Annex 8

CHAPTER 1.4.

ANIMAL HEALTH SURVEILLANCE

Article 1.4.1.

Introduction and objectives

1) In general, *surveillance* is aimed at demonstrating the absence of *infection* or *infestation*, determining the presence or distribution of *infection* or *infestation* or detecting as early as possible exotic diseases or *emerging diseases*. Animal health *surveillance* is a tool to monitor disease trends, to facilitate the control of *infection* or *infestation* ~~disease~~ ~~*infection or infestation*~~, to provide data for use in *risk analysis*, for animal or public health purposes, to substantiate the rationale for *sanitary measures* and for providing assurances to trading partners. The type of *surveillance* applied depends on the objectives of the *surveillance*, the available data sources and the outputs needed to support decision-making. The general recommendations in this chapter may be applied to all *infections* or *infestations* and all susceptible species (including *wildlife*) and may be ~~refined~~ adapted to national or local settings. *Specific surveillance* is described in some *listed disease*-specific chapters.

2) *Wildlife* may be included in a *surveillance* system because they can serve as reservoirs of *infection* or *infestation* and as indicators of *risk* to humans and domestic *animals*. However, the presence of an *infection* or *infestation* in *wildlife* does not mean it is necessarily present in domestic *animals* in the same country or *zone,* or vice versa. *Surveillance* in *wildlife* presents challenges that may differ significantly from those in *surveillance* in domestic *animals*.

3) Prerequisites to enable a Member Country to provide information for the evaluation of its *animal health status* are:

   a) that the Member Country complies with the provisions of Chapters 3.1. to 3.4. on *Veterinary Services*;

   b) that, where possible, *surveillance* data be complemented by other sources of information, such as scientific publications, research data, *population* demographic data, animal production data, documented field observations and other data;

   c) that transparency in the planning, execution and results of *surveillance* activities, is in accordance with Chapter 1.1.

4) The objectives of this chapter are to:

   a) provide guidance on the design of a *surveillance* system and the type of output it should generate;

   b) provide recommendations to assess the quality of *surveillance* systems.

Article 1.4.2.

Definitions

The following definitions apply for the purposes of this chapter:

Bias: means a tendency of an estimate to deviate in one direction from a true *population* parameter.

Confidence: means the probability that the type of *surveillance* applied would detect the presence of *infection* or *infestation* if the *population* were infected and is equivalent to the sensitivity of the *surveillance*. Confidence depends on, among other parameters, the assumed prevalence of *infection* or *infestation*.

Annex 8 (contd)

Probability sampling: means a sampling strategy in which every unit is chosen at random and has a known non-zero probability of inclusion in the sample.

Sample: means the group of elements (sampling units) drawn from a *population*, on which tests are performed or parameters measured to provide *surveillance* information.

Sampling unit: means the unit that is sampled~~, either in a random survey or in non-random *surveillance*~~. This may be an individual *animal* or a group of *animals*, such as an *epidemiological unit*. ~~Together, they comprise the sampling frame.~~

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

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

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

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

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

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

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

Article 1.4.3.

Surveillance systems

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

1. Design of surveillance system

   a) Populations

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

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

   b) Timing and temporal validity of surveillance data

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

   – objectives of the *surveillance*;

   – biology and epidemiology (e.g. pathogenesis, *vectors*, transmission pathways, seasonality);

   – *risk* of introduction and spread;

– husbandry practices and production systems;

– accessibility of target *population*;

– geographical factors;

– environmental factors, including climate conditions.

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

c) Case definition

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

d) Epidemiological unit

The relevant *epidemiological unit* for the *surveillance* system should be defined to ensure that it is appropriate to meet the objectives of *surveillance*.

e) Clustering

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

ebis) Diagnostic tests

Surveillance involves the 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.

Comments: AU proposes that the sentence "*Surveillance* involves the detection of *infection* or *infestation* according to appropriate *case* definitions." Be deleted.

AU also seeks clarification on whether laboratory test includes penside test.

Rationale: The focus of *ebis* is on "diagnostic test" and not on surveillance. Besides surveillance is covered under introduction and objectives paragraph 1.

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 drawn from *surveillance*. Therefore, these parameters should be taken into account in the design of *surveillance* systems and analysis of *surveillance* data.

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

f) Analytical methodologies

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

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

Annex 8 (contd)

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

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

g) Scope of the surveillance system

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

h) Follow up actions

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

2. Implementation of the surveillance system

a) Diagnostic tests

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

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

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

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

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

b) Data collection and management

The success of a *surveillance* system is dependent on a reliable process for data collection and management. The process may be based on paper or electronic records. Even where data are collected for non-survey purposes (e.g. during disease control interventions, inspections for movement control or during disease eradication schemes), the consistency and quality of data collection and event reporting in a format that facilitates analysis is critical. Software may offer the possilibity 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 significant deviations of procedures from those specified in the design, in order to implement appropriate corrective actions.

