Introduction and objectives

1. In general, surveillance is aimed at demonstrating the absence of disease or infection, determining the occurrence or distribution of disease or infection, while also detecting as early as possible exotic or emerging diseases. The type of surveillance applied depends on the desired outputs needed to support decision-making. The following recommendations may be applied to all diseases, their agents and all susceptible species (including wildlife) as listed in the Terrestrial Code, and are designed to assist with the development of surveillance methodologies. Except where a specific surveillance method for a certain disease or infection is already described in the Terrestrial Code, the recommendations in this chapter may be used to further refine the general approaches described for a specific disease or infection. Where detailed disease/infection-specific information is not available, suitable approaches should be based on the recommendations in this chapter.

2. Animal health surveillance is an essential tool to detect disease or infection, to monitor disease trends, to facilitate the control of disease or infection, to support claims for freedom from disease or infection, to provide data for use in risk analysis, for animal and/or public health purposes, and to substantiate the rationale for sanitary measures. Both domestic and wild animals are susceptible to certain disease/infection. However, in the presence of appropriate biosecurity measures, disease/infection in wild animals does not imply mean that the same disease/infection is necessarily present in domestic animals in the same country or zone. Surveillance data underpin the quality of disease status reports and should satisfy information requirements of risk analysis for international trade and for national decision-making. Wildlife may be included because they can serve as reservoirs and as indicators of human and domestic animal and wildlife disease. Wildlife disease/infection surveillance presents specific challenges that may differ significantly from surveillance in livestock.

3. Prerequisites to enable an OIE Member to provide information for the evaluation of its animal health status are:
   a. that the Member complies with the provisions of Chapter 3.1. of the Terrestrial Code;
   b. that, where possible, surveillance data be complemented by other sources of information (e.g. scientific publications, research data, documented field observations and other non-survey data);
   c. that transparency in the planning and execution of surveillance activities and the analysis and availability of data and information, be maintained at all times, in accordance with Chapter 1.1. of the Terrestrial Code.

4. The objectives of this chapter are to:
   a. provide guidance to the type of outputs that a surveillance system should generate;
b. provide recommendations to assess the quality of disease/infection 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 value.

**Case definition:** means a set of criteria used to classify an animal as a case.

**Confidence:** in the context of demonstrating freedom from infection, confidence is the probability that the type of surveillance applied would detect the presence of infection if the population were infected. The confidence depends on, among other parameters, the assumed level of infection in an infected population. The term refers to confidence in the ability of the surveillance applied to detect disease/infection, and is equivalent to the sensitivity of the surveillance system.

**Probability sampling:** means a sampling strategy in which every unit 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 units:** 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 (e.g. an epidemiological unit). Together, they comprise the sampling frame.

**Sensitivity:** means the proportion of truly positive units that are correctly identified as positive by a test.

**Specificity:** means the proportion of truly negative units that are correctly identified as negative by a test.

**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 a method of surveillance that may involve one or more component activities that generates information on the health, disease or zoonosis status of animal populations.

**Survey:** means an investigation in which information is systematically collected, usually carried out on a sample of a defined population group, within a defined time period.

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

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

**Test system:** means a combination of multiple tests and rules of interpretation which are used for the same purpose as a test.
Principles of surveillance

1. Types of surveillance

a. Surveillance may be based on many different data sources and can be classified in a number of ways, including:

i. the means by which data are collected (active versus passive surveillance);

ii. the disease focus (pathogen-specific versus general surveillance); and

iii. the way in which units for observation are selected (structured surveys versus non-random data sources).

b. In this chapter, surveillance activities are classified as being based on:

EITHER

i. structured population-based surveys, such as:
   - systematic sampling at slaughter;
   - random surveys;
   - surveys for infection in clinically normal animals, including wildlife;

OR

ii. structured non-random surveillance activities, such as:
   - disease reporting or notifications;
   - control programmes/health schemes;
   - targeted testing/screening;
   - ante-mortem and post-mortem inspections;
   - laboratory investigation records;
   - biological specimen banks;
   - sentinel units;
   - field observations;
   - farm production records;
   - wildlife disease data.
c. In addition, surveillance data should be supported by related information, such as:

i. data on the epidemiology of the disease/infection, including environmental, host population distribution, and climatic information;

ii. data on animal movements, including transhumance, as well as natural wildlife migrations;

iii. trading patterns for animals and animal products;

iv. national animal health regulations, including information on compliance with them and their effectiveness;

v. history of imports of potentially infected material; and

vi. biosecurity measures in place;

vii. the risk likelihood and consequence of disease/infection introduction.

