation, fear, and stress, and pain to the reptile animal;
- be appropriate for the species, size, age and health of the ~~animal~~ reptile;
- be reliable and reproducible;
- ~~ensure that any stunning used is in accordance with Article 7.Y.2.; and~~
- include the use of a stunning method (in accordance with Article 7.Y.2.) followed by a killing step, or alternatively a one-step direct killing method. a killing method if the stunning method does not result in death of the animal reptile during unconsciousness; and
- ≡ whenre it includes a stunning step, ensure that death occurs during unconsciousness kill the reptile while it is unconscious.

While economic or cost factors may influence the choice of the method used for stunning or killing, these factors should not compromise the welfare of the reptiles and the outcomes described in this chapter.

Article 7.Y.56.

Criteria (or measurables) for the outcome of the stunning and killing of reptiles

The following animal-based criteria (or measurables) can be useful indicators of *animal welfare*. The use of these criteria and their appropriate thresholds should be adapted to the different methods used to stun and kill reptiles. These criteria can be considered as tools to monitor the impact of the method and management used, given that both of these can affect *animal welfare*.

Annex 10 (contd)

As far as criteria to measure the effectiveness of stunning and killing methods are concerned and whilst multiple criteria are preferable for the verification establishment of unconsciousness or *death*, the presence of any of the following criteria should be regarded as sufficient to establish suspicion of consciousness:

- pupillary response to light or movementing objects;
- ~~pupillary response to objects or movement~~;
- eye movement in response to objects or movement;
- blink or nictitating membrane responses to touch or contact of the cornea;
- spontaneous eyelid opening or closing;
- intentional defensive responses;
- tongue movement~~;~~;
- jaw tone (except crocodilians).

In addition to the absence of all the criteria above, *death* may be inferred by confirming permanent cessation of the following:

- response to ~~somatic~~ stimuli applied to the head, indicating brain activity;
- respiration;
- cardiac activity (while presence of a heartbeat does not necessarily mean that an the reptile animal is alive, permanent cessation of a heartbeat indicates *death*). Cardiac activity should not be used as the sole indicator of death. It is important to note that a reptile's heartbeat may change from beats per minute to beats per hour.

Article 7.Y. 67.

Physical restraint

Physical restraint is often required in the process of stunning and *killing* of reptiles to control movement and improve the precision of application. Special considerations for the restraint of reptiles are needed due to the physical and behavioural characteristics of this taxonomic group.

As far as recommendations for effective physical restraint in relation to *animal welfare* are concerned, the method of restraint should:

- avoid injuries due to excessive pressure applied by equipment or personnel;
- be applied rapidly to avoid excessive or prolonged struggling of the ~~animal~~ reptile;
- exclude features that may cause pain or injury;
- not hoist or suspend animals by the feet, legs, tail or head;
- not restrain only one area of the body (e.g. head or neck) leaving the rest able to move excessively;
- ensure animals can breathe freely through the nostrils where the mouth is restrained;
- adequately support the animal's body when moving it;

Annex 10 (contd)

- avoid taping or binding the legs or feet of the animals as the sole method of restraint, and, where required, the method should not cause injuries or pain.

Procedures or practices unacceptable on animal welfare grounds are:

- not breaking legs, cutting limb tendons or blind animals damaging the eyes of the reptiles in order to immobilise them;
- not severing the spinal cord to immobilise animals the reptiles, causing any unnecessary injuries, for example, severing the spinal cord, breaking limbs, cutting limb tendons or damaging eyes, whether for immobilisation or any other reason;
- pulling or probing sensitive body parts, other than for the purposes of verifying some reflex such as the cloacal reflex.

Animal-based criteria (or measurables): excessive struggling, excessive movements, excessive vocalisation, trauma and injuries.

Article 7.Y.78.

Introduction to stunning and killing methods

Stunning may be used to facilitate the *killing* of reptiles. *Stunning* methods may result in the *death* of the reptile animal following unconsciousness, or may require an additional *killing* step.