Article 1.4.4.

Surveillance methods

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

1. Disease reporting systems

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

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

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

~~2. Data generated by control programmes and health schemes~~

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

2. Surveys

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

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

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

Annex 8 (contd)

a) Survey design

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

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

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

b) Sampling

i) 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 so that data from the study *population* can be extrapolated to the target *population* in a statistically-valid manner. When selecting *epidemiological units* within a *population*, probability-based sampling, such as a simple random selection, should be used.

Where probability-based sampling is not feasible, non-probability-based methods may be applied and should provide the best practical chance of generating a sample that ~~is~~ can be considered as representative of the target *population*. ~~The objective of non-probability based sampling should be to maximise the likelihood of detection of the *infection* or *infestation*.~~ However, this type of sampling may ~~not~~ only be representative of the study and target *population*~~, unless~~ if risk factors are weighted~~. and t~~Those weights should be underpinned by relevant scientific evidence and should capture the relative differences in risk and proportion between the *subpopulation* and the *population*.

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

ii) Sample size

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

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

iii) Sample selection

— probability-based sampling methods, such as:

- simple random selection;
- cluster sampling;
- stratified sampling;
- systematic sampling; ~~or~~
- risk-based sampling.

— non-probability-based sampling methods, depending on:

- convenience;
- expert choice;
- quota;
- *risk*.

3. Risk-based methods

Surveillance activities targeting selected *subpopulations* in which an *infection* or *infestation* is more likely to be introduced or found, or more likely to spread, or cause other consequences ~~(e.g. large economic losses or trade restrictions)~~ are useful to increase the efficiency of detection and can contribute to early detection, freedom claims, disease control activities, and estimation of *prevalence*. Risk-based methods can be used for both probability-based and non-probability-based ~~selection of~~ sampling ~~units~~ methods and data collection. The effect of the selection (i.e. its impact on probability of detection) should be estimated.

Risk-based methods should be based on *risk assessment* and 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 extent to which the *Competent Authority* is involved ~~involvement of the *Competent Authority*~~ in the supervision of ante-mortem and post-mortem inspection, including reporting systems;

d) the quality of construction of the *slaughterhouse/abattoir*, speed of the slaughter chain, lighting quality, etc.; and

e) independence of the inspection staff.

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

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

~~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.~~

Annex 8 (contd)

~~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.~~

5~~7~~. Surveillance of ~~S~~sentinel units

Surveillance of ~~S~~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, *infection* or *infestation*~~, or of their distribution~~.

6~~8~~. Clinical ~~observations~~ surveillance

Clinical observations of *animals* in the field are an important source of *surveillance* data. The sensitivity and specificity of clinical observations are highly dependent on the criteria used to define a suspected *case*. In order to allow comparison of data, the *case* definition should be standardised. 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.

7~~9~~. Syndromic ~~data~~ surveillance

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

8~~10~~. Other useful data ~~sources~~

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

d~~*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.

c~~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.

f~~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.

g~~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*.

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.

Annex 8 (contd)

~~Article 1.4.5.~~

~~Considerations in survey design~~

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

~~1.~~ ~~Types of surveys~~

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

~~Surveys conducted in order to document freedom from *infection* or *infestation* should be conducted using probability-based sampling methods so that data from the study *population* can be extrapolated to the target *population* in a statistically valid manner.~~

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

~~2.~~ ~~Survey design~~

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

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

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

~~3.~~ ~~Sampling~~

~~*a)* Objective~~

~~The objective of probability sampling from a *population* is to select a subset of units that is representative of the *population* of interest with respect to the objective of the study, taking into account practical constraints imposed by different environments and production systems. When selecting *epidemiological units* within a *population*, probability sampling, such as a simple random selection, should be used. Where probability sampling is not feasible, non-probability based methods may be applied and should provide the best practical chance of generating a sample that is representative of the target *population*. The objective of non-probability based sampling is to maximise the likelihood of detection of the *infection* or *infestation*. However, this type of sampling will not be representative of the study and target *population*.~~

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

~~*b)* Sample size~~

~~In surveys conducted to demonstrate the presence or absence of an *infection* or *infestation* the method used to calculate sample size depends on the size of the *population*, the design of the survey, the expected prevalence, the level of confidence desired of the survey results and the performance of the tests used.~~

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

~~*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~~
- ~~*ii)* non-probability-based sampling methods, depending on:~~
  - ~~convenience;~~
  - ~~expert choice;~~
  - ~~quota;~~
  - ~~*risk*.~~

Article 1.4.5.

