USA COMMENTS

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 available data sources and the outputs needed to support decision-making. The general recommendations in this chapter may be applied to all infections or infestations and all susceptible species (including wildlife) and may be refined. 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 Chapter 3.1. on Veterinary Services;
   b) that, where possible, surveillance data be complemented by other sources of information, such as scientific publications, research 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, either in a random survey or in non-random surveillance. This may be an individual animal or a group of animals, such as an epidemiological unit. Together, they comprise the sampling frame.

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

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

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

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

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

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

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

Article 1.4.3.

Surveillance systems

In designing, implementing and assessing a surveillance system, the following components should be addressed in addition to the quality of Veterinary Services.

1. Design of surveillance system

   a) Populations

   Surveillance should take into account all animal species susceptible to the infection or infestation in a country, zone or compartment. The surveillance activity may cover all individuals in the population or only some of them. When surveillance is conducted only on a subpopulation, inferences to the target population should be justified based on the epidemiology of the infection or infestation and the degree to which the subpopulation is representative of the target population.

   Rationale: Sampling (rather than conducting a census) tests only a fraction of the population. Results from the sampled set can be used to make inferences about the full population. However, if the sample is not representative of the full population (i.e., has different characteristics than the full population), then the inferences may be biased or inaccurate.

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

   b) Diagnostic tests

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

   Rationale: We are proposing to add the phrase “involving antigen or antibody detection” to the paragraph above to improve clarity. The design of surveillance systems depends on available test types.

   Tests should be chosen in accordance with the relevant chapters of the Terrestrial Manual.
i) Sensitivity and specificity: The performance of a test at the population level (including field observations) may be described in terms of its sensitivity, specificity and predictive values. Imperfect sensitivity or specificity, as well as prevalence, will impact the conclusions from surveillance. Therefore, these parameters should be taken into account in the design of surveillance systems and analysis of surveillance data. The sensitivity and specificity values of the tests used should be specified for each species in which they may be used, and the method used to estimate these values should be documented in accordance with Chapter 1.1.6. of the Terrestrial Manual.

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

**Rationale:** We are proposing that Article 1.4.3.2. a) Diagnostic tests (in its entirety), be moved here as a new Article 1.4.3.1. b). Diagnostic test choice and/or availability impacts sample size, animal/tissue selection, and sample processing decisions, and is essential to surveillance design.

cb) Timing and Temporal validity of surveillance data

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

– objectives of the surveillance;
– epidemiology (e.g. vectors, transmission pathways, seasonality);
– pathogenesis (e.g., incubation and infectious period, acute or chronic presentation, strain virulence or strain pathogenicity);
– husbandry practices and production systems;
– accessibility of target population;
– geographical factors;
– climate conditions;
– Risk of pathogen introduction
– historical evidence of presence or absence
– consequence of infection

**Rationale:** We are proposing to add the listed factors above because they are critical elements in surveillance design. For example, incubation/infectious periods, as well as chronicity, impact how soon and how long a population should be tested following a potential exposure. Pathogenicity, which will influence these same characteristics, may vary by genotype or strain. Pathogens may require ongoing surveillance even after freedom of disease has been demonstrated if the consequence of an error in assessment is extremely high. These factors were previously included; we believe they need to be reinstated.

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

dc) 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.
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.

Clustering

Infection or infestation in a country, zone or compartment usually clusters rather than being uniformly or randomly distributed through a population. Clustering may occur at a number of different levels (e.g. a cluster of infected animals within a herd or flock, a cluster of pens in a building, or a cluster of farms in a compartment). Clustering should be taken into account in the design of surveillance activities and considered in the statistical analysis of surveillance data, at least at what is judged to be the most significant level of clustering for the particular animal population and infection or infestation.

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 should only be carried out when may be justified by the objectives of the surveillance and the availability and quality of field data.

Rationale: Suggested edits will improve clarity and not discourage the use of analytics.

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.

Scope of the surveillance system

When designing the surveillance system consideration should be given to the purpose 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.

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.

Resources (e.g., personnel, time, funding, lab capacity etc.)

Availability of resources may constrain the considered options when designing the surveillance system.

Rationale: We are proposing to add j) “Resources” as an additional component that should be addressed in addition to the quality of Veterinary Services. Resource availability constrains options for design of surveillance systems.
2. Implementation of the surveillance system

a) Diagnostic tests

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

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

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

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

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

Rationale: We are proposing that this Article 1.4.3.2. Point a) Diagnostic tests, be moved up and inserted as Article 1.4.3.1. Point b). Diagnostic test choice and/or availability impacts sample size, animal/tissue selection, and sample processing decisions, and is essential to surveillance design – so it belongs best in this Article.

ab) 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. 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 Evaluation

Surveillance systems should be subjected to periodic auditing to ensure that all components function and provide verifiable documentation of procedures and basic checks to detect significant deviations of procedures from those specified in the design, in order to implement appropriate corrective actions.

