

MEETING OF THE OIE TERRESTRIAL ANIMAL HEALTH STANDARDS COMMISSION**Paris, 19–28 February 2019****List of participants****MEMBERS OF THE CODE COMMISSION**

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

ITALY

Tel.: +39 06 570 52447

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

Sidi Thabet -2020

TUNISIA

Tel.: + 216 71 552 200

Mail: hammami.salah@iresa.agrinet.tnMail: saleehammami@yahoo.fr**Dr Lucio Ignacio Carbajo Goñi***Attaché*Ministry of Agriculture, Food and Environment
Spanish Embassy in Brazil
SPAINMail: lcarbajo@mapama.esMail: lcg958@gmail.com**Dr Masatsugu Okita***2nd Vice-President*

Director

International Animal Health Affairs Office
Animal Health Division
Ministry of Agriculture, Forestry and Fisheries
1-2-1 Kasumigaseki

Chiyoda-ku

Tokyo 100-8950

JAPAN

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

1050 Brussels

BELGIUM

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

BRAZIL

Mail: bernardo.todeschini@agricultura.gov.br**OIE HEADQUARTERS**

Dr Gillian Mylrea

Head

Standards Department

Mail: g.mylrea@oie.int**Dr Charmaine Chng**

Chargée de mission

Standards Department

Mail : c.chng@oie.int**Dr Francisco D'Alessio**

Deputy head

Standards Department

Mail: f.dalessio@oie.int**Dr Kiyokazu Murai**

Chargé de mission

Standards Department

Mail: k.murai@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. Performance Management Framework**
- 3. Adoption of agenda**
- 4. Cooperation with other Specialist Commissions**
- 5. Texts to be proposed for adoption at the General Session in May 2019**
 - 5.1. Glossary
 - 5.2. Animal health surveillance (Chapter 1.4)
 - 5.3. Draft new chapter on introduction to recommendations for the prevention and control of transmissible animal diseases (Chapter 4.Z)
 - 5.4. The role of the Veterinary Services in food safety systems (Articles 6.2.3, 6.2.4)
 - 5.5. Guiding principles for the use of measures to assess animal welfare (Article 7.1.4)
 - 5.6. Animal welfare and pig production systems (Articles 7.13.4. and 7.13.15.)
 - 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 *Chlamydomphila abortus* (Enzootic abortion of ewes, ovine chlamydiosis) (Article 14.4.1)
 - 5.10. Infection with African swine fever virus (Articles 15.1.1bis, 15.1.2, 15.1.3, 15.1.16, 15.1.22, 15.1.31)
- 6. Texts circulated for Member Country comments**
 - 6.1. Glossary
 - 6.2. Notification of diseases, infections and infestations, and provision of epidemiological information (Chapter 1.1)
 - 6.3. Procedures for self-declaration and for official recognition by the OIE (Chapter 1.6)
 - 6.4. Veterinary legislation (Chapter 3.4)
 - 6.5. Draft new chapter on official control programmes for listed and emerging diseases (Chapter 4.Y)
 - 6.6. Draft new chapter on animal welfare and laying hen production systems (Chapter 7.Z)
 - 6.7. Infection with avian influenza viruses (Chapter 10.4)
 - 6.8. Infection with classical swine fever virus (Chapter 15.2)

Annex 2 (contd)**7. New amendments or draft new chapters proposed for Member Country comments**

- 7.1. User's Guide
- 7.2. Infection with *Mycobacterium tuberculosis* complex (Chapter 8.11)
- 7.3. Infection with Rift Valley fever virus (Chapter 8.15)
- 7.4. Infection with equine influenza (Article 12.6.6)
- 7.5. Infection with peste des petits ruminants virus (Articles 14.7.3, 14.7.34)

8. Other ongoing topics

- 8.1. Veterinary Services (Chapter 3.1) and Evaluation of Veterinary Services (Chapter 3.2)
- 8.2. Update on the work on semen and embryos (Chapters 4.5 to 4.9)
- 8.3. Update on the outcomes of the second *ad hoc* Group meeting on the revision of Chapter 7.5 slaughter of animals and Chapter 7.6 killing of animals for disease control purposes
- 8.4. Draft Terms of Reference for an *ad hoc* Group on the revision of Chapter 7.7. Stray dog population control
- 8.5. Infection with rinderpest virus (Chapter 8.16)
- 8.6. Outcomes of three *ad hoc* Group meetings on the revision of BSE chapter (Chapter 11.4)
- 8.7. New/revised articles for the temporary movement of horses
- 8.8. Outcomes of the *ad hoc* Group on animal trypanosomoses
- 8.9. Harmonisation of *Terrestrial Code* chapters for diseases with OIE official status recognition
- 8.10. Establishment of a Standard Operating Procedure guiding listing decisions for pathogenic agents
- 8.11. Consideration of specified dairy products as safe commodities
- 8.12. Control of Shiga toxin-producing *E. coli* (STEC) in food-producing animals
- 8.13. Update on standards for pet food