If *stunning* is used, the method should:

- be appropriate for the species, size, age and health of the animal-reptile;
- be reliable and reproducible;
- avoid agitation, excitement, and stress and pain to the animal reptile;
- avoid or minimise restraint in accordance with Article 7.Y.67.;
- result in the immediate onset of unconsciousness or the absence of pain, distress and suffering until the onset of unconsciousness that lasts until the reptile animal is dead;
- be followed by a *killing* method if stunning does not result in *death* of the reptile animal during unconsciousness.

The equipment used should be maintained and operated properly and in accordance with the manufacturer's recommendations, in particular with regard to the species and size of the animal. The maintenance of the equipment is the responsibility of the management of the facility, and should be under the supervision of the *Competent Authority* or accredited delegated body. If the primary method of stunning fails to produce unconsciousness as described in Article 7.Y.56 and, in accordance with this article, a back-up stunning or *killing* method should be used immediately (Articles 7.Y.89. to 7.Y.15-16.).

Animal-based criteria (or measurables): immediate onset of unconsciousness or *death* as described in Article 7.Y.56.

Article 7.Y.89.

Electrical stunning (for crocodylians only)

Electrical stunning is the application, through the brain, of an electric current of sufficient strength and duration, and suitable frequency to through electrodes for the purpose of causing immediate unconsciousness that lasts until *death*.

Annex 10 (contd)

Recommendations for effective use in relation to *animal welfare* are:

- the equipment and the procedure for its application should be approved by the *Competent Authority* or an accredited designated authority;
- the apparatus should deliver sufficient current through the brain;
- the equipment should be scientifically validated, tested and calibrated prior to use and maintained according to a set protocol;
- minimum electrical parameters (current, voltage and frequency) should be applied; Parameters may vary with size, age, weight, etc., within a species;
- minimum length of time of application of the current ~~stun duration~~ should be achieved; Duration may vary with size, age, weight etc., within a species;
- animals reptiles should be killed in accordance to Articles 7.Y. 910. to 7.Y. 15-16 without delay following confirmation of effective stunning to avoid recovery of consciousness;
- reptiles should be effectively restrained when accurate application of the electrodes is dependent upon it;
- equipment should be selected to suit the type and size of the reptile;
- equipment should be cleaned, maintained and stored following manufacturer's recommendations.

Animal-based criteria (or measurables): immediate onset of unconsciousness as described in Article 7.Y. 56.

Article 7.Y. 910.

Penetrative captive bolt

The aim of this method is to produce a state of unconsciousness and cause severe damage to the brain by the impact and penetration of a captive bolt using a mechanical device. The force of impact and the physical damage caused by the passage of the bolt should result in immediate unconsciousness and *death*. If *death* does not occur following the passage of the penetrative bolt, then an additional *killing* method in accordance with Articles 7.Y. 910. to 7.Y. 16. should be used immediately to ensure *death*.

Recommendations for the effective use in relation to *animal welfare* are:

- animals reptiles should be effectively restrained;
- the device should be correctly positioned on the head to result in the penetration of the brain by the bolt;
- the bolt should be of appropriate mass, length, diameter and shape;
- cartridge or compressed air specifications should be determined to deliver the correct bolt velocity;
- equipment and charge should be selected to suit the species, type and size of ~~animal~~ the reptile;
- equipment should be cleaned, maintained and stored, following manufacturer's recommendations.

Animal-based criteria (or measurables): immediate onset of unconsciousness ~~and~~ or *death* as described in Article 7.Y. 56.

Article 7.Y.1011.

Non-penetrative captive bolt

The non-penetrative captive bolt method is sometimes called 'concussive stunning', although concussion is the underlying principle for both penetrative and non-penetrative methods. The concussion may result in both unconsciousness and *death*. If *death* does not occur following the application of the percussive blow, then an additional *killing* method in accordance with Articles 7.Y.910. to 7.Y.16. should be used immediately to assure *death*.

Recommendations for an effective use in relation to *animal welfare* are:

- ~~animals~~ reptiles should be effectively restrained;
- the device should be correctly positioned on the head to allow optimum transfer of energy to the brain;
- the bolt should be of appropriate mass, diameter and shape appropriate to the anatomy of the cranium and brain;
- the equipment should be appropriately selected and maintained and adjusted for the species, size and type of reptile;
- cartridge or compressed air specifications should be determined to deliver the correct bolt velocity;
- equipment and charge should be selected to suit the species, type and size of ~~animal~~ the reptile;
- equipment should be cleaned, maintained and stored, ~~preferably~~ following manufacturer's recommendations.