Rationale: We are proposing to change the title for this Article 1.4.3.3. to Surveillance Evaluation which is the term currently used in international conferences and publications.
Surveillance methods

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

1. Disease reporting systems

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

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

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

2. Data generated by control programmes and health schemes

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

3. Risk-based methods

Risk-based methods are useful to optimise the use of surveillance resources.

Rationale: Change made and text added to improve clarity. This concept is well described by Hoinville et al. 2013. Citation: Hoinville.L, Alban, L., Gibbens, J., Gustafson, L., Hasler, B., Saegerman, C., Salman, M., Stark K. 2013. Proposed terms and concepts for describing and evaluating animal-health surveillance systems. Preventive Veterinary Medicine 112, 1-12.

Risk-based methods are useful to optimise the use of surveillance resources.

4. Ante-mortem and post-mortem inspection

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

a) clinical and pathological signs;

b) the training, experience and number of the inspection staff;

c) the involvement of the Competent Authority in the supervision of ante-mortem and post-mortem inspection;
d) the quality of construction of the slaughterhouse/abattoir, speed of the slaughter chain, lighting quality, etc.; and

e) independence of the inspection staff.

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

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

5. Laboratory investigation records

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

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

6. Biological specimen banks

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

7. Sentinel units

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, likelihood of infection or infestation, cost and other practical constraints. Sentinel units may provide evidence of freedom from infection or infestation, or of their distribution.

8. Clinical observations

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

9. Syndromic data

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

10. Other data sources

a) 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.
b) 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.

c) 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.

d) 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; and

viii) expert opinion elicitation data (e.g., to identify or weight risk factors or estimate disease spread model parameters.

**Rationale:** Expert opinion elicitation data can be useful when published data are lacking.

**Article 1.4.5.**

**Considerations in survey design**

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

1. **Types of surveys**

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

**Rationale:** Probability-based sampling has been introduced previously in this document and should be offered as an option in the sampling section – whether probability or non-probability based. Disease freedom fits under Article 1.4.6.1.

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

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

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

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

3. **Sampling**

   a) **Objective**

       The objective of probability sampling from a *population* is to select a subset of units that is representative of the *population* of interest with respect to the objective of the study, taking into account practical constraints imposed by different environments and production systems.

       When selecting epidemiological *units* within a *population*, probability sampling, such as a simple random selection, should be used. Where probability sampling is not feasible, non-probability based methods may be applied and should provide the best practical chance of generating a sample that is representative of the target *population*. The objective of non-probability based sampling is to maximise the likelihood of detection of the *infection or infestation*. However, this type of sampling will not be representative of the study and target *population*. Risk-based sampling can be used to estimate general population status if risk factors are weighted and those weights capture relative difference in subpopulation risk and population proportion.

       **Rationale:** Non-probability based sampling describes a range of methods from convenience sampling to risk-based sampling, some of which can be very effective for surveillance design. Risk-based sampling can be used to estimate general population status if risk factors are weighted and those weights capture the relative difference in subpopulation risk and population proportion.

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

   b) **Sample size**

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

       **Rationale:** Multi-stage sampling (e.g., farms within a county, and animals within a farm) is an important strategy addressing potential clustering of disease occurrence. Risk-based sampling can also be considered probability-based if risk factors are weighted and those weights capture relative difference.

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

   c) A sample may be selected by either:

       i) probability-based sampling methods, such as:

           – simple random selection;

           – cluster sampling;
stratified sampling; systematic sampling; or risk-based sampling; or

Rationale: Risk-based sampling can be either probability or non-probability based.

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

– convenience;
– expert choice;
– quota;
– risk.

Article 1.4.6.

Surveillance to demonstrate freedom from an infection or infestation

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

1. Demonstration of freedom

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

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

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

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

Rationale: All types of listed surveys can be structured, so we are not sure what the intent of the sentence is and perhaps needs further editing and clarification.

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

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

i) the infection or infestation has been a notifiable disease;

ii) an early warning system has been in place for all relevant species;

iii) measures to prevent the introduction of the infection or infestation have been in place;

iv) no vaccination against the disease has been carried out;

v) 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) the prerequisites listed in a) are complied with for at least the past 10 years;

ii) the pathogenic agent is likely to produce identifiable clinical or pathological signs in susceptible animals;

iii) for at least 25 years there has been no occurrence of infection or infestation or eradication has been achieved for the same length of time.

**Rationale:** for consistency with Article 1.4.6. 2. b) i) above.

c) Where historical freedom cannot be achieved:

i) the prerequisites listed in a) are complied with, starting at least as early as the initiation of surveillance and continuously thereafter.

