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;
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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.