Outcome-based criteria (or measurable): immediate onset of unconsciousness or *death* as described in Article 7.Y.56.

Article 7.Y.1112.

Percussive blow to the head

A percussive blow to the head to induce cerebral concussion can be achieved manually. A concussive state is normally associated with a sudden loss of consciousness with associated loss of reflexes. Inducing unconsciousness requires the transfer of sufficient energy into the brain to disrupt normal neural function. If the severity of the blow is sufficient then it will result in the *death* of the animal. If *death* does not occur following the application of the percussive blow, then an additional *killing* method in accordance with Articles 7.Y.910. to 7.Y.16. should be used immediately to ensure *death*. It is important to note that due to anatomical differences between species (e.g. thickness of braincase in crocodylians), this method may be difficult to apply and in such cases, other stunning and killing methods should preferentially be used.

Recommendations for effective use in relation to *animal welfare* are:

- ~~animals~~ reptiles should be effectively restrained;
- the blow should be correctly applied to result in optimum transfer of energy to the brain;
- the tool should be of appropriate size and weight, and the blow of sufficient force to induce concussion;
- equipment and method should be selected to suit the species, type and size of ~~animal~~ the reptile.

Animal-based criteria (or measurables): immediate onset of unconsciousness or *death* as described in Article 7.Y.56.

Annex 10 (contd)Article 7.Y. 1213.**Gunshot**

An effective gunshot, where the projectile enters the brain, can cause immediate unconsciousness and *death*. A gunshot to the heart or neck does not immediately render an reptile animal unconscious and therefore should not be used. If *death* does not occur following the gunshot, then an additional *killing* method in accordance with Articles 7.Y. 910 to 7.Y. 16 should be used immediately to ensure *death*.

Manual restraint of the reptile animal should not be used due to safety concerns for humans in the line of fire.

Recommendations for effective use in relation to *animal welfare* are:

- ensure accurate targeting of the brain;
- select firearm and projectile suitable for the species, type and size of ~~animal~~ the reptile;
- equipment should be cleaned and stored following manufacturer's recommendations.

Animal-based criteria (or measurables): immediate onset of unconsciousness or *death* as described in Article 7.Y. 56.

Article 7.Y. 1314.**Pithing**

Pithing is an adjunct method used to ensure death by destruction of brain tissue. It is carried out by inserting a rod or probe through the foramen magnum or shot hole from a penetrative captive bolt or gunshot, into the brain ~~to ensure thorough brain destruction~~. After insertion of the rod or probe it should be promptly turned a minimum of four to six times in a centrifugal motion to ensure destruction of the brain tissue.

Recommendations for effective use in relation to *animal welfare* are:

- should only be used in unconscious ~~animal~~ reptiles;
- movement of the pithing implement should ensure maximum destruction of brain tissue.

Animal-based criteria (or measurables): confirmation of *death* as described in Article 7.Y. 56.

Article 7.Y. 1415.**Decapitation or spinal cord severance**

Decapitation involves cutting the neck of the animal, between the skull and the first cervical vertebra using a sharp instrument (guillotine, axe or blade) leading to severance of the head. For some reptile species, ~~this method~~ decapitation is not anatomically feasible. For severance of the spinal cord, complete separation of the head from the neck is not necessary. Some reptiles may remain conscious for over an hour after decapitation or spinal cord severance, which makes ~~this method~~ decapitation or severance of the spinal cord acceptable only in stunned and unconscious reptiles animals and when followed by immediate destruction of the brain ~~by pithing or percussive blow~~.

Recommendations for effective use in relation to *animal welfare* are:

- should only be used on unconscious ~~animal~~ reptiles;
- should always be followed immediately by physical intervention to destroy the brain, i.e. immediate crushing of the brain or pithing.

Animal-based criteria (or measurables): confirmation of *death* as described in Article 7.Y. 56.

Article 7.Y. ~~15~~16.