**Rationale:** At a minimum Article 1.4.6.2. Point a) conditions should be in place at the start of surveillance. Also at a minimum, they should continue (as they ensure veterinary service competency) for as long as the country/region/zone wishes to maintain its disease freedom status.

ii) pathogen-specific surveillance has been applied as described in this chapter and in the relevant chapter of the *Terrestrial Code*, if it exists, and has not detected any occurrence of the infection or infestation for a minimum frequency and duration appropriate to the epidemiology of the pathogen and the pathogen introduction risk to the system.

**Rationale:** The time period should not be arbitrary. If the Code will not specify durations, then Member countries should be encouraged to consider the epidemiology of the pathogen (as noted in Article 1.4.3.1. Point b) when setting the duration of surveillance. Similarly, the risk of new introduction of the pathogen should influence how frequently the surveillance needs to repeated, or how frequently the confidence derived from surveillance needs to be re-assessed. This is because the risk of introduction will impact the value (longevity) of historical data.

3. **Requirements to declare a compartment free from infection or infestation**

a) The prerequisites listed in 2.a) i) to iv) are complied with, starting at least as early as the initiation of surveillance and continuously thereafter.

**Rationale:** At a minimum the conditions should be in place at the start of surveillance. Also at a minimum, they should continue (as they ensure veterinary service competency) for as long as the country/region/zone wishes to maintain its disease freedom status.

b) ongoing pathogen-specific surveillance has been applied as described in this chapter and in the relevant chapter of the *Terrestrial Code*, if they exist, and has not detected any occurrence of the infection or infestation for a minimum frequency and duration appropriate to the epidemiology of the pathogen and the biosecurity of the system.

**Rationale:** The time period should not be arbitrary. If the Code will not specify durations, then Member countries should be encouraged to consider the epidemiology of the pathogen (as noted in Article 1.4.3.1. Point b) when setting the duration of surveillance. Similarly, the risk of new introduction of the pathogen should influence how frequently the surveillance needs to repeated, or how frequently the confidence derived from surveillance needs to be re-assessed. This is because the risk of introduction will impact the value (longevity) of historical data.
4. **Recommendations for the maintenance of freedom from infection or infestation**

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

**Rationale:** to include *compartments* as defined in the glossary.

a) the *infection or infestation* is a *notifiable disease*;

b) an *early warning system* is in place for all relevant species;

c) measures to prevent the introduction of the *infection or infestation* are in place;

d) surveillance adapted to the likelihood of occurrence of *infection or infestation* is carried out. *Specific surveillance* may not need to be carried out if supported by a *risk assessment* addressing all identified pathways for introduction of the pathogenic agent and provided it is likely to produce identifiable clinical or pathological signs in susceptible *animals*;

e) *vaccination* against the disease is not applied;

f) for countries or zones, the *infection or infestation* is not known to be established in *wildlife*. It can be difficult to collect sufficient epidemiological data to prove absence of *infection or infestation* in *wild animal* populations. In such circumstances, a range of supporting evidence should be used to make this assessment.

**Rationale:** To improve clarity of the intended areas; *wildlife assessment* is most critical to zones and countries which may not have the same barriers to pathogen entry.

**Article 1.4.7.**

**Surveillance considerations in support of disease control programmes**

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

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

1) prevalence or incidence of *infection or infestation*;

2) morbidity and mortality;

3) frequency of risk factors and their quantification;

4) frequency distribution of results of the laboratory tests;

5) post-vaccination monitoring results;

6) frequency distribution of *infection or infestation* in *wildlife*.

The spatial and temporal distribution of these variables and other data such as *wildlife*, public health and environmental data as described in point 10) of Article 1.4.4. can be useful in the assessment of disease control programmes.

**Article 1.4.8.**

**Early warning systems**

An *early warning system* is essential for the timely detection, identification and reporting of occurrence, incursion or emergence of *infections or infestations*, and should include the following:
1) appropriate coverage of target animal populations by the Veterinary Services;

2) effective disease investigation and reporting;

3) laboratories capable of diagnosing and differentiating relevant infections or infestations;

4) training and awareness programmes for veterinarians, veterinary paraprofessionals, livestock owners or keepers and others involved in handling animals from the farm to the slaughterhouse/abattoir, for detecting and reporting unusual animal health incidents;

5) a legal obligation by relevant stakeholders to report suspected cases or cases of notifiable diseases or emerging diseases to the Veterinary Authority;

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

7) a national chain of command.

Early warning systems are an essential component of emergency preparedness.

Article 1.4.9.

Combination and interpretation of surveillance results

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

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

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

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

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

[...]

EARLY WARNING SYSTEM

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

[...]