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*, 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 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*.

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. This may be an individual *animal* or a group of *animals*, such as an *epidemiological unit*.

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 and the degree to which the *subpopulation* is representative of the target *population* stated.

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

b) Timing and temporal validity of surveillance data

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

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

c) Case definition

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

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.

f) Diagnostic tests

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

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

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

g) Analytical methodologies

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

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

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

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

h) Scope of the surveillance system

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

i) Follow up actions

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

2. Implementation of the surveillance system

a) Diagnostic tests

The sensitivity and specificity values of the tests used should be specified for target species and the method used to estimate these values should be documented in accordance with the *Terrestrial Manual*.

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

b) Data collection and management

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

– the distribution of, and communication between, those involved in generating and transferring data from the field to a centralised location; this requires effective collaboration among all stakeholders, such as government or non-governmental organisations, and others, particularly for data involving *wildlife*;

– the ability of the data processing system to detect missing, inconsistent or inaccurate data, and to address these problems;

– maintenance of raw data rather than the compilation of summary data;

– minimisation of transcription errors during data processing and communication.

3. Quality assurance

Surveillance systems should be subjected to periodic auditing to ensure that all components function and provide verifiable documentation of procedures and basic checks to detect 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 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 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. 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.

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) Sampling

i) Objective

The objective of sampling from a *population* is to select a subset of *units* 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*.

When selecting *units* 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 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*.

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;
  - 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 and 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 sampling 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 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.

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. 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*.

6. Clinical 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 are important. Ideally, both the number of positive observations and the total number of observations should be recorded.

7. Syndromic 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*.

8. Other useful data

a) Data generated by control programmes and health schemes

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

b) Laboratory investigation records

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

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

c) Biological specimen banks

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

d) Wildlife data

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

e) 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.

f) 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.

g) Additional supporting data such as:

i) data on the epidemiology of the *infection* or *infestation*, including host *population* distribution;

ii) data on animal movements, including transhumance and natural *wildlife* migrations;

iii) trading patterns for *animals* and animal products;

iv) national animal health regulations, including information on compliance and effectiveness;

v) history of imports of potentially infected material;

vi) *biosecurity* in place; and

vii) the *risk* of introduction of *infection* or *infestation*.

9. Combination and interpretation of surveillance results

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

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

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

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

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

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 access to, and authority over, the target *animal populations* by the *Veterinary Services*;

2) access to *laboratories* capable of diagnosing and differentiating relevant *infections* or *infestations*;

3) training and awareness programmes for *veterinarians*, *veterinary paraprofessionals*, *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*, including the description of the findings;

5) epidemiological investigations of suspected *cases* and *cases* conducted by the *Veterinary Services* in order to confirm *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*;

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

7) a national chain of command.

Article 1.4.6.

Surveillance for freedom from a disease, infection or infestation

1. Demonstration of freedom

   A *surveillance* system to demonstrate freedom from a 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 4.18.

   Freedom implies the absence of *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 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 chapters of the *Terrestrial Code*.

   It can be difficult to collect sufficient epidemiological data to demonstrate 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 consequences of the presence of *infection* or *infestation* in *wildlife* in the same country or *zone* on the status of domestic *animals* should be assessed in each situation, as described in the relevant chapters of the *Terrestrial Code*.

   Evidence from probability and non-probability risk-based data collection may increase the sensitivity of the *surveillance*.

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) 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;

      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*.

   c) Where historical freedom cannot be demonstrated:

      i) A pathogen-specific *surveillance* programme has been applied as described in this chapter and in the relevant chapter of the *Terrestrial Code*, 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) A pathogen-specific *surveillance* programme has been applied as described in this chapter and in the relevant chapter of the *Terrestrial Code*, 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 the pathogenic agent is likely to produce identifiable clinical or pathological signs in susceptible *animals*;

e) the *infection* or *infestation* is not known to be established in *wildlife*.

Article 1.4.7.

Surveillance 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 8) of Article 1.4.4. can be useful in the assessment of disease control programmes.

NB: FIRST ADOPTED IN 2005; MOST RECENT UPDATE ADOPTED IN 2019.