Chemical agents

There are a number of ~~acceptable~~ chemical agents that, subject to relevant regulatory approvals, can be used for the restraint or *killing* of reptiles. The use of these agents for either restraint or *killing* should be supervised by *veterinarians* or *veterinary paraprofessionals* in accordance with the requirements of the *Competent Authority*. If *death* does not occur following administration of the agent, then an additional *killing* method in accordance with Articles 7.Y. ~~9~~10, to 7.Y. ~~15~~16, should be used immediately to ensure *death*.

The effectiveness of the chemical agent will vary according to the metabolic rate of reptiles.

Recommendations for effective use in relation to *animal welfare* are:

- ensure proper physical restraint is used for administration;
- ensure chemicals and dosage used are appropriate for the species and size of animal-reptiles;
- ensure the route of administration is appropriate for the animal-reptiles.

Animal-based criteria (or measurables): confirmation of *death* as described in Article 7.Y. ~~55~~56.

Article 7.Y. ~~16~~17.

Methods that are unacceptable for stunning and killing reptiles

Due to particular anatomical and physiological characteristics of reptiles the use of any method other than those described in Articles 7.Y. ~~9~~10, to Article 7.Y. ~~15~~16, are is considered inappropriate and unacceptable. Some examples of unacceptable methods are:

- exsanguination,
- freezing or cooling,
- heating or boiling,
- suffocation or drowning,
- inflation using compressed gas or liquid,
- live evisceration or skinning,
- constriction bands to induce cardiac arrest,
- ~~inhaled-inhalation of asphyxiating gases~~ carbon dioxide (CO₂), carbon monoxide (CO) or nitrogen (N),
- use of paralysing paralytic agent drugs;
- ≡ cervical dislocation.

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CHAPTER 8.14.

INFECTION WITH RABIES VIRUS

Article 8.14.1.

General provisions

Rabies is a disease caused by neurotropic viruses of the Genus *Lyssavirus* in the family *Rhabdoviridae* of the order Mononegavirales and is transmissible to all mammals. Populations of the orders Carnivora and Chiroptera are considered to be the main reservoir hosts.

Rabies virus, the taxonomic prototype species in the *Lyssavirus* Genus formerly referred to as 'classical rabies virus, genotype-1', is found worldwide in most parts of the world, and is responsible for the vast majority of reported animal and human rabies cases. The most common source of exposure of humans to rabies virus is the dog.

Other *Lyssavirus* species have more restricted geographical and host range, with the majority having been isolated from bats, with limited public and animal health implications.

The aim of this chapter is to mitigate the risk of infection with rabies virus to the public and animal health and to prevent the international spread of rabies virus.

Official control programmes to reduce the economic and public health burden of rabies are recommended, even in those countries where only haematophagous bat-mediated rabies or wild carnivore-mediated rabies are present.

The incubation period for rabies is highly variable depending on viruses, hosts and sites of entry, and the majority of cases infected animals will develop disease within six months of exposure.

The infective period for rabies virus is variable and can start before the onset of clinical signs. In dogs, cats and ferrets virus shedding can start up to ten days before the onset of the first clinical signs and through last until death.

~~Official control programmes to reduce the economic and public health burden of the disease are recommended even in those countries where only haematophagous bat-mediated rabies or wild carnivore-mediated rabies are present.~~

~~The aim of this chapter is to mitigate the risk of rabies to human and animal health and to prevent the international spread of rabies virus.~~

For the purposes of the *Terrestrial Code*:

- 1) rabies is a disease caused by one member of the *Lyssavirus* genus: the *Rabies virus* (formerly referred to as classical rabies virus, genotype-1); all mammals are susceptible to infection;
- = a case is any animal infected with the rabies virus species;
- = dog-mediated rabies is defined as any infection with case caused by rabies virus maintained in the dog population (*Canis familiaris*) independently of other animal reservoir species, as determined by epidemiological studies;
- = the incubation period of infection with rabies virus shall be six months.

Globally, the most common source of exposure of humans to rabies virus is the dog. Other mammals, particularly members of the Orders Carnivora and Chiroptera, also present a risk.

Annex 11 (contd)

The aim of this chapter is to mitigate the risk of rabies to human and animal health and to prevent the international spread of the disease.