9. New topics

- 9.1. Responsible and prudent use of antimicrobial agents in veterinary medicine (Chapter 6.10)
- 9.2. Update on OIE Curricula Guidelines for Veterinary Paraprofessionals

10. Applications for OIE Collaborating Centres**11. Update on the Code Commission's work programme****12. Date of next meeting**

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 4 (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 4 (contd)

- husbandry practices and production systems;
- disease prevention and control measures (e.g. vaccination, restocking after disinfection);
- accessibility of target *population*;
- geographical factors;
- environmental factors, including climate conditions.

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 use of tests for 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 to rapid field and detailed laboratory assays.

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

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

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 4 (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** **target species** 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:

Annex 4 (contd)

- 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 4 (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 from 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 from a target *population* to have a representative sample, 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*.

When the objective of non-probability-based sampling is to maximise the likelihood of detection of the *infection* or *infestation*, this type of sampling may not be 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*.

When using non-probability-based sampling, representativeness can only be achieved if *risk* factors are weighted and the weights are supported by relevant scientific evidence capturing the relative differences in *risk* and proportion between the study *population* and the target *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 a risk assessment and are useful to optimise the use of *surveillance* resources.

4. Ante-mortem and post-mortem inspections

Inspection of *animals* at *slaughterhouses/abattoirs* may provide valuable *surveillance* data. The sensitivity and specificity of *slaughterhouse/abattoir* inspections 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 inspections, 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.

Annex 4 (contd)

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.

Post-mortem inspection conducted in locations other than *slaughterhouses/abattoirs* (e.g. rendering plants, hunting places) may also provide valuable *surveillance* data.

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.

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 Sentinel units

Surveillance of Sentinel 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, disease, *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. Awareness and training of potential field observers, including animal keepers, in the application of the case definition and reporting is are 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.

840. 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.

Annex 4 (contd)

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 disease, infection or infestation, and may allow certain studies to be conducted more quickly and at lower cost than other approaches.

da) 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.

ec) 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.

ed) 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.

Annex 4 (contd)

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.

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.

- e) 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 access to, and authority over, of the 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 animal owners or keepers and others involved in handling animals at the farm or other places where they are kept during their transport or at 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 cases 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;

Annex 4 (contd)

- ≡ biosecurity to be observed when entering and leaving the establishment, premises or locality;
 - ≡ clinical examinations to be undertaken (number and types of animals);
 - ≡ samples to be taken from animals showing signs or not (number and types of animals), with specified sampling and sample handling equipment and sample handling procedures, including for the safety of the investigator and animal owners;
 - ≡ procedure for submitting samples for testing;
 - ≡ size of the affected establishment, premises or locality and possible entry pathways;
 - ≡ investigation of the approximate numbers of similar or possibly susceptible animals in the establishment and its surroundings;
 - ≡ details of any recent movements of possibly susceptible animals or vehicles or people to or from the affected establishments, premises or locality;
 - ≡ any other relevant epidemiological information, such as presence of the suspected disease in wildlife or abnormal vector activity;
 - ≡ 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 **disease**, 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 **disease**, *infection* and *infestation* should meet the following, in addition to the general principles outlined in Article 1.4.3. It should also take into account any prevention measures in place such as vaccination in accordance with this chapter and Chapter 4.17.

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^s of the *Terrestrial Code*.

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. The implications consequences for the status of domestic animals of when of the presence of *infection* or *infestation* is present in *wildlife* in the same country or zone on the status of domestic animals should be assessed in each situation, as indicated described in the relevant chapters of the *Terrestrial Code*.

Evidence from probability-based and non-probability 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 chapters 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; in particular, the importations or movements of *commodities* into the country or zone have been carried out in accordance with the relevant chapters of the *Terrestrial Code*;
- 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) A pathogen-specific *surveillance programme* 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*.
- ii) The prerequisites listed in point a) have been complied with for at least as long as the pathogen-specific *surveillance* has been in place.