d. The sources of evidence should be fully described. In the case of a structured survey, this should include a description of the sampling strategy used for the selection of units for testing. For structured non-random data sources, a full description of the system is required including the source(s) of the data, when the data were collected, and a consideration of any biases that may be inherent in the system.

2. Critical elements

In assessing the quality of a surveillance system, the following critical elements need to be addressed over and above quality of Veterinary Services (Chapter 3.1).

a. Populations

Ideally, surveillance should be carried out in such a way as to take into account all animal species susceptible to the infection in a country, zone or compartment. The surveillance activity may cover all individuals in the population or part of them. When surveillance is conducted only on a subpopulation, care should be taken regarding the inferences made from the results.

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

b. Time frame (or temporal values of surveillance data)

Surveillance should be carried out at a frequency that reflects the biology of the infection and the risks of its introduction.

c. Epidemiological unit

The relevant epidemiological unit(s) for the surveillance system should be defined to ensure that it is representative of the population appropriate to meet the objectives of surveillance. Therefore, it should be chosen taking into account factors such as carriers, reservoirs, vectors, immune status, genetic resistance and age, sex, and other host criteria.
d. Clustering

Infection 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, 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 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.

e. Case definition

A clear case definition should be defined developed for each disease/infection under surveillance, using clear criteria and, where they exist, the standards in the Terrestrial Code. For wildlife disease/infection surveillance, it is essential to correctly identify and report host animal taxonomy (including genus and species).

f. Analytical methodologies

Surveillance data should be analysed using appropriate methodologies, and at the appropriate organisational levels to facilitate effective decision making, whether it be planning interventions or demonstrating 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 needed to accommodate the relevant host species, pathogens, varying production and surveillance systems, and types and amounts of data and information available.

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

Consistency in the application of different methodologies should be encouraged and transparency is essential in order to ensure fairness 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. Testing

Surveillance involves the detection of disease or infection by the use of appropriate case definitions based on the results of one or more tests for evidence of infection or immune status. In this context, a test may range from detailed laboratory examinations to field observations and the analysis of production records. The performance of a test at the population level (including field observations) may be described in terms of its sensitivity and specificity and predictive values. Imperfect sensitivity and/or specificity 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 values of sensitivity and specificity for the tests used should be specified for each species in which they may be used, and the method used to determine or estimate these values should be
documented. Alternatively, where values for sensitivity and/or specificity for a particular test are specified in the *Terrestrial Manual*, these values may be used as a guide.

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.

h. Quality assurance

*Surveillance* systems should incorporate the principles of quality assurance and be subjected to periodic auditing to ensure that all components of the system function and provide verifiable documentation of procedures and basic checks to detect significant deviations of procedures from those documented in the design.

i. Validation

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.

j. 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 records or computerised. 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. 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 ministries, 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 disaggregated data rather than the compilation of summary data;

- minimisation of transcription errors during data processing and communication.

**Article 1.4.4.**

**Structured population-based surveys**

In addition to the principles for *surveillance* discussed above, the following recommendations should be used 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. A sample may be selected in either of the two following ways:
a. non-probability based sampling methods, such as:
   i. convenience;
   ii. expert choice;
   iii. quota;

b. probability based sampling methods, such as:
   i. simple random selection;
   ii. cluster sampling;
   iii. stratified sampling;
   iv. systematic sampling.

Periodic or repeated surveys conducted in order to document disease freedom should be done 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 information 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 made of any biases that may be inherent in the survey design.

2. Survey design

The population of epidemiological units should first be clearly defined; hereafter sampling units appropriate for each stage, depending on the design of the survey, should be defined.

The design of the survey will depend on the size and structure and degree of understanding of the population being studied, the epidemiology of the infection and the resources available.