~~For the purposes of the *Terrestrial Code*, a country that does not fulfil the requirements in Article 8.14.3 is considered to be infected with Rabies virus.~~

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

Article 8.14.2.

Control of rabies in dogs

~~In order to minimise public health risks due to rabies, and eventually eradicate rabies in dogs, *Veterinary Authorities* should implement the following:~~

- ~~1) rabies should be notifiable in the whole country and any change in the epidemiological situation or relevant events should be reported in accordance with Chapter 1.1.;~~
- ~~2) an effective system of *disease surveillance* in accordance with Chapter 1.4. should be in operation, with a minimum requirement being an ongoing early detection programme to ensure investigation and reporting of suspected cases of rabies in animals;~~
- ~~3) specific regulatory measures for the prevention and control of rabies should be implemented consistent with the recommendations in the *Terrestrial Code*, including *vaccination*, identification and effective procedures for the importation of dogs, cats and ferrets;~~
- ~~4) a programme for the management of *stray dog* populations consistent with Chapter 7.7. should be implemented and maintained.~~

Article 8.14.2~~3~~.**Rabies-free Country or zone free from infection with rabies virus**

- 1) A country or zone may be considered free from infection with rabies virus when:
 - a) the disease *infection with rabies virus* is a notifiable disease in the entire country and any change in the epidemiological situation or relevant events are reported in accordance with Chapter 1.1.;
 - b) all susceptible animals showing clinical signs suggestive of rabies are subjected to appropriate field and laboratory investigations;
 - c) an ongoing system of *disease surveillance* in accordance with Chapter 1.4. and Article 8.14.9. has been in operation place for the past two years 24 months, with a minimum requirement being an ongoing early warning system detection programme to ensure investigation and reporting of animals suspected of being infected rabies suspect animals;
 - d) regulatory measures for the prevention of infection with rabies virus are implemented consistent in accordance with the relevant recommendations in the *Terrestrial Code* including Articles 8.14.4. to 8.14.7.; including for the importation of animal;
 - e) no case of indigenously acquired infection with rabies virus ~~infection~~ has been confirmed during the past two years 24 months;
 - f) if an imported case is confirmed outside a quarantine station, epidemiological investigations have ruled out the possibility of secondary cases.

- 2) Preventive vaccination of at-risk animals does not affect the rabies free status.
- 3) An imported human case of rabies does not affect the rabies free status.

Article 8.14.2bis.

Country or zone infected with rabies virus

A country or zone that does not fulfil the requirements of Article 8.14.2. is considered to be infected with rabies virus.

Article 8.14.2ter.

Country or zone free from dog-mediated rabies

- 1) A country or zone may be considered free from dog-mediated rabies when:
 - a) dog-mediated rabies is a notifiable disease in the entire country and any change in the epidemiological situation or relevant events are reported in accordance with Chapter 1.1.;
 - b) an ongoing system of surveillance in accordance with Chapter 1.4. and Article 8.14.9. has been in place for the past 24 months, with a minimum requirement being an early warning system to ensure control, investigation and reporting of animals suspected of infection with rabies virus;
 - c) regulatory measures for the prevention of infection with rabies virus are implemented in accordance with the relevant recommendations in the Terrestrial Code and including Articles 8.14.94. to 8.14.7.;
 - d) no case of indigenously acquired dog-mediated rabies has occurred during the past 24 months;
 - e) a dog population control programme for the management of stray dog populations is has been implemented and maintained in accordance with Chapter 7.7.
- 2) The following do not affect the status of a country or zone free from dog-mediated rabies:
 - preventive vaccination;
 - presence of rabies virus in wildlife animals;
 - imported human cases of rabies.

Article 8.14.34.

Recommendations for importation of domestic and captive wild mammals from countries or zones free from infection with rabies virus free countries

For domestic mammals, and captive wild mammals

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

- 1) showed no clinical sign of rabies the day prior to or on the day of shipment;
- 2) and either:
 - a) were kept since birth or at least six months prior to shipment in a free country or zone; or
 - b) were imported in accordance with ~~the regulations stipulated in Articles 8.14.56., 8.14.67., or 8.14.78. or 8.14.9.~~

Annex 11 (contd)

Article 8.14.45.