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;

Annex 4 (contd)

~~ba)~~ ~~ongoing~~ A pathogen-specific surveillance programme 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*.

~~b)~~ The prerequisites listed in points 2 a)i) to iii) have been complied with for at least as long as the pathogen-specific surveillance has been in place.

4. Recommendations for the maintenance of freedom from a disease, 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:

- 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 ~~g40~~ 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.

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 THE DISEASE PREVENTION AND CONTROL OF TRANSMISSIBLE ANIMAL DISEASES

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 in 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 links s 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 6.2.

THE ROLE OF THE VETERINARY SERVICES IN FOOD SAFETY SYSTEMS

[...]

Article 6.2.3.

Characteristics of a food safety system

1. Food chain approach

Food safety is best assured by an integrated, multidisciplinary approach that considers the entire food chain. A food safety system should take into account the complexity of food production and the globalisation of the food supply, and should be risk-based. It should consider *hazards* and potential associated *risks* at each stage of the food chain, i.e. primary production, transport, processing, storage and distribution, and integrate *risk management* responses to such *risks* at the most appropriate points along the food chain.

The prevention, detection, and control of foodborne *hazards* throughout the food chain is generally more effective in reducing or eliminating the *risk* of unwanted health effects than relying on controls of the final product. The application of traceability systems and sharing food chain information enhance the effectiveness of a food safety system. Everyone involved in the food chain, including food business operators, *Veterinary Services* and consumers, has a responsibility to ensure that food is safe.

2. Risk-based food safety systems

Risk-based food safety systems include measures based on good practices (such as good agricultural practice, good hygienic practice), hazard analysis and critical control points (HACCP) principles and *risk analysis*. The design and application of a risk-based food safety system depends on the availability of adequate scientific information and effective utilisation of the technical resources of food business operators and *Competent Authorities*.

Monitoring food safety outcomes and reviewing control measures are essential to ensure the effective performance of a risk-based food safety system. For example, providing information on the occurrence of *infections* on the farm prior to dispatch of animals for *slaughter* may allow more targeted, risk-based inspection at the *slaughterhouse/abattoir*.

3. Responsibilities of food business operators for food safety

Food business operators, including *feed* producers, farmers, processors, wholesalers, distributors, importers, exporters and retailers, have primary responsibility for ensuring the safety of their products and should be able to demonstrate that they comply with relevant food safety regulatory requirements. Food business operators have a responsibility to inform the *Competent Authority* in their country of any non-compliance associated with their product and take action to manage the *risk* e.g. the withdrawal of the product.

4. Responsibilities of the relevant Competent Authorities

Competent Authorities are responsible for developing policies, legislation and regulations relevant to food safety. They should also take steps to communicate these within their country and with trading partners.

Competent Authorities should ensure that roles and responsibilities for food safety systems, including responses to foodborne disease *outbreaks*, are addressed in a coordinated manner.

Annex 6 (contd)

The relevant *Competent Authorities* should verify that the control systems used by food business operators are appropriate, validated and effective, and operated in such a way that the regulatory requirements are met. This can be achieved through activities such as inspection and audit. In the event of noncompliance, appropriate corrective actions and sanctions should be applied.

If the *Competent Authority* delegates some control responsibilities to a third party, it should **regularly** assess **regularly** that third party's competency.

Article 6.2.4.

Roles and responsibilities of Veterinary Services in a food safety system1. 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 a** 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 *Veterinary Services* also play a key role** 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.

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 *animal* 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

- 1) For the OIE animal welfare standards to be applicable globally, they should emphasise favourable outcomes for the animals, although, in some circumstances, it may be necessary to recommend specific conditions of the animals' environment and management. Outcomes are generally measured by assessing the extent to which animals experience the "five freedoms" described in Article 7.1.2.
- 2) For each principle listed in Article 7.1.5., the most relevant criteria (or measurables), ideally comprising animal-based measures, should be included in the standard. Any given animal-based measure may be linked to more than one principle.
- 3) Recommendations should, whenever possible, define explicit targets or thresholds that should be met for animal-based measures. Such target values should be based on relevant science and experience of experts.
- 4) In addition to animal-based measures, resource-based measures and management-based measures may be used and should be defined on the basis of science and expert experience showing that a welfare outcome is clearly linked to a resource or to a management procedure.
- 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 data relevant data that can be use for the users to set target and threshold values.
- 6) Whatever the basis of the measure, if outcomes are unsatisfactory, users should consider what changes to resources or management are necessary to improve outcomes.

[...]

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.

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.

[...]

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 9 (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.