Data on wild animal population size often do not exist and should be determined before a survey can be designed. The expertise of wildlife biologists may 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

The objective of 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. Sampling should provide the best likelihood that the sample will be representative of the population, within the practical constraints imposed by different environments and production systems.

Specimens from wildlife for surveillance may be available from sources such as hunters and trappers, road-kills, wild animal meat markets, sanitary inspection of hunted animals, morbidity-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.

4. **Sampling methods**

When selecting *epidemiological units* from within a population, probability sampling (e.g. simple random selection) should be used. When this is not possible, sampling should provide the best practical chance of generating a sample that is representative of the target population.

In any case, the sampling method used at all stages should be fully documented.

5. **Sample size**

In general, surveys are conducted either to demonstrate the presence or absence of a factor (e.g. *infection*) or to estimate a parameter (e.g. the prevalence of *infection*). The method used to calculate sample size for surveys depends on the purpose of the survey, the expected prevalence, the level of confidence desired of the survey results and the performance of the tests used.

Article 1.4.5.

**Structured non-random surveillance**

*Surveillance* systems routinely use structured non-random data, either alone or in combination with surveys.

1. **Common non-random surveillance sources**

A wide variety of non-random *surveillance* sources may be available. These vary in their primary purpose and the type of *surveillance* information they are able to provide. Some *surveillance* systems are primarily established as early detection systems, but may also provide valuable information to demonstrate freedom from *infection*. Other systems provide cross-sectional information suitable for prevalence estimation, either once or repeatedly, while yet others provide continuous information, suitable for the estimate of incidence data (e.g. disease reporting systems, sentinel sites, testing schemes).

a. **Disease reporting or notification systems**

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 detection. Effective laboratory support is an important component of any reporting system. Reporting systems relying on laboratory confirmation of suspect clinical cases should use tests that have a high specificity. Reports should be released by the laboratory in a timely manner, with the amount of time from *disease* detection to report generation minimized (to hours in the case of introduction of a foreign animal disease).

Whenever the responsibility for disease notification falls outside the scope of the *Veterinary Authority*, for example in some countries for *diseases* in wildlife, effective communication and data sharing should be established with the relevant authorities to ensure comprehensive and timely disease reporting.

b. **Control programmes / health schemes**
Animal disease control programmes or health schemes, while focusing on the control or eradication of specific diseases, should be planned and structured in such a manner as to generate data that are scientifically verifiable and contribute to structured surveillance.

c. Targeted testing / screening

This may involve testing targeted to selected sections of the population (subpopulations), in which disease is more likely to be introduced or found. Examples include testing culled and dead animals, swill fed animals, those exhibiting clinical signs, animals located in a defined geographic area and specific age or commodity group.

d. Ante-mortem and post-mortem inspections

Inspections of animals at slaughterhouses may provide valuable surveillance data. The sensitivity and specificity of slaughterhouse inspection for detecting the presence of specified diseases under the inspection system in place should be pre-determined. The accuracy of the inspection system will be influenced by:

i. the training, experience and number of the inspection staff;

ii. the involvement of the Competent Authorities in the supervision of ante-mortem and post-mortem inspections;

iii. the quality of construction of the slaughterhouse, speed of the slaughter chain, lighting quality, etc.; and

iv. staff morale and motivation for efficient performance.

Slaughterhouse inspections are likely to provide good coverage for particular age groups and geographical areas only. Slaughterhouse surveillance data are subject to biases in relation to target populations (e.g. only animals of a particular class and age are likely to be slaughtered for human consumption in significant numbers). Such biases need to be recognised when analysing surveillance data.

For traceback and analysis of spatial and herd-level coverage, there should be, if possible, an effective identification system that relates animals in the slaughterhouse to their locality of origin.

e. Laboratory investigation records

Analysis of laboratory investigation records may provide useful surveillance information. The coverage of the system will be increased if analysis is able to incorporate records from national, accredited, university and private sector laboratories. Valid analysis of data from different laboratories depends on the existence of standardised diagnostic procedures and standardised methods for interpretation and data recording. As with abattoir inspections, there needs to be a mechanism to relate specimens to the farm of origin.