Recommendations for importation of wild and feral mammals from ~~rabies-free countries~~ or zones free from infection with rabies virusFor wild mammals

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

- 1) showed no clinical sign of rabies the day prior to or on the day of shipment;
- 2) and either:
 - a) have been captured at a distance that precludes any contact with animals in an infected country or zone. The distance should be defined in accordance with the biology of the species exported, including home range and long distance movements; or
 - b) have been kept in captivity for the six months prior to shipment in a country or zone free from infection with rabies virus free country.

Article 8.14.56.

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

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

- 1) showed no clinical sign of rabies the day prior to or on the day of shipment;
- 2) were permanently identified and their identification number stated in the *certificate*;
- 3) and either:
 - a) were vaccinated or revaccinated not more than 12 months prior to shipment in accordance with the recommendations of the manufacturer. ~~The~~ with a vaccine should have been that was produced and used in accordance with the *Terrestrial Manual*, and They were subjected not less than 1 & one months and not more than 12 months prior to shipment after the last vaccination to an antibody titration test as prescribed in the *Terrestrial Manual* with a positive result of at least 0.5IU/ml;

OR

- b) were kept in a *quarantine station* for six months prior to export.

Article 8.14.67.

Recommendations for importation of other susceptible animals ~~domestic ruminants, equids, camelids and suids~~ members of the order Carnivora and of members of the order Chiroptera from countries or zones ~~considered~~ infected with rabies virus

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

- 1) showed no clinical sign of rabies on the day prior to or on the day of shipment;

Annex 11 (contd)

- 2) were permanently identified and the identification number stated in the *certificate*;
- 23) **either** EITHER
- a) were kept for the 6 months prior to shipment in an *establishment* where **separation from susceptible animals was maintained and where** there has been no case of *rabies* for at least 12 months prior to shipment.;
- OR**
- b) were vaccinated or revaccinated in accordance with the recommendations of the manufacturer. The vaccine was produced and used in accordance with the *Terrestrial Manual*.;
- 3) **if domestic animals, were permanently identified and the identification number stated in the *certificate*.**

Article 8.14.78.

Recommendations for importation of **susceptible laboratory animals from countries **or zones** considered infected with *rabies virus***

For rodents and lagomorphs born and reared in a biosecure facility

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

- 1) showed no clinical sign of *rabies* the day prior to or on the day of shipment;
- 2) were born and kept since birth in a biosecure facility as described in the *Terrestrial Manual* Chapter 1.1.4 on Management of veterinary diagnostic laboratories, and where there has been no case of *rabies* for at least 12 months prior to shipment.

Article 8.14.8.

OIE endorsed official control programme for dog-mediated rabies

The overall objective of an OIE endorsed *official control programme* for dog-mediated rabies is for Member Countries to progressively improve their dog-mediated rabies situation and eventually be able to make a self-declaration in accordance with Chapter 1.6. as a country free from dog-mediated rabies. The *official control programme* should be applicable to the entire country even if certain measures are directed towards defined *subpopulations* only.

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

For its *official control programme* for dog-mediated rabies to be endorsed by the OIE, the Member Country should:

- 1) have a record of regular and prompt animal disease reporting in accordance with Chapter 1.1.;
- 2) submit documented evidence (including relevant legislation) of the capacity of the *Veterinary Services* to control dog-mediated rabies. This evidence may be provided using data generated by the OIE PVS Pathway;
- 3) submit a detailed plan of the programme to control and eventually eradicate dog-mediated rabies in the country **or zone** including:

Annex 11 (contd)