43. Behaviour ~~Behavioural~~ Considerations for handling, restraining, stunning and killing

Handling, restraining, stunning and killing methods should take into account the following specific reptile behaviours characteristics of reptiles 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 injuries bite wounds to handlers, and via bite wounds, frequently with wound infection, constriction, blunt trauma 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;
- propensity to regurgitate and choke when restrained inappropriately.

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).

Reptiles should be accompanied by relevant documentation related to the their 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;
- = the extent to which movement of the reptile can be restricted during the killing process;
- 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 a reptile, animal animals or humans;
- ability to maintain equipment in proper working order;
- cost of the method.

The killing process used should:

- minimise avoid excitement agitation, fear, and stress, and pain to the reptiles 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.

Annex 9 (contd)

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*.

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 in species where eyelids are present;
- spontaneous eyelid opening or closing in species where eyelids are present;
- 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.6Z.

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.

Annex 9 (contd)

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;
- avoid taping or binding the legs or feet of the animals reptiles 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;
- minimise 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.

Annex 9 (contd)

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.45-16.).

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 at a suitable frequency to through electrodes for the purpose of causing immediate unconsciousness that lasts until *death*.

Recommendations for effective use of electrical stunning 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.45-16. 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 species, size and type ~~species 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*.

Annex 9 (contd)

Recommendations for the effective use of a penetrative captive bolt 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, size and type 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.5-6.

Article 7.Y.4-11.

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.9-10. to 7.Y.16. should be used immediately to assure *death*.

Recommendations for an effective use of non-penetrative captive bolt 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 the 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, size and type of ~~animal~~ the reptile;
- equipment should be cleaned, maintained and stored, ~~preferably~~ following manufacturer's recommendations.

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

Article 7.Y.4-12.

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.9-10. 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 crocodilians), this method may be difficult to apply and in such cases, other stunning and killing methods should preferentially be used.

Annex 9 (contd)

Recommendations for effective use of percussive blow to the head 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, size and type of ~~animal~~ the reptile.

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

Article 7.Y.4213.

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 of gunshot in relation to *animal welfare* are:

- accurate targeting of the brain should be ensured;
- selected firearm and projectile should be suitable for the species, size and type 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.4314.

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 of pithing in relation to *animal welfare* are:

- pithing 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.4415.

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~~.

Annex 9 (contd)

Recommendations for effective use of decapitation or spinal cord severance in relation to *animal welfare* are:

- decapitation or spinal cord severance should only be used on unconscious ~~animal~~ reptiles;
- decapitation or spinal cord severance 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.4516.

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.910. to 7.Y.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 of chemical agents in relation to *animal welfare* are:

- ensure proper physical restraint is used for administration;
- ensure chemicals and dosages used are appropriate for the species and size of animal the 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.56.

Article 7.Y.4617.

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.910. to 7.Y.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 (N₂),
- use of paralyzing neuro-muscular blocking ~~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 can cause clinical signs similar to those caused by rabies virus, but have more restricted geographical and host range, with the majority having been isolated only from bats, with thus having 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 posed by infection with rabies virus 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 lupus 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 10 (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 8.14.23.

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:
 - a4) it has a record of regular and prompt animal disease reporting in accordance with Chapter 1.1.;
 - b) 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.;
 - bc) all susceptible animals showing clinical signs suggestive of rabies are subjected to appropriate field and laboratory investigations;
 - e2d) 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;
 - e3e) 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;
 - e4f) no case of indigenously acquired *infection with rabies virus* ~~*infection*~~ has been confirmed during the past two years 24 months;

Annex 10 (contd)

- 5) ~~no imported case in the Orders Carnivora or Chiroptera has been confirmed outside a quarantine station for the past six months.~~
- fg)** 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 8.14.2.-bis

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 8.14.2.-ter

Country or zone free from dog-mediated rabies

- 1) A country or zone may be considered free from dog-mediated rabies when:
- a)** it has a record of regular and prompt animal disease reporting in accordance with Chapter 1.1.;
 - b)** 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.;
 - bc)** 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;
 - ed)** 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.;
 - de)** no case of indigenously acquired dog-mediated rabies has occurred during the past 24 months;
 - ef)** 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.;
 - =** imported case outside a quarantine station whenever epidemiological investigations have ruled out the possibility of secondary cases.

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

Annex 10 (contd)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.~~

Article 8.14.45.

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

For 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 and were subjected not less than 1 3 one 3 months and not more than 12 months prior to shipment after the last vaccination prior to shipment 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 shipment.