f. Biological specimen banks

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

Sentinel units/sites involve the identification and regular testing of one or more of animals of known health/immune status in a specified geographical location to detect the occurrence of disease/infection (usually serologically). They are particularly useful for surveillance of diseases/infections with a strong spatial component, such as vector-borne diseases/infections. Sentinel units provide the opportunity to target surveillance depending on the likelihood of infection (related to vector habitats and host population distribution), cost and other practical constraints. Sentinel units may provide evidence of freedom from infection, or provide data on prevalence and incidence as well as the distribution of disease/infection.

h. Field observations

Clinical observations of animals in the field are an important source of surveillance data. The sensitivity and specificity of field observations may be relatively low, but these can be more easily determined and controlled if a clear standardised case definition is applied. Education of potential field observers in application of the case definition and reporting is an important component. Ideally, both the number of positive observations and the total number of observations should be recorded.

i. Farm production records

Systematic analysis of farm production records may be used as an indicator of the presence or absence of disease/infection at the herd or flock level. In general, the sensitivity of this approach may be quite high (depending on the disease), but the specificity is often quite low.

j. Wildlife data

Specimens from wild animals for disease/infection surveillance 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.

2. Critical elements for structured non-random surveillance

There are a number of critical factors which should be taken into account when using structured non-random surveillance data such as coverage of the population, duplication of data, and sensitivity and specificity of tests that may give rise to difficulties in the interpretation of data. Surveillance data from non-random sources can, however, be a cost-efficient method of early detection, and may increase the level of confidence or detect a lower level of prevalence compared to random sampling surveys.

3. Analytical methodologies

Different scientifically valid methodologies may be used for the analysis of non-random surveillance data. Where no data are available, estimates based on expert opinions, gathered and combined using a formal, documented and scientifically valid methodology may be used.
4. **Combination of multiple sources of data**

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. Such evidence gathered over time may be combined to provide an overall level of confidence. For instance, repeated annual surveys may be analysed to provide a cumulative level of confidence. However, a single larger survey, or the combination of data collected during the same time period from multiple random or non-random sources, may be able to achieve the same level of confidence in just one year a shorter period of time.

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, specificity and completeness of data from each source should also be taken into account for the final overall confidence level estimation.

**Article 1.4.6.**

**Surveillance to demonstrate freedom from disease/infection**

1. **Requirements to declare a country, zone or compartment free from disease/infection without pathogen specific surveillance**

   This Article provides general principles for declaring a country, *zone* or *compartment* free from *disease/infection* in relation to the time of last occurrence and in particular for the recognition of historical freedom.

   The provisions of this Article are based on the principles described in Article 1.4.3. of this chapter and the following premises:

   - in the absence of *disease* and vaccination, the animal population would become susceptible over a period of time;
   
   - the disease agents to which these provisions apply are likely to produce identifiable clinical signs in susceptible *animals*;
   
   - competent and effective *Veterinary Services* will be able to investigate, diagnose and report disease, if present;
   
   - *disease/infection* can affect both wild and domestic *animals*;
   
   - the absence of *disease/infection* over a long period of time in a susceptible population can be substantiated by effective disease investigation and reporting by a Member.

a. **Historically free**

   Unless otherwise specified in the relevant *disease* chapter, a country, *zone* or *compartment* may be recognised free from *infection* without formally applying a pathogen-specific *surveillance* programme when:
i. there has never been occurrence of disease, or

ii. eradication has been achieved or the disease/infection has ceased to occur for at least 25 years, provided that for at least the past 10 years:

iii. it has been a notifiable disease;

iv. an early detection system has been in place for all relevant species;

v. measures to prevent disease/infection introduction have been in place; no vaccination against the disease has been carried out unless otherwise provided in the Terrestrial Code;

vi. infection is not known to be established in wildlife within the country or zone intended to be declared free. A country or zone cannot apply for historical freedom if there is any evidence of infection in wildlife.

b. Last occurrence within the previous 25 years

Countries, zones or compartments that have achieved eradication (or in which the disease/infection has ceased to occur) within the previous 25 years, should follow the pathogen-specific surveillance requirements in the Terrestrial Code if they exist. In the absence of specific requirements for surveillance in the Terrestrial Code, countries should follow the general recommendations on surveillance to demonstrate animal health status outlined in this chapter provided that for at least the past 10 years:

i. it has been a notifiable disease;

ii. an early detection system has been in place;

iii. measures to prevent disease/infection introduction have been in place;

iv. no vaccination against the disease has been carried out unless otherwise provided in the Terrestrial Code;

v. infection is not known to be established in wildlife within the country or zone intended to be declared free. A country or zone cannot apply for freedom if there is any evidence of infection in wildlife.