- a) the timeline;
 - b) the performance indicators for assessing the effectiveness of the control measures to be implemented;
 - c) documentation indicating that **dog-mediated rabies is a notifiable disease and that the official control programme** for dog-mediated rabies is applicable to the entire country;
- 4) submit a dossier on dog-mediated rabies in the country describing the following:
- a) the general epidemiology in the country highlighting the current knowledge and gaps in knowledge and the progress that has been made in controlling dog-mediated rabies;
 - b) the measures implemented to prevent introduction of *infection*;
 - bbis) the rapid detection of, and response to, dog-mediated rabies cases, to reduce the *incidence* and to eliminate transmission in at least one *zone* in the country;**
 - c) dog population **management including stray dog control programme in accordance with Chapter 7.7.**
 - d) collaboration agreements or programmes with other *Competent Authorities* such as those responsible for public health and management of *wild and feral animals*;
- 5) submit evidence that *surveillance* of dog-mediated rabies is in place:
- a) by taking into account provisions in Chapter 1.4. and Article 8.14.9.;
 - b) by having diagnostic capability and procedures, including regular submission of samples to a *laboratory* that carries out diagnosis to support epidemiological investigation;
- 6) where *vaccination* is practised as part of the *official control programme* for dog-mediated rabies, provide:
- a) evidence (such as copies of legislation) that *vaccination* of selected populations is compulsory and **the vaccines are produced** in accordance with the *Terrestrial Manual*;
 - b) detailed information on *vaccination* campaigns, in particular on:
 - i) target *populations*;
 - ii) monitoring of *vaccination* coverage;
 - iii) technical specifications of the vaccines used and description of the regulatory procedures in place;
- 7) provide preparedness and contingency plans.

The Member Country's *official control programme* for dog-mediated rabies will be included in the list of programmes endorsed by the OIE only after the submitted evidence, based on the provisions of Article 1.6.Xbis, has been accepted by the OIE. Retention on the list requires an annual update on the progress of the *official control programme* and information on significant changes concerning the points above. Changes in the epidemiological situation and other significant events should be reported to the OIE in accordance with Chapter 1.1.

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

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

Article 8.14.9.

Recommendations for importation of wildlife from countries considered infected with rabies

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

- 1) ~~showed no clinical sign of rabies the day prior to or on the day of shipment;~~
- 2) ~~were kept for the six months prior to shipment in an establishment where separation from susceptible animals was maintained and where there has been no case of rabies for at least 12 months prior to shipment.~~

Article 8.14.9.

General principles of surveillance

- 1) A Member Country should justify the surveillance strategy chosen in accordance with Chapter 1.4., as being adequate to detect the presence of infection with rabies virus, given the prevailing epidemiological situation. Surveillance should be under the responsibility of the Veterinary Authority.

For the purposes of rabies surveillance a suspected case is a susceptible animal that shows any change in behaviour followed by death within ten days or that displays any of the following clinical signs: hypersalivation, paralysis, lethargy, abnormal aggression, abnormal vocalisation.

In particular, Member Countries should have in place:

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

Rabies surveillance provides data that are indicators of the effectiveness of a rabies control programme and of the maintenance of freedom of infection with rabies virus in a country or zone.

- 2) In addition to principles in Chapter 1.4. the following are critical for rabies surveillance:

- a) Public awareness

The Veterinary Services should implement programmes to raise awareness among the public, as well as veterinary paraprofessionals, veterinarians and diagnosticians, who should report promptly any cases or suspected cases.

- b) Clinical surveillance

Clinical surveillance is a critical component of rabies surveillance and essential for detecting suspected cases. Therefore, a process should be in place and documented for the identification and investigation of suspected cases as well as for sample collection for laboratory diagnosis when rabies cannot be ruled out. Animals (especially carnivores and bats) found dead are recognised as an important source of information for rabies surveillance and should be part of the clinical surveillance.

Laboratory testing should use the recommended sampling techniques, types of samples and tests described in the Terrestrial Manual.

Annex 11 (contd)c) Sampling

Surveillance should target suspected cases. Probability sampling strategies are not always useful, as sampling of healthy animals (e.g. not involved in human exposure) rarely returns useful surveillance data.

d) Epidemiological investigation

In all situations, especially in countries or zones considering self-declaration of freedom, routine epidemiological investigation of cases and molecular characterisation of virus isolates from human and animal cases is encouraged. Such an investigation allows identification of sources of infection, their geographic origin and their epidemiological significance.

e)Article 8.14.10.**Cooperation with other Competent Authorities**

The Veterinary Authority should coordinate in a timely manner with public health and other Competent Authorities and share information to support the decision-making process for the management of human and animal exposure.

In all regions, Veterinary Authorities of neighbouring countries should cooperate in the control of dog-mediated rabies.

CHAPTER 15.1.