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~~ **mammals** 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;
- 2) were permanently identified and the identification number stated in the *certificate*;
- 23) ~~either~~ 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 **OR for mammals for which vaccines and protocols are applicable:**
 - 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*;~~
 - b) were vaccinated or revaccinated in accordance with the recommendations of the manufacturer, with a vaccine that was produced 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 4.1.1 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:

Annex 10 (contd)

- 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 **its 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:
 - 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*;
 - bis*) 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 quality of the Veterinary Services as per Section 3 of the Terrestrial Code; 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 from 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.

Annex 10 (contd)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*.

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 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 1.3.

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

[...]

Article 1.3.3.

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

- Caprine arthritis/encephalitis
- Contagious agalactia
- Contagious caprine pleuropneumonia
- Infection with ~~*Chlamydothrix*~~ *Chlamydia abortus* (Enzootic abortion of ewes, ovine chlamydiosis)
- Infection with peste des petits ruminants virus
- Maedi–visna
- Nairobi sheep disease
- Ovine epididymitis (*Brucella ovis*)
- Salmonellosis (*S. abortusovis*)
- Scrapie
- Sheep pox and goat pox.

[...]

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 of suids 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 **or pathological lesions** 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 **clinical** signs **or pathological lesions** 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 13 (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 of suids are imported in accordance with the relevant Articles 15.1.7. to 15.1.20 of this chapter.

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 of suids are imported in accordance with the relevant Articles 15.1.7. to 15.1.20 of this chapter.

3. Freedom in domestic and captive wild pigs

A country or *zone* which does not meet the conditions of point 1) or of point 2) b) above, including i.e. when there are cases of infection with ASFV in feral or wild pigs suids, 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 of suids are imported in accordance with the relevant Articles 15.1.7. to 15.1.20 of this chapter.

~~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 15.1.16.

Recommendations for the importation of meat products of pigs

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

- 1) have been prepared:
 - a) exclusively from *fresh meat* meeting the relevant conditions in Articles 15.1.13., 15.1.14. and 15.1.15.;

Annex 13 (contd)

- b) in a processing facility:
- i) approved by the *Veterinary Authority* for export purposes;
 - ii) processing only *meat* meeting the relevant conditions in Articles 15.1.13. or Article 15.1.14. and 15.1.15.;

OR

- 2) have been processed in a facility approved by the *Veterinary Authority* for export purposes so as to ensure the destruction of ASFV in accordance with Article 15.1.22., and that the necessary precautions were taken after processing to avoid contact of the product with any source of ASFV.

[...]

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) a) heat treatment for at least 30 minutes at a minimum temperature of 70°C, which should be reached throughout the *meat*. or~~
- b) any equivalent heat treatment which has been demonstrated to inactivate ASFV in *meat*.

2. Dry cured pig meat

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

[...]

Article 15.1.31.

Surveillance for ASFV in wild and feral pigs and African wild suids

- 1) The objective of a *surveillance* programme is either to demonstrate that *infection* with ASFV is not present in *wild* and *feral* suids or, if known to be present, to estimate the geographical distribution of the *infection*.

Surveillance in *wild* and *feral* suids presents additional challenges including:

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

The geographic distribution and estimated size of *wild* and *feral* suid populations should be assessed as a prerequisite for designing a population monitoring system following Chapter 1.4.

Annex 13 (contd)

- 2) For implementation of the *surveillance* programme, the limits of the area over which *wild* and *feral* pigs range should be defined. *Subpopulations* of *wild* and *feral* suids may be separated from each other by natural or artificial barriers.
- 3) The *surveillance* programme **may should** include animals found dead, road kills, animals showing abnormal behaviour and hunted animals, and **may should** also include awareness campaigns targeted at hunters and farmers.
- 4) There may be situations where a more targeted *surveillance* programme can provide additional assurance. The criteria to define high risk areas for targeted *surveillance* include:
 - a) areas with past history of ASF;
 - b) subregions with large populations of *wild* or *feral* pigs or African *wild* suids;
 - c) border regions with ASF affected countries or *zones*;
 - d) interface between *wild* and *feral* pig populations, and domestic and *captive wild* pig populations;
 - e) areas with farms with free-ranging and outdoor pigs;
 - f) areas with a high level of hunting activity, where animal dispersion and feeding as well as inappropriate disposal of waste can occur;
 - g) other risk areas determined by the *Veterinary Authority* such as ports, airports, garbage dumps and picnic and camping areas.

[...]