2. Recommendations for the discontinuation of pathogen-specific screening after recognition of freedom from infection

A country, zone or compartment that has been recognised as free from infection following the provisions of the Terrestrial Code may discontinue pathogen-specific screening while maintaining the infection-free status provided that:

a. it is a notifiable disease;

b. an early detection system is in place;

c. measures to prevent disease/infection introduction are in place;

d. vaccination against the disease is not applied;
e. *infection* is known not to be established in wildlife. It can be difficult to collect sufficient epidemiological data to prove absence of *disease/infection* in wild animal populations. In such circumstances, a range of supporting evidence should be used to make this assessment.

3. **Self declaration of disease/infection**

Members may make a self declaration that a country, *zone* or *compartment* is free from a *listed disease*, based on the implementation of the provisions of the *Terrestrial Code* and the *Terrestrial Manual* - see relevant provisions in Chapter 1.5. The *Veterinary Authority* may wish to transmit this information to the OIE *Central Bureau*, which may publish the information.

4. **International recognition of disease/infection free status**

For *diseases* for which procedures exist whereby the OIE can officially recognise the existence of a *disease/infection* free country, *zone* or *compartment*, a Member wishing to apply for recognition of this status shall, via its Permanent Delegate, send to the OIE all the relevant documentation relating to the country, *zone* or *compartment* concerned. Such documentation should be presented according to the recommendations prescribed by the OIE for the appropriate animal *diseases*.

5. **Demonstration of freedom from infection**

A *surveillance* system to demonstrate freedom from *infection* should meet the following requirements in addition to the general requirements for *surveillance* outlined in Article 1.4.3. of this chapter.

Freedom from *infection* implies the absence of the pathogenic agent in the country, *zone* or *compartment*. Scientific methods cannot provide absolute certainty of the absence of *infection*. Demonstrating freedom from *infection* involves providing sufficient evidence to demonstrate (to a level of confidence acceptable to Members) that *infection* with a specified pathogen is not present in the population. In practice, it is not possible to prove (i.e., be 100% confident) that a population is free from *infection* (unless every member of the population is examined simultaneously with a perfect test with both sensitivity and specificity equal to 100%). Instead, the aim is to provide adequate evidence (to an acceptable level of confidence), that *infection*, if present, is present in less than a specified proportion of the population.

However, finding evidence of *infection* at any level in the target population automatically invalidates any freedom from *infection* claim unless otherwise stated in the relevant *disease* chapter. The implications of *disease/infection* in wildlife for the status of domestic *animals* in the same country or *zone* should be assessed in each situation, as indicated in the relevant chapter on each *disease* in the *Terrestrial Code*.

Evidence from targeted, random or non-random data sources, as stated before, may increase the level of confidence or be able to detect a lower level of prevalence with the same level of confidence compared to structured surveys.
Article 1.4.7.

Surveillance for distribution and occurrence of infection

*Surveillance* to determine distribution and occurrence of infection or of other relevant health related events is widely used to assess progress in the control or eradication of selected *diseases* and pathogens and as an aid to decision making. It has, however, relevance for the international movement of *animals* and products when movement occurs among infected countries.

In contrast to *surveillance* to demonstrate freedom from infection, *surveillance* used to assess progress in control or eradication of selected *diseases* and pathogens is usually designed to collect data about a number of variables of animal health relevance, for example:

1. prevalence or incidence of *infection*;
2. morbidity and mortality rates;
3. frequency of *disease/infection risk* factors and their quantification;
4. frequency distribution of *herd sizes* or the sizes of other *epidemiological units*;
5. frequency distribution of antibody titres;
6. proportion of immunised *animals* after a vaccination campaign;
7. frequency distribution of the number of days elapsing between suspicion of *infection* and *laboratory* confirmation of the diagnosis and/or to the adoption of control measures;
8. farm production records;
9. role of wildlife in maintenance or transmission of the *infection*. 