INFECTION WITH AFRICAN SWINE FEVER VIRUS

[...]

Article 15.1.1-bis**Safe commodities**

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

1) canned meat in a hermetically sealed container with a F₀ value of 3.00 or more above;

2) gelatine.

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

Article 15.1.2.

General criteria for the determination of the ASF status of a country, zone or compartment

- 1) ASF is a *notifiable disease* in the entire country, and all suids showing clinical signs suggestive of ASF are subjected to appropriate field and *laboratory* investigations;
- 2) an ongoing awareness programme is in place to encourage reporting of all suids showing signs suggestive of ASF;
- 3) the *Veterinary Authority* has current knowledge of, and authority over, all domestic and *captive wild pig herds* in the country, zone or compartment;
- 4) the *Veterinary Authority* has current knowledge of the species of *wild* and *feral* pigs and African *wild* suids present, their distribution and habitat in the country or zone;
- 5) for domestic and *captive wild* pigs, an appropriate *surveillance* programme in accordance with Articles 15.1.27. to 15.1.30. and 15.1.32. is in place;
- 6) for *wild* and *feral* pigs, and for African *wild* suids, if present in the country or zone, a *surveillance* programme is in place in accordance with Article 15.1.31., considering the presence of natural and artificial boundaries, the ecology of the *wild* and *feral* pig and African *wild* suid populations and an assessment of the likelihood of ASF spread including taking into account the presence of *Ornithodoros* ticks where relevant;
- 7) the domestic and *captive wild* pig populations are separated by appropriate *biosecurity*, effectively implemented and supervised, from the *wild* and *feral* pig and African *wild* suid populations, based on the assessed likelihood of spread within the *wild* and *feral* pig and African *wild* suid populations, and *surveillance* in accordance with Article 15.1.31.; they are also protected from *Ornithodoros* ticks where relevant.

~~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 this article, even if they notify infection with ASFV in wild or feral pigs or African wild suids.~~

Annex 12 (contd)

Article 15.1.3.

Country or zone free from ASF1. Historical freedom

A country or *zone* may be considered historically free from ASF without pathogen-specific *surveillance* if the provisions of point 1 a) of Article 1.4.6. are complied with, and pig commodities are imported in accordance with Articles 15.1.7. to 15.1.20.

2. Freedom in all suids

A country or *zone* which does not meet the conditions of point 1) above may be considered free from ASF in all suids when it complies with all the criteria of Article 15.1.2. and when:

- a) *surveillance* in accordance with Articles 15.1.27. to 15.1.32. has been in place for the past three years;
- b) there has been no *case of infection* with ASFV during the past three years; this period can be reduced to 12 months when the *surveillance* has demonstrated no evidence of presence or involvement of *Ornithodoros* ticks;
- c) pig *commodities* are imported in accordance with Articles 15.1.7. to 15.1.20.

3. Freedom in domestic and captive wild pigs

A country or *zone* which does not meet the conditions of point 1) or 2) above, including cases of infection with ASFV in feral or wild pigs, may be considered free from ASF in domestic and *captive wild* pigs when it complies with all the criteria of Article 15.1.2. especially point 7), and when:

- a) *surveillance* in accordance with Articles 15.1.27. to 15.1.32. has been in place for the past three years;
- b) there has been no *case of infection* with ASFV in domestic or *captive wild* pigs during the past three years; this period can be reduced to 12 months when the *surveillance* has demonstrated no evidence of presence or involvement of *Ornithodoros* ticks;
- c) pigs and pig *commodities* are imported in accordance with Articles 15.1.7. to 15.1.20.

Commodities of domestic or captive wild pigs can be traded safely in accordance with the relevant articles of this chapter from countries free from ASF in domestic and captive wild pigs, even if they notify infection with ASFV in wild or feral pigs or African wild suids.

[...]

Article 15.1.22.

Procedures for the inactivation of ASFV in meat

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

1. Heat treatment

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

- ~~a) heat treatment in a hermetically sealed container with a F0 value of 3.00 or more; or~~
- ~~b) heat treatment for at least 30 minutes at a minimum temperature of 70°C, which should be reached throughout the *meat*.~~

2. Dry cured pig meat

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

[...]