Early warning systems

An early warning system is essential for the timely detection, reporting and communication of occurrence, incursion or emergence of diseases, *infections* or *infestations*~~,~~ and is an integral component of emergency preparedness. It should be under the control of the *Veterinary Authority* and should include the following:

1) appropriate coverage of target *animal populations* by the *Veterinary Services*;

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

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

4) a legal obligation by veterinarians and other relevant stakeholders to report suspected *cases* or *cases* of *notifiable diseases* or *emerging diseases* to the *Veterinary Authority*, ~~with following information~~ including the description of the findings~~:~~.

   ~~–~~ ~~the disease or pathogenic agent suspected, with brief descriptions of clinical signs or lesions observed, or laboratory test results as relevant;~~

   ~~–~~ ~~the date when the signs were first noticed at the initial site and any subsequent sites;~~

   ~~–~~ ~~the names and addresses or geographical locations of suspected infected *establishments* or premises;~~

   ~~–~~ ~~the animal species affected, including possible human cases, and the approximate numbers of sick and dead animals;~~

   ~~–~~ ~~initial actions taken, including biosecurity and precautionary movement restrictions of *animals*, products, staff, *vehicles* and equipment;~~

5) epidemiological investigations of suspected *cases* and *cases* conducted by the *Veterinary Services*~~, taking into account the following:~~ in order to confirm the *case* 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*.

   ~~–~~ ~~biosecurity to be observed when entering and leaving the *establishment*, premises or locality;~~

   ~~–~~ ~~clinical examinations to be undertaken (number and types of *animals*);~~

   ~~–~~ ~~samples to be taken from *animals* showing signs or not (number and types of *animals*), with specified sampling and sample handling equipment and sample handling procedures, including for the safety of the investigator and animal owners;~~

   ~~–~~ ~~procedure for submitting samples for testing;~~

   ~~–~~ ~~size of the affected *establishment*, premises or locality and possible entry pathways;~~

   ~~–~~ ~~investigation of the approximate numbers of similar or possibly susceptible animals in the *establishment* and its surroundings;~~

   ~~–~~ ~~details of any recent movements of possibly susceptible animals or *vehicles* or people to or from the affected *establishments*, premises or locality;~~

Annex 8 (contd)

- any other relevant epidemiological information, such as presence of the suspected disease in *wildlife* or abnormal *vector* activity;

- all suspected *case* investigations should provide a result, either positive or negative. Criteria should be established in advance for a *case* definition;

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

7) a national chain of command.

Early warning systems are an essential component of emergency preparedness.

When a case of a *listed disease* is detected, *notification* shall be made to the OIE in accordance with Chapter 1.1.

Article 1.4.6.

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

However, finding evidence of *infection* or *infestation* at any prevalence in the target *population* automatically invalidates any freedom claim unless otherwise stated in the relevant chapter of the *Terrestrial Code*. The implications for the status of domestic *animals* ~~of~~ when *infection* or *infestation* is 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 nonprobability risk-based data ~~sources~~ collection~~, as stated before,~~ may increase the sensitivity of the *surveillance* ~~level of confidence or be able to detect a lower prevalence with the same level of confidence as structured surveys~~.

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

a) Prerequisites, unless otherwise specified in the relevant 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;~~

iv) the *infection* or *infestation* is not known to be established in *wildlife* within the country or *zone*.

b) Historical freedom

Unless otherwise specified in the relevant chapter of the *Terrestrial Code*, a country or *zone* may be considered free without formally applying a pathogen-specific *surveillance* programme when:

i) for at least the past 10 years:

- no *vaccination* against the disease has been carried out;
- the prerequisites listed in point *a)* are complied with ~~for at least the past 10 years~~;

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

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

c) Where historical freedom cannot be ~~achieved~~ demonstrated:

i) the prerequisites listed in *a)* ~~are~~ have been complied with for at least as long as the *surveillance* has been in place;

ii) 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*.

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

a) The prerequisites listed in points 2 *a)i)* to *iii*~~*iv*~~*)* are complied with for at least as long as the *surveillance* has been in place;

b) ongoing pathogen-specific *surveillance* has been applied as described in this chapter and in the relevant chapter of the *Terrestrial Code*~~, if they it exists~~, and has not detected any occurrence of the *infection* or *infestation*.

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* that has achieved freedom in accordance with the provisions of the *Terrestrial Code* may maintain its free status provided that:

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

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

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

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

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

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

Article 1.4.7.

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

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

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

Annex 8 (contd)

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~~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